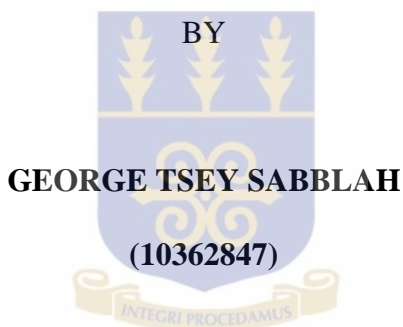


**SCHOOL OF PUBLIC HEALTH  
COLLEGE OF HEALTH SCIENCES  
UNIVERSITY OF GHANA**

**ADVERSE DRUG REACTIONS REPORTING BY DOCTORS IN THE GREATER  
ACCRA REGION**



THIS DISSERTATION IS SUBMITTED TO THE UNIVERSITY OF GHANA, LEGON IN  
PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE AWARD OF MASTER OF  
PUBLIC HEALTH DEGREE

JULY, 2012

## DECLARATION

I, **George Sabblah**, declare that except for other peoples investigation which have been fully acknowledged, this work is the result of my own original research and this dissertation either in part or in whole has not been presented elsewhere for another degree.

**George Sabblah**      Signature .....

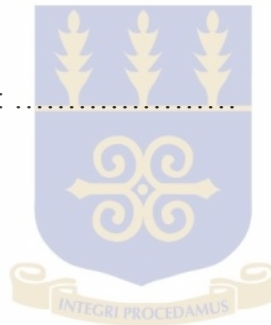
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Date: .....

Academic Supervisor



## DEDICATION

This dissertation is dedicated to my wonderful wife and best friend; Dorcas and to God's precious gifts to me; Seyram, Elorm and Klenam.



## ACKNOWLEDGEMENT

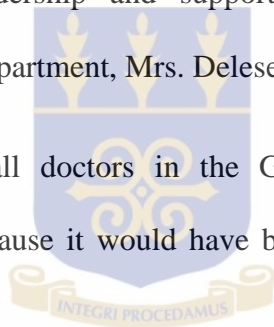
I would like to give thanks to the Almighty God for taking me through the Master of Public Health Programme.

It would not have been possible to write this dissertation without the help and support of the kind people around me, of which only few can be mention here.

I would like to sincerely thank my supervisor Dr. Patricia Akweongo for her support, understanding and patience during this work.

Special thanks also go to the Chief Executive of the Food and Drugs Board, Dr. Stephen Opuni for the selfless leadership and support and to the Head of the Safety Monitoring/Clinical Trials Department, Mrs. Delese Darko for being a great mentor.

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## ABSTRACT

**Background:** Spontaneous reporting is the most efficient and cost effective method of monitoring the safety of registered drugs. The programme was launched in Ghana in June 2001. The spontaneous adverse drug reaction system is affected by underreporting by doctors and other healthcare professionals; there is however, limited knowledge about the factors that contribute to low reporting of adverse drug reactions and the reporting rate in Ghana.

**Objective:** The general objective of this study is to review the spontaneous adverse drug reaction reporting system in the Greater Accra region of Ghana.

**Methods:** The study was a cross sectional survey of 259 doctors involved in clinical practice in 23 hospitals classified as government 199 (76.8%), quasi-governmental 43(16.6%) and private 17 (6.6%) hospitals in the Greater Accra Region of Ghana. The questionnaire was self-administered by the doctors. The 23 hospitals in which the questionnaires were distributed were selected at random and the doctors within the hospitals by convenient sampling. All analysis was done using STATA Version 10 and histograms constructed with MS Excel, 2007.

**Findings:** The response rate in this study was 86.3%. Of the 259 doctors who completed the questionnaire, 154 (59.5%) had seen a patient with suspected adverse drug reaction in the past one year but only 31 (21%) of them had reported it by completing the spontaneous adverse drug reaction reporting form. The reasons given by the doctors for

not reporting were unavailability of the reporting form (43.1%) and lack of knowledge of the reporting procedures (28.5%). One hundred and twenty-one (46.9%) of the doctors had excellent knowledge and 32 (12.4%) had good knowledge of the reporting system. Place of work, rank of the doctor, training and knowledge of the reporting system were significantly associated with adverse drug reaction reporting. Doctors working in government hospitals were about 5 times more likely to report than those in private hospitals [OR=4.94, 95%CI (1.55-15.69)] and medical officers about twice likely to report than other ranks [OR=1.77, 95%CI (0.93-3.40)].

**Conclusion and Recommendation:** Despite the fact that about 47% of the doctors had excellent knowledge of the reporting system, this was not translated into adverse drug reaction reporting. To improve reporting, the reporting forms should be made readily available to the doctors in their consulting rooms and patient wards, training and refresher courses should be organized, and each report submitted by a doctor should be acknowledged and prompt feedback given on the actions taken.

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**LIST OF ACRONYMS**

ADR:	Adverse Drug Reaction
FDB:	Food and Drugs Board
GMDC:	Ghana Medical and Dental Council
ICSRs:	Individual Case Safety Reports
NDRA:	National Drugs Regulatory Authority
UMC:	Uppsala Monitoring Centre
WHA:	World Health Assembly
WHO:	World Health Organization

## **DEFINITION OF TERMS**

### **Pharmacovigilance**

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem (WHO, 2002)

### **Adverse Drugs Reactions**

An adverse drug reaction (ADR) is a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man (WHO, 2002).

### **Spontaneous Reporting**

Spontaneous reporting - System whereby case reports of adverse drug events are voluntarily submitted from health professionals and pharmaceutical manufacturers to the national regulatory authority (WHO, 2002).

## CHAPTER ONE

### INTRODUCTION

#### 1.1 Background

Adverse drug reaction reporting is the cornerstone of pharmacovigilance and it is the way by which unknown negative consequences of drugs can be detected after the drug has been approved for use in the general population. Adverse drug reactions (ADRs) are an important clinical issue because they have resulted in morbidity, mortality and extra cost to the healthcare system (Lazarou, Pomeranz, & Corey, 1998; Pirmohamed, et al., 2004).

Spontaneous reporting of suspected adverse drug reactions is important because it is the means by which rare and fatal adverse drug reactions that were undetected during clinical trials can be detected. The incidence of hospitalizations and deaths related to adverse drug reactions in the United Kingdom has been estimated at 6.5% and 0.15% respectively (Pirmohamed, et al., 2004). The costs associated with these reactions have influenced health care policy and economics, however, little is known about the cost of adverse drug reactions in Ghana.

International efforts to document ADRs began after the thalidomide incidence in 1961; the system however is affected by underreporting. It is estimated worldwide that healthcare professionals report only 6% of ADRs (Hazell, & Shakir, 2006). Information on underreporting in low and middle-income countries is limited because spontaneous reporting is a new concept and most countries do not allocate any budget for pharmacovigilance activities (Olsson, Pal, Stergachis & Couper, 2010). Gharaibeh,

Greenberg and Waldman (1998) estimated that in the developing countries and particularly in Africa the incidence of underreporting may be worse because reactions to particular drugs may be difficult to establish (as cited by Enwere, & Fawole, 2008). Some studies in Nigeria indentify lack of knowledge and ignorance of the reporting procedure as the major cause of under-reporting of ADRs (Bello, & Umar, 2011; Fadare, Enwere, Afolabi, Chedi, & Musa, 2011; Enwere, & Fawole, 2008).

The need for adverse drug reaction reporting in the developing countries particularly in Africa is important because of the different genetic makeup and drug interactions as a result of the use of alternative and herbal medicines together with allopathic medicines. Identification of safety signals specific to African countries is hampered by underreporting.

Pharmacovigilance and spontaneous adverse drug reaction monitoring activities in Ghana was officially launched on June 11, 2001 and Ghana became the 65<sup>th</sup> country to join the World Health Organization Programme for International Drug Monitoring and the first country in West Africa to become a full member of the WHO Programme (Dodoo, 2002). The system is affected by low reporting by healthcare professionals. However, there has been little evidence in Ghana to determine the reporting rate and factors contributing to underreporting by doctors and other healthcare professionals. The purpose of this study is therefore to determine adverse drug reaction reporting rate by doctors, assess the knowledge of the doctors about the adverse drug reaction reporting system and identify factors contributing to under reporting of ADRs by doctors in the Greater Accra Region of Ghana.

## **1.2 Problem Statement**

Rare and unknown adverse drug reactions after drugs approval may lead to negative consequences of these drugs. Spontaneous reporting of suspected adverse drug reaction is the means by which this can be achieved; this is however affected by underreporting by healthcare professionals.

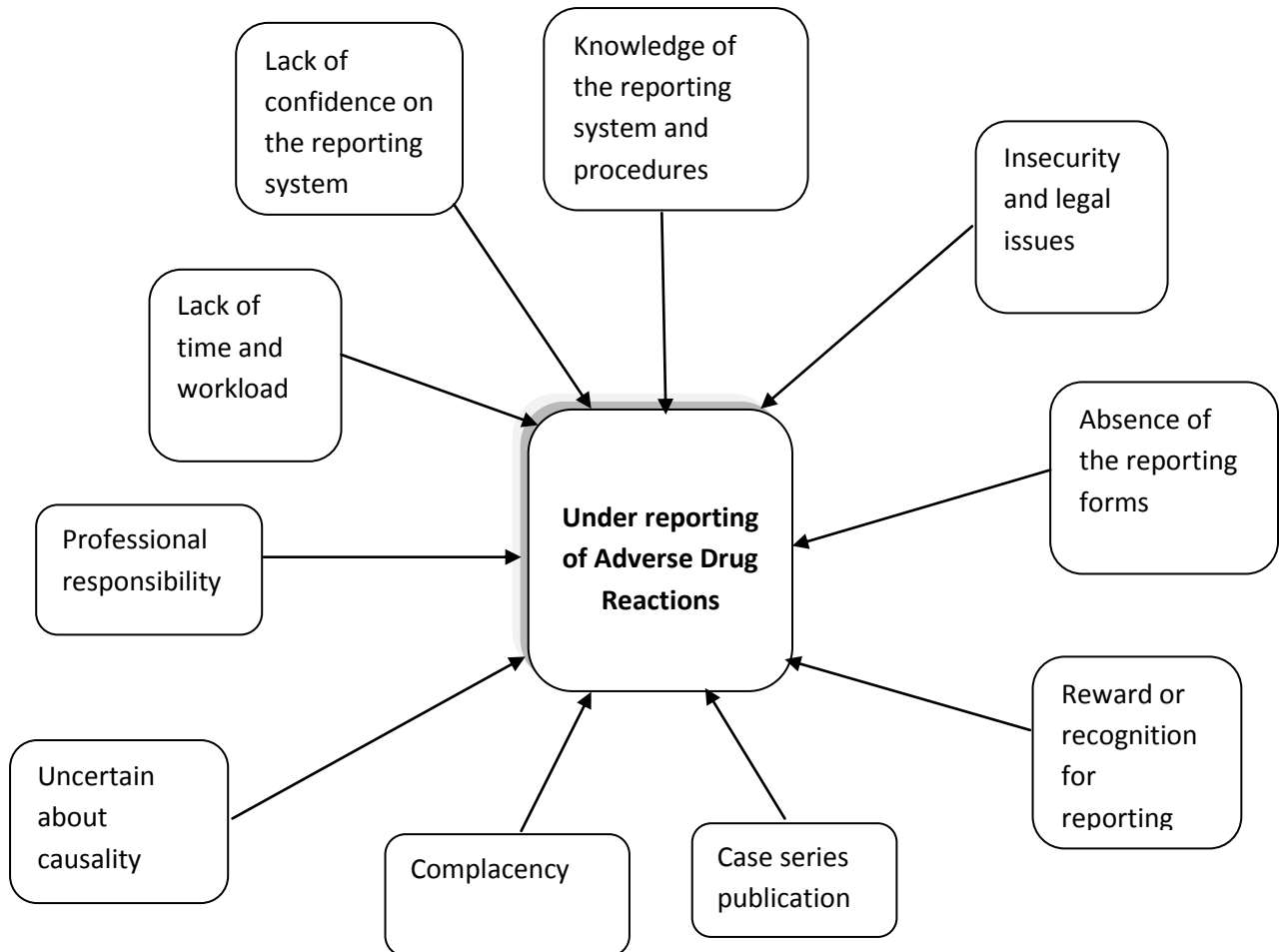
The average number of reports received by the National Centre for Pharmacovigilance in Ghana is 150 reports annually, which implies that just about 6 reports are received per 1,000,000 population in a year. This is significantly less than the WHO recommended annual reporting rate of 200 reports per 1,000,000 population per year (WHO, 2012).

In Ghana 12% of the ADR reports received by the National Pharmacovigilance Centre come from doctors who are the most qualified to provide ADR information

The purpose of this study is therefore to investigate the factors contributing to this low reporting rate by doctors so that appropriate interventions can be made to improve the reporting rate.

## **1.3 Factors Affecting ADR Reporting**

The main construct for the conceptual framework is underreporting of adverse drug reactions by doctors.

**Figure 1: Factors Affecting ADR Reporting**

The framework is based on the factors contributing to underreporting of ADRs (Inman 1996) as cited by Lopez-Gonzalez, Herdeiro, & Figueiras (2009) and other contextual factors affecting underreporting. Underreporting of adverse drug reactions may be due to any of the following factors; lack of knowledge about the reporting system, complacency, uncertainty about causality, lack of time and workload, insecurity and legal issues, desire to publish rather than report, the need for reward or recognition for reporting, absence of the reporting form, lack of confidence on the reporting system and finally some doctors may consider ADR reporting not part of their responsibility.

Doctors who have adequate knowledge of the reporting system and reporting procedures for example are most likely to report suspected ADRs than those with limited or no knowledge of the system. Improved knowledge of the doctors is expected to improve ADR reporting rate and reduce the incidence of underreporting. Underreporting may be influenced by the lack of confidence in the reporting system; this implies that doctors who have adequate knowledge of the reporting system and the procedure but do not have any confidence on the system may fail to report ADR they observe during their practice.

Complacency is the belief that only safe drugs are allowed to be marketed and that a single case reported cannot contribute to medical knowledge. Doctors who think this way may not report adverse drug reactions they observe in their practice. High level of complacency amongst doctors can result in high level of underreporting.

Uncertainty about causality defines the inability to recognize or diagnose ADRs. Doctors with limited knowledge about the diagnosis and management of ADRs may not be able to identify ADRs and therefore may not report. The implication for healthcare is that safety signals will not be detected. The situation when improved by training and education, on diagnosis and management of ADRs and continuous refresher courses and reminders about ADR reporting, then doctors will be more likely to report ADRs .

The excuse some doctors may give for their inability to report ADRs is the fact that they do not have sufficient time to report as a result of heavy workload. Doctors who are busy

may not report ADRs although they may come across them. This phenomenon can result in lower reporting rate and high incidence of underreporting.

Some doctors may have the desire to publish individual case safety reports in scientific journals instead of submitting these reports to the National Pharmacovigilance Centre. The greater the number of doctors with this ambition the lower the reporting rate and therefore high incidence of underreporting.

It is expected that doctors who report ADRs may want some recognition in the form of acknowledgement letters, award, etc. the absence of this type of reward can therefore prevent those who consider this important from reporting ADRs.

Absence of the reporting form is one of the factors that can contribute to underreporting. When the factors contributing to ADR reporting as listed above are addressed and there were no reporting forms, doctors will be unable to report ADRs. Unavailability of ADR forms can significantly reduce the number of ADRs reported.

Insecurity and legal issues defines a situation where the doctors may think that reporting a suspected ADR may result in him/her being accused legally or blamed for giving the wrong medication; where this perception exists underreporting is expected to be high.

Finally, doctors who consider ADR reporting not part of their responsibility can fail to report and thus contributing to low reporting rate and higher incidence of underreporting.

A better understanding of the factors contributing to underreporting will provide answers to the research questions below.

#### **1.4 Research Questions**

What are the factors contributing to underreporting of ADR by doctors in the Greater Accra region of Ghana?

What is the level of knowledge of doctors about the reporting system in the Greater Accra Region?

What is the ADR reporting rate by doctors in the Greater Accra region?

What are the possible ways of improving the adverse drug reaction reporting system in Ghana?

#### **1.5 Justification for the study**

The spontaneous reporting of adverse drug reactions is a proven method for detecting adverse effects of registered medicines. Doctors are important in ensuring the success of the system, however little is known about the factors contributing to underreporting of adverse drug reactions among this group of health professionals in Ghana. The identification of the factors contributing to underreporting of ADRs and the assessment of the knowledge of doctors about ADR reporting can identify measures to be taken to improve knowledge in order to improve reporting of ADRs. Improved ADR reporting can result in timely collection and identification of safety and efficacy issues related to drugs in Ghana. The generation of important safety signals may help prevent patients from negative consequences of drugs including substandard and counterfeit medicines.

## **1.6 Objectives**

### **1.6.1 General Objective**

- i. To determine factors affecting spontaneous adverse drug reaction reporting system in the Greater Accra region of Ghana.

### **1.6.2 Specific Objectives**

- i. To determine adverse drug reaction reporting rate by doctors in the Greater Accra Region.
- ii. To assess the knowledge of doctors about the ADR reporting system.
- iii. To identify factors contributing to underreporting of suspected ADRs by doctors in the Greater Accra Region.

## CHAPTER TWO

### LITERATURE REVIEW

#### 2.1 History of Spontaneous Reporting

The first systematic international efforts to address medicine safety issues at the global level began after 1961 when the supposedly safe drug; thalidomide, was linked to increased incidence of phocomelia and micromelia in new born babies whose mothers used this medicine for the treatment of morning sickness and nausea during pregnancy (Pal, Dodoo, Mantel, & Olsson, 2011; Venulet, & Helling-Borda, 2010). Because of this, several countries all over the world began collecting reports of adverse drug reactions to marketed drugs. In 1962 the World Health Assembly of the World Health Organization identified the seriousness of the problem and adopted the first resolution (WHA 15.41) which requested for the clinical and pharmacological evaluation of drugs. This was proceeded by other resolutions which finally culminated in the 1967 resolution (WHA 20.51) which set up the WHO Pilot Research Project for International Monitoring of Adverse Reactions to Drugs with ten countries in 1968 (Venulet, & Helling-Borda, 2010). The objective of the pilot project was to develop a system, applicable internationally, for detecting previously unknown or poorly understood adverse drug reactions of medicines. The pilot project later developed into the WHO Programme for International Drug Monitoring (the Uppsala Monitoring Centre). Under this Programme, systems have been developed in member states for the collection of individual case safety reports (ICSRs) and their evaluation, this is the start of spontaneous reporting programme worldwide (Venulet, & Helling-Borda, 2010).

The objective of the WHO Programme for International Drug Monitoring is to develop a comprehensive global pharmacovigilance strategy that responds to the healthcare needs of low- and middle-income countries. In December 2010, there were 136 countries participating in the Programme worldwide (Pal, Dodoo, Mantel, & Olsson, 2011; Olsson, Pal, Stergachis, & Couper, 2010).

The system relies on health professionals on observing suspected adverse drug reactions to report these to a regional or national pharmacovigilance centre. The national pharmacovigilance centre (which is usually a part of or closely linked to the national drug regulatory authority (NDRA) forwards the reports to a central database that is managed and maintained by the WHO Collaborating Centre for International Drug Monitoring, the Uppsala Monitoring Centre (UMC) in Sweden (Pal, Dodoo, Mantel, & Olsson, 2011).

ADRs are classified into different types based on the mechanism of the reaction and the dose of the drug.

## **2.2 Types of Adverse Drug Reactions**

Edwards and Aronson (2000) defines an adverse drug reaction as an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product.

Adverse drug reactions (ADRs) are commonly classified into two main categories; type A and type B reactions based on the perceived relation of the adverse reaction to the mechanism and the dose of the drug (Snodin, 2004).

Type A reactions are often referred to as augmented reactions and are result from an exaggeration of a medicine's normal pharmacological actions when given at the usual therapeutic dose. They are normally dose dependent. Examples include: low blood pressure with antihypertensives and haemorrhage with warfarin.

Type B reactions are usually bizarre reactions and represent a novel response not expected from the known pharmacological actions of the medicine. These are idiosyncratic reactions and are normally not dose dependent. Examples include: anaphylaxis with penicillin and skin rashes with antibiotics (Snodin, 2004; Edwards, & Aronson, 2000).

Other categories of adverse drug reactions are Types C, D, E and F (Edwards & Aronson, 2000). Type C adverse drug reactions are due to the cumulative dose of the drug and can be managed by reducing the dose of the drug. Types D and E adverse drug reactions are described as delayed and end of use reactions respectively. Type F adverse drug reactions however, results from unexpected failure of therapy with a medicinal product.

An assessment of the adverse drug reaction reports contained in the pharmacovigilance database of the Chzech Institute for Drug Control over a five-year period (2005-2009) found that the pharmacovigilance department received 7,708 adverse drug reaction reports

of which 73.6% were serious and 2.1% resulted in death. The number of spontaneous adverse drug reactions reports per 1000 inhabitants ranged from 13 to 17 per year. The number of reports contributed by healthcare professionals, marketing authorization holders and patients were 64.2%, 35.5%, and 0.3% respectively. Vaccines, ketoprofen, amoxicillin, statins, and estradiol were amongst the top ten molecules that gave the highest number of spontaneous adverse drug reactions reports. Finally, the study revealed that doctors contributed more than 56% of the spontaneous adverse drug reaction reports to the Chzech database (Kopečna, Desciková, Vlček, & Mláda, 2011).

### **2.3 Burden of Adverse Drug Reactions**

Adverse drug reactions are an important public health issue and have influenced healthcare policy and economics. Incidence of ADRs has contributed to mortality, morbidity, hospitalizations and has resulted in additional cost to the patient, the healthcare system and the society as a whole. It was estimated that in 1994 adverse drug reactions caused over 100, 000 deaths in the United States of America (Lazarou, Pomeranz, & Corey, 1998). Pirmohammed and colleagues conducted a prospective analysis in 2004 of 18,820 patients in the United Kingdom and established that ADRs contributed to 1,225 hospital admissions with a prevalence of 6.5%. The study also found that the projected annual cost of such admissions to the National Health Service (NHS) is \$847 million with fatality of 0.15%. It was also found that fatal adverse drug reactions accounted for approximately 3% of all deaths in the general population (Wester, Jönsson, Spigset, Druid, & Hagg, 2008). A meta-analysis of observational studies by Beijer and de Blaey (2002) established that the incidence of adverse drug reaction (ADR) due to established drugs

range from 3.1% in children, 6-8.5% in the young adult and middle age, and 20% in the geriatric group. There is however, limited data on the economic and social burden of adverse drug reactions in African countries including Ghana.

#### **2.4 Diagnosis and Treatment of ADRs**

Diagnosis of ADRs is a complex issue involving consideration of a number of factors (Edwards, & Aronson, 2000) and the differential diagnosis for any patient taking medication should include the possibility of an adverse drug reaction. The first problem is to find out whether the ADR is actually due to the suspected drug or concomitant therapies including herbal or traditional remedies, recreational drugs or drugs of abuse and long-term treatments such as oral contraceptives. The second step is to find out whether the effect could be due to a medicine, however, if the patient is taking several medicines, the problem is to distinguish which, if any, is causative. Diagnosis of ADRs is further complicated if the patient's complaints might be due to other diseases or one or more of the drugs. Important issues to consider in considering differential diagnosis of an ADR are the time relationship between the occurrence of the ADR and the administration of the suspected drug; the disappearance of the reaction on withdrawal of the suspected drug; the relation between the dose of the drug and the adverse drug reaction and whether the reaction be explained by other drugs or the disease condition (Edwards, & Aronson, 2000).

In the management or treatment of ADRs the doctor has to take clinical benefit-risk decision taking into account when assessing the need of the patient. Whereas serious

adverse drug reactions such as anaphylaxis require immediate withdrawal of the suspected drug less serious adverse drug reaction will require reassurance of the patient. In cases where the patient is taking several medications and there is lack of information as to which of these is the causative drug; it is recommended that all medicines are withdrawn and then gradually reintroduced one at a time. Dose reduction may be considered if the adverse drug reaction is dose related. However, if the patient cannot do without the drug it is advisable that symptomatic relief is provided while continuing the essential treatment (Edwards, & Aronson, 2000).

## **2.5 Approaches to Monitoring ADRs**

There are basically two major methods of monitoring the safety of registered medicines, namely, spontaneous reporting and prescription event monitoring (or cohort event monitoring).

The WHO (2002) defines spontaneous reporting as “a system whereby case reports of adverse drug events are voluntarily submitted from health professionals and pharmaceutical manufacturers to the national regulatory authority”. Spontaneous adverse drug reaction reporting systems are the easiest to establish and the cheapest to run and it is used as an early warning system for identification of safety problem with medicines such as the risk of rhabdomyolysis with the statins. It is however difficult to determine the actual number of individuals experiencing adverse drug reaction to medicines because of low and irregular reporting (Pal, Dodoo, Mantel, & Olsson, 2011).

The second method of monitoring safety of medicines after approval is cohort event monitoring (CEM) which is a prospective, observational study of adverse events associated with one or more medicines. This methodology is often referred to as prescription event monitoring (PEM); this terminology is however inappropriate when individual prescription with subsequent dispensing by pharmacists is not part of the process of supplying medicines to patients. The advantage of this method is that it is able to produce rates because the total number exposed to the medicine is known and also accurate comparisons can be made between medicines. However, the disadvantage of this method is that it is more labour intensive and more costly than spontaneous reporting (WHO, 2009). Thus spontaneous reporting is the approach used by many countries including Ghana.

Pharmacovigilance and spontaneous adverse drug reaction monitoring activities in Ghana are the mandate of the National Pharmacovigilance Centre, the Food and Drugs Board. The activities are coordinated by the Safety Monitoring Department of the Food and Drugs Board. The spontaneous reporting system relies on healthcare professionals (including but not limited to doctors, pharmacists, nurses and medical assistants), pharmaceutical companies and consumers to submit reports of suspected adverse drug reactions to the Food and Drugs Board (National Pharmacovigilance Centre).

The National Pharmacovigilance Centre has developed tools like the adverse drug reaction reporting form and the guideline for reporting adverse drug reactions to assist healthcare professionals report adverse drug reactions, product quality problems and therapeutic

failures. The Centre also trained designated contact persons for pharmacovigilance in health facilities across the country; this system is however, affected by high staff turnover and frequent transfers (FDB, 2010). An assessment of the Ghana's pharmacovigilance system in 2009 revealed that healthcare professionals are aware of the pharmacovigilance system and the reporting forms are readily available in the health facilities (Nwokike & Eghan, 2010). The staff of the FDB collates the completed adverse drug reaction reports received by the National Pharmacovigilance Centre, which is regularly reviewed by the Technical advisory Committee on Safety Monitoring for signal generation and advice on the possible regulatory action to be taken when necessary (FDB, 2011).

Although the current guidelines requests marketing authorization holders to submit reports of unexpected serious adverse drug reactions to the Food and Drugs Board in accordance with specific timelines in the guidelines (FDB, Guidelines for Safety Monitoring, 2011) this is not been adhered to because currently there are no adequate provisions in the FDB legislation to enforce this requirement. Spontaneous reporting of adverse drug reaction in Ghana is however voluntary for all healthcare professionals. Spontaneous adverse drug reaction reports received by the National Centre are entered into the WHO Vigiflow database hosted by the Uppsala Monitoring Centre and into an in-house database.

Other approaches of monitoring the safety of registered medicines are anecdotal reporting, cohort studies, case-control studies, case-cohort studies, population statistics, record linkages and meta-analysis (Edwards, & Aronson, 2000).

## **2.6 Factors Affecting Spontaneous Adverse Drug Reactions Reporting**

Spontaneous adverse drug reactions reporting programmes depend on healthcare professionals to submit suspected ADRs to National Pharmacovigilance Centre for entry into an ADR database, which serve as a source of information on drug safety and signal generation. The system is crucial in identifying adverse drug reactions, substandard and efficacy issues related to marketed products. In Ghana the spontaneous adverse drug reaction programme is coordinated by the Food and Drugs Board which is the National Centre for Pharmacovigilance. However, the system in Ghana is affected by underreporting of adverse drug reactions.

The National Pharmacovigilance Centre receives approximately 150 reports annually corresponding to a reporting rate of about 6 reports per million inhabitants. This is significantly less than annual reporting rates of about 300-500 reports per million population in Australia, Denmark, France, Ireland, Sweden and UK (Belton et al., 1997; Aagaard, Stenver, & Hansen, 2007).

In Ghana, doctors are expected to voluntarily report suspected ADRs to the National Pharmacovigilance Centre, however, reports received over the years showed that the proportion of reports received from doctors constitute only 12% of the total number of reports, this is significantly less than the 56% adverse drug reaction reports submitted by doctors to the Chzech Republic pharmacovigilance database (Kopečna, Desciková, Vlcek, & Mláda, 2011).

The factors contributing to low reporting of ADRs among health professionals have been summarized as the ‘seven deadly sins’ (Inman (1996); as cited by Lopez-Gonzalez, Herdeiro, & Figueiras, (2009). He describes the ‘seven deadly sins’ as follows: **Complacency** (the belief that only safe drugs are allowed on to the market); **Insecurity and legal issues** (fear of possible involvement in litigation or being accused of prescribing the wrong medicine); **Case series publication** (ambition to compile and publish a personal case series; Lack of knowledge (ignorance of the requirements for reporting); **Diffidence** (prospect of appearing ridiculous for reporting merely suspected ADRs); **Professional responsibility** (indifference on the part of an individual doctor to his/her essential role as a clinical researcher who should be contributing to medical knowledge); **Lethargy** (an amalgam of procrastination, lack of interest or time to find a report card and other excuses); **Financial incentives to report**. Other factors contributing to underreporting that were not mentioned by Inman are ignorance, insecurity, lack of yellow cards or forms for reporting, lack of information and feedback of reported ADR to doctors and fear of the negative impact the report may have on the company that produced or marketed the drug (Rogers, Israel, & Smith, 1998; as cited by Lopez-Gonzalez, Herdeiro, & Figueiras, 2009; Vallano, Cereza, Pedròs, Agustí, Danés, Aguilera, & Arnau 2005).

Hazell and Shakir (2006) conducted a systematic review of 37 studies from 22 countries and estimated that only 6% of all adverse drug reactions are reported, this provided a strong evidence to show that underreporting is a major limitation of spontaneous ADR reporting systems. On the one hand, this high rate of underreporting prevents risk from being quantified, and on the other hand, it leads to excessive delay in triggering alert

signals, with the ensuing repercussions on public health.

A second systematic review by Lopez-Gonzalez, Herdeiro and Figueiras (2009) reviewed 45 publications with varying sample size of between 12 to 4808 respondents; only two of the studies reviewed were publications from African countries. The studies identified personal or professional factors and attitudes associated with underreporting. About 76% of the studies identified medical specialty (or training) as most frequently personal or professional factor associated with reporting ADR. This was followed by sex, reporter's workplace, workload, number of prescriptions issued per day, type of education received by the reporter and specific training in pharmacovigilance. One study identified involvement in teaching and research activities as the main factor most likely linked to ADR reporting. The systematic review also identified ignorance (95%); diffidence (72%); lethargy (77%); indifference and insecurity (67%); complacency (47%); and fear (24%) as attitudes associated with failure to report ADRs. In 25 studies that included information about the availability of the reporting form, 76% percent identified absence of the reporting form as the reason for not reporting. Other reasons cited for not reporting in some of the studies were that some healthcare professionals do not regard ADR reporting as their professional responsibility. 35% out of 17 studies considered the reporting system too bureaucratic, hence the failure to report ADRs.

Although the reasons for underreporting have been extensively studied in the Europe and the Americas, there is limited information about underreporting in Africa. Secondly, reasons for underreporting may vary from one country to another, whereas study in Spain identified complacency as the main reason for underreporting (Irujo, Beitia, Bes-Rastrollo, Figueiras, Hern´andez-D´iaz & Lasheras, 2007). Studies in Nigeria identified lack of

knowledge as the main factor (Bello, & Umar, 2011; Fadare, Enwere, Afolabi, Chedi, & Musa, 2011; Oshikoya, & Awobusuyi, 2009; Enwere, & Fawole, 2008). A literature search identified five studies that have identified factors contributing to under reporting in Africa, none of these studies was however conducted in Ghana (Bello, & Umar, 2011; Fadare, Enwere, Afolabi, Chedi, & Musa, 2011; Oshikoya, & Awobusuyi, 2009; Enwere, & Fawole, 2008; Robins, Weir, & Biersteker, 1987).

Bello and Umar (2011) interviewed sixty-one doctors in a specialist hospital in Sokoto, north-western Nigeria to assess the documentation of ADRs and the knowledge of doctors on spontaneous reporting. The study discovered that only 4.9% of medical officers had reported ADRs they encountered in their practice although 70.5% of the respondents had seen a patient with a potential ADR twelve months prior to the study, this translated reporting rate of 7%. The study also discovered that very high proportion (95.1%) of the respondents were not aware of the ADR reporting system in Sokoto. Additional factors identified as contributing to underreporting are that the doctors do not trust the authority to use the information to be provided on the form properly, failure to identify ADRs and reports from patients are not reliable for documentation.

Oshikoya and Awobusuyi (2009) carried out study in Lagos, Nigeria to determine the knowledge and attitude of doctors in a teaching hospital on spontaneous ADR reporting and to suggest possible ways of improving the method. They interviewed one-hundred and twenty doctors and discovered that 40.4% of the respondents knew about the existence of adverse drug reaction reporting system in Nigeria, 32.3% were aware of the adverse drug

reaction reporting form but only two had ever reported ADRs to the National Pharmacovigilance Centre. Respondents also identified education and training as the means of improving ADR reporting.

Another study amongst healthcare workers (doctors, nurses and pharmacists) in a tertiary hospital in Kano, northern Nigeria to determine knowledge, attitude and practice of ADR monitoring and reporting revealed that only 35.9% of the health workers were aware of the adverse drug reaction reporting form and 42.7% had ever reported an ADR with 75% of the reported cases being verbal to another member of the managing medical team. Ignorance of the rules and procedures of reporting, lack of knowledge of the reporting forms for reporting and which ADRs to report were some of the factors identified as contributing to non reporting of ADRs among healthcare workers (Fadare, Enwere, Afolabi, Chedi, & Musa, 2011).

Although some of the studies have mentioned financial reward as one of the factors contributing to underreporting, reward in the form of recognition has not been assessed, since not everybody will want financial incentives for reporting ADRs. This study will explore whether reward in the form of acknowledgement letters, publication of the names of best reporter in the local scientific journal and award of credits for continuing professional medical education will be one of the factors to consider in an attempt to improve reporting.

Secondly, the study will identify the differences between private and public hospitals concerning the practice and knowledge of ADR reporting.

Finally, there is currently little information on the possible factors contributing to underreporting of adverse drug reactions by doctors in Ghana and since these factors vary from country to country; this study will seek to identify the factors affecting ADR reporting in Ghana and the possible interventions to improve reporting by doctors.

## CHAPTER THREE

### METHODOLOGY

#### 3.1 Study Design and Location

The study was a cross sectional survey of doctors involved in clinical practice (patient care and prescription of drugs to patients) in government, quasi-governmental and private hospitals in the Greater Accra Region of Ghana. The Greater Accra Region was chosen because 38% (920) of the 2421 doctors registered by the Ghana Dental and Medical council to practice medicine in Ghana are in the region (GMDC, 2011).

The study population was made-up of doctors involved in clinical practice within the past one year in the Region and the study unit was the doctors who completed the questionnaire. One year was chosen to reduce recall bias. The study was conducted amongst only doctors although other groups of healthcare professionals (e.g. nurses, pharmacists, medical assistants) are encouraged to report ADRs due to number of patients a doctor would see and the likelihood of seeing suspected ADR cases.

The population of the Greater Accra region is 4,010,054 (GSS, 2012) with a doctor to patient ratio of one doctor to 9,939 patients (MOH, 2009). The region currently has 10 administrative districts with 314 hospitals. These hospitals are classified as government, quasi-government and private facilities.

### 3.2 Study Variables

The main construct for the study is the dependent variable, underreporting of adverse drug reactions. The independent variables such as knowledge of ADR reporting system, training on drug safety and ADR reporting and so on are used in the study to establish the determinants of ADR reporting by doctors (Table 1).

**Table 1: Independent Variables and Indicators**

<b>Independent Variables</b>	<b>Indicator</b>
Knowledge of the ADR reporting system and procedures	<ul style="list-style-type: none"> <li>- Awareness of the ADR reporting system,</li> <li>- Having seen the reporting form</li> <li>- How to obtain the reporting form and</li> <li>- Where to send the form when completed</li> </ul>
Average number of patients seen per day	- Total number of patients the doctor attends to during the day
Level of hospital	- Teaching hospital, Regional Hospital or District hospital*
Place of work	- Government, Quasi-government and Private hospitals
Rank of the Doctor	- House officer, Medical officer, Senior medical officer, Principal Medical officer, Specialist, Consultant
Training on drug safety and ADR reporting	- Participation in training program on drug safety and ADR reporting
Sex	- Male or Female
Age	- Years

\*Private hospitals are classified as District Hospital

### 3.3 Sample Size Determination

The sample size determination was based on the formula;

$$n = Z^2 P(1-P) / d^2$$

where  $n$  = sample size,

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

$P$  = expected prevalence and

$d$  = precision [this is fixed at 5% (i.e. 0.05)].

There is no information about the prevalence of underreporting or an estimate of unreported ADRs in the Greater Accra Region of Ghana, assuming 50% (i.e. 0.5) of underreporting in the region as suggested by Macfarlane (1997) and with a precision of 0.05 at 95% confidence interval. The maximum sample size obtained using the formula was 384.

Since this sample size exceeds 5% of the population of the doctors in the Greater Accra region (i.e. 920), Cochran's (1977) correction formula as cited by Bartlett II, Kotrlik, & Higgins (2001) was used to calculate the final sample size as shown.

$$\text{i.e. } n_1 = \frac{n_0}{(1 + n_0 / \text{Population size})}$$

Where population size = 920

$n_0$  = required sample size (384)

$n_1$  = required return sample size because sample > 5% of population.

The minimum sample size required is therefore 271.

In order to cater for non-response from participants, a 10% non-response rate was used to bring the total sample size to 298, which was approximated to 300 doctors.

### **3.4 Sampling**

The required sample size of 300 for the study was obtained from about 920 doctors who were involved in clinical practice in 314 hospitals in the Greater Accra Region. The hospitals were grouped into government, quasi-government and private hospitals. The hospitals in which the questionnaires were administered were selected by simple random and the doctors who completed the questionnaire were selected by convenient sampling. A hospital selected at random was visited by the study team and the questionnaire administered to the doctors, if the required sample size of 300 is not obtained at this hospital, the next hospital is selected until the sample size was obtained. Twenty-three hospitals whose doctors participated in this study came from 13 government hospitals, 4 quasi-government and 6 private hospitals.

The inclusion criteria for a doctor to participate in the study were, s/he must be involved in clinical practice and should have practiced for at least one year.

Doctors who were not involved in clinical practice in the past one year were excluded from the study.

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

Data collection was from May 5, 2012 to July 6, 2012. A semi-structured self-administered anonymous questionnaire (Appendix 1) was distributed to the 300 doctors in 23 different hospitals.

The questionnaire was four pages in length and contained four sections (Sections A-D) to

collect the following information; background characteristics of the doctors and knowledge about the ADR reporting system. Other information to be collected were ADR reporting and reasons why doctors who had seen patients with suspected ADRs are unable to complete the reporting form and the factors perceived by doctors as contributing to underreporting of ADRs (includes section on motivation/reward/recognition for reporting and ADR reporting as a professional responsibility).

The additional multiple response questions on reasons for not reporting ADRs, aimed at finding out the actual reasons for which doctors who had seen a patient with an ADR in the past one year failed to report by completing the form; this was needed to compute the reporting rate.

The questionnaire was delivered to the doctors in their consulting rooms or at the clinical meetings after permission was sought from the Head of the hospital or the Department in the hospital. A brief explanation of the study objectives, overview of the questionnaire and assurance of confidentiality was provided to the doctors before their participation. Agreement to complete the questionnaire was taken as an informed consent to take part in the study.

### **3.6 Quality Control**

The survey questionnaire was pretested to determine its appropriateness and suitability for the study. The pretesting resulted in correction, rephrasing and rearrangement of sentences and sections in the questionnaire. In order to ensure uniformity of the process, the two research assistants involved in the study were trained on how to explain the study

objectives and overview of the questionnaire to the doctors. To improve the response rate, the doctors were requested to complete the questionnaires in the presence of the investigator or study assistants. However, doctors who preferred to complete the questionnaires later were given a maximum of two working days after which they were revisited for collection, three re-visits were allowed and if the questionnaire was not completed by the doctor, it was retrieved but if this was not done, this was assumed to be a non-response.

### **3.7 Data Processing and Data analysis**

The data collected during the interview process was entered into STATA Version 10. Descriptive statistics (frequency tables) was used to describe the background characteristics of the doctors. The rank of the doctors were re-grouped into three categories, namely House officers, Medical officers (consisting of Medical officers, Senior Medical officers and Principal Medical officers) and Specialist (consisting of Specialists and Consultants).

Chi squared test and simple logistic regression were used to test for the association between the dependent variable (ADR reporting) and independent variables. Multiple regression was used to test for the strength of association between the variables that proved significant in the analysis using the Chi squared test (i.e. place of work, training, rank and knowledge of the reporting system). The results were expressed as chi-squared, p-values, odd ratios and corresponding confidence intervals, a p-value  $\leq 0.05$  was considered statistically significant. All analysis was done using STATA Version 10

(StataCorp, 4905 Lakeway Drive, TX). Histograms were obtained using MS Excel (Microsoft INC, 2007).

Four questions, namely; “awareness of the reporting system”, “having seen the reporting form”, “how to obtain the form” and “where to send the form once completed” were used to assess the basic knowledge of the doctors about the reporting system in Ghana and each of the questions was graded 1. The responses were coded on a scale from 0 to 4. Knowledge of the doctor was obtained by adding the score obtained for each question; with 0, 1, 2, 3 and 4 representing no knowledge, poor knowledge, average knowledge, good knowledge and excellent knowledge in that sequence.

The proportion of doctors reporting ADR reporting was calculated by dividing the number of doctors who had seen a patient with an ADR in the past one year prior to the study divided by the total number of doctors who had seen a patient with an ADR but did not report.

The factors perceived by doctors as contributing to underreporting was determined by multiple response to questions such as lack of time and heavy workload, unaware of the reporting procedure and how the reporting form can be obtained and lack of confidence in the reporting system.

### **3.8 Ethical considerations**

Ethical approval was sought from the Ghana Health Service Ethical Review Committee of the Research and Development Division of the Ghana Health Services for the conduct of the study.

The identity of the doctors who completed the questionnaires were kept confidential and their consent was sought before participation in the study. There was minimal or no risk associated with participation in this study and no compensation was paid to the participants.

This research was for academic purposes, but the author had an interest in this study because he works for the Food and Drugs Board (the National Centre for Pharmacovigilance), the institution responsible for coordinating pharmacovigilance and spontaneous adverse drug reaction activities in Ghana. However, there is no conflict of interest because he is not involved in the actual spontaneous reporting of ADRs that comes from the healthcare professionals.

### **3.9 Limitations of the study**

Factors associated with self-reporting studies such as accuracy of recall and personal bias may affect the study. It may be difficult for some of the doctors to remember if they had seen a patient with an adverse drug reaction or the reporting form during their practice, this was however minimized by use of one year recall period.

Secondly, some of the doctors may give socially acceptable responses like having reported an adverse drug reaction in the past one year. The probability of this was reduced by informing the doctors that their identity will be kept confidential.

Thirdly, it may not be possible to generalize the study to all doctors in the region since those who participated in the study were selected by convenient sampling.

Lastly, the number of doctors selected from the facilities classified as government, quasi-government and private facilities may not be the actual representation from the different places of work. The best type of sampling to use will be sampling proportionate to size, however, the proportion of doctors who practiced in these category of facilities was not available.

## CHAPTER FOUR

### RESULTS

Two hundred and fifty-nine doctors in 23 hospitals consisting of 199 (76.8%) doctors working in government hospitals, 43 (16.6%) doctors working with quasi-government hospitals and 17 (6.6%) doctors working in private hospitals in the Greater Accra region completed the questionnaire. The response rate was 86.3%. The hospitals visited were teaching hospitals (2), regional hospitals (2) and district (19) hospitals. Approximately, 130 (50.2%) reports were obtained from the teaching hospitals, 54 (20.9%) reports from the regional hospitals and 75 (28.9%) reports from the 19 district hospitals.

There were 166 (64.1%) male doctors and 93 (35.9%) female doctors. The mean age of the doctors' was 35.9 (SD8.1) with the youngest age reported as 26 years and oldest 70 years (Table 2). The average number of years practiced was 8.4 years (SD7.4), with a range of 2 to 42 years. The average number of patients seen by each doctor per day was 32.1 (SD20.1) patients.

**Table 2: Background Characteristics of Doctors Participating in ADR Reporting Study in Greater Accra Region (N=259)**

Background Characteristics		Frequency	Percent
Age (years)	≤29	53	20.5
	30-34	86	33.2
	35-39	58	22.4
	40-44	28	10.8
	45-49	13	5.0
	50-54	11	4.3
	≥55	10	3.9
Gender	Male	166	64.1
	Female	93	35.9
Marital Status	Married	174	67.2
	Single	84	32.4
Rank	House Officer	51	19.7
	Medical Officer	136	52.5
	Specialist	72	27.8
Place of Work	Government	199	76.8
	Quasi-government	43	16.6
	Private	17	6.6
Level of Facility	Teaching Hospital	130	50.2
	Regional Hospital	54	20.9
	District Hospital	75	28.7
Patients seen per day (N=256)	≤14	23	9.0
	15-24	57	22.3
	25-34	77	30.1
	35-44	51	19.9
	≥45	48	18.8
Number of years practiced	≤8	170	65.6
	≥9	89	34.4
Trained on Drug Safety and ADR reporting (N=71)	Government	52	73.2
	Quasi- Government	17	24.0
	Private	2	2.8

House officers constitute 51 (19.7%) of the respondents, 136 (52.5%) were medical officers and 172 (27.8%) were specialists. The rank of the doctor significantly associated with adverse drug reaction reporting ( $X^2=6.7$ ,  $p\text{-value}=0.035$ ), medical officers were almost twice more likely to report adverse drug reactions than House officers [OR=1.77, 95%CI (0.93-3.40)] (Table 3).

Overall, the study showed that the age of the doctor is not a significant determinant of adverse drug reaction reporting, however, doctors above 55 years were about three times more likely to report adverse drug reactions than those below 29 years [OR=2.82, 95%CI (0.66-12.1)]. The study revealed that where the doctor works increased the likelihood of adverse drug reaction reporting with doctors who worked in the government hospitals about five times more likely to report suspected adverse drug reactions than those who worked in private hospitals [OR=4.94, 95%CI (1.55-15.69)]. Other factors that significantly influenced adverse drug reaction reporting by doctors were training and knowledge of the reporting system (Table 3).

**Table 3: Odds of Adverse Drug Reaction Reporting**

Characteristics		X <sup>2</sup> (df), p-value	Crude OR, CI95%	
Gender	Male		1.00	
	Female	0.16(1), 0.688	1.42	0.85-2.36
Age	≤29		1.00	
	30-34		1.53	0.77-3.04
	35-39		1.29	0.61-2.73
	40-44	6.34(6), 0.386	1.05	0.56-6.69
	45-49		1.93	0.56-6.69
	50-54		1.45	0.39-5.34
	≥55		2.82	0.66-12.10
Average patients/day	≤32		1.00	
	≥33	1.71(1), 0.191	0.89	0.54-1.46
Level of Facility	Teaching		1.00	
	Regional		1.23	0.64-2.30
	District	1.92(2), 0.384	0.65	0.37-1.56
Place of Work	Private		1.00	
	Government	6.81(2), 0.033	4.94	1.55-15.69
	Quasi-government		1.26	0.34-4.63
Training	No		1.00	
	Yes	11.60(1), 0.001	1.14	0.66-1.98
Marital Status	Married		1.00	
	Single	0.98(1), 0.321	1.08	0.64-1.81
Additional Qualification	No		1.00	
	Yes	0.06(1), 0.804	1.03	0.53-1.99
Involved in clinical Research	No		1.00	
	Yes	0.81(1), 0.368	1.07	0.62-1.85
Rank	House Officer		1.00	
	Medical Officer	6.71(2), 0.035	1.77	0.93-3.40
	Specialist		1.32	0.64-2.71
Knowledge	None		1.00	
	Poor		0.82	0.30-2.25
	Average	27.36(4), <0.001	1.44	0.47-4.41
	Good		0.97	0.32-2.92
	Excellent		1.51	0.60-3.82

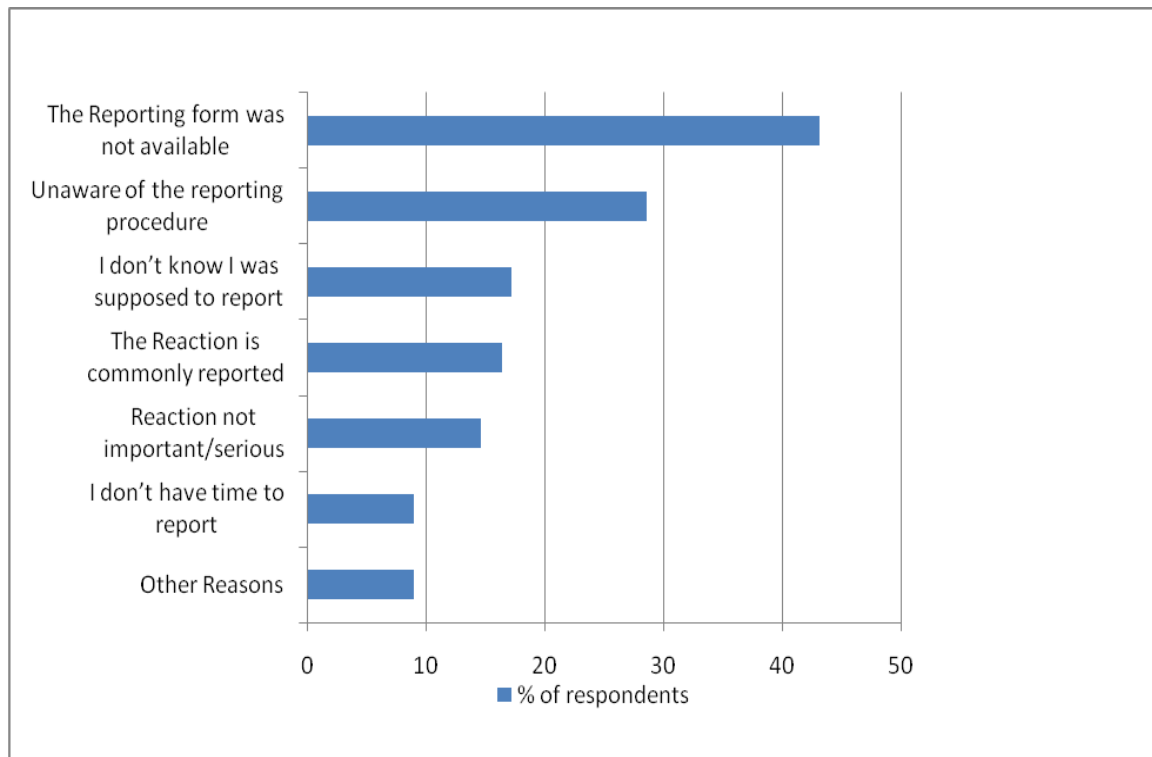
Factors such as knowledge of the reporting system, rank of the doctor, training and place of work did not turn out statistically significant in the multivariate logistic regression as determinants of reporting suspected ADRs (Table 4).

**Table 4: Determinants of Adverse Drug Reaction Reporting**

Variables	Adjusted OR	p-value	95% CI
Training	1.03	0.914	0.57-1.88
Place of Work	0.64	0.113	0.18-1.59
Rank	1.05	0.573	0.90-1.22
Knowledge of ADR reporting system	1.17	0.104	0.97-1.40

#### **4.1 Adverse drug reactions reporting by Doctors in the Greater Accra Region**

Only seventy-one (27.4%) of the 259 doctors who participated in the study received training on drug safety and ADR reporting. One hundred and fifty-four (59.5%) of these doctors had seen a patient with suspected adverse drug reaction in the past one year but only 31 (21%) of them had reported it by completing the spontaneous adverse drug reaction reporting form. The reporting rate of suspected adverse drug reaction in the Greater Accra Region was therefore 21% (31) among the doctors in this study. Of the 31 doctors who reported the suspected adverse drug reactions in the past one year, 18 (58.1%) received training and education on drug safety and ADR reporting. For the 123 (79%) doctors who did not report suspected ADRs they had seen, the dominant reason (Figure 2) for not reporting was the unavailability 53(43.1%) of the reporting form followed by lack of knowledge of the reporting procedure 35(28.5%).

**Figure 2: Reasons for Poor Reporting of Adverse Drug Reactions by Doctors**

Eleven doctors who provided answers to the open ended question on additional reasons for not reporting adverse drug reactions, gave reasons such as difficult to attribute causality 4(36.4%), forgotten to report 2(18.2%) and expected other team members to report 2(18.2%). Others stated not directly responsible for the patient 2 (18.2%) and patient lost to follow-up 1 (9.1%) as factors that contributed to their inability to complete the reporting form.

Eighteen (56.1%) of the 31 doctors in quasi-government hospitals who did not report adverse drug reactions mentioned non-availability of the reporting form at the hospital as the major reason for not reporting adverse drug reactions.

#### 4.2 Factors Contributing to Underreporting of ADRs by Doctors

The perception of the doctors about the factors contributing to underreporting of suspected ADRs was reported by one hundred and eighty-nine (74.7%) of doctors as due to lack of time and heavy workload (Table 5). Other reasons were lack of awareness about the reporting procedure and how the form could be obtained 187 (73.9%) and the lack of confidence of the doctors on the reporting system 91 (36.0%).

**Table 5: Factors Perceived Contributed to Underreporting of Adverse Drug Reactions (N=253)**

<b>Factors</b>	<b>Frequency</b>	<b>Percent</b>
Lack of time and heavy workload	189	74.7
Unaware of the reporting procedure and how the form can be obtained	187	73.9
Lack of confidence in the reporting system	91	36.0
The reporting form is not available at the hospitals	87	34.4
Inability to recognize or diagnose ADRs	79	31.2
No idea that ADRs are to be reported	79	31.2
No reward or recognition for doctors who report ADRs	40	15.8
Fear of being accused of administering the wrong drug	39	15.4
Fear of negative impact the report may have on the company that produces the drug	16	6.3
ADRs are well documented before drug marketing	16	6.3
Responsibility of consumers to report	14	5.5
Single case reported cannot contribute to medical knowledge	15	5.9
Preference to publish than report to FDB	13	5.1
Not doctors professional responsibility to report ADRs	9	3.6

### 4.3 Knowledge about the Reporting System

Thirty-five (13.5%) of the 259 doctors who participated in the study had never heard about the spontaneous adverse drug reaction reporting system in Ghana and 106 (40.1%) of the doctors had never seen the spontaneous adverse drug reaction reporting form. Sixty-seven (25.9%) did not know how or where to obtain the reporting form and about 124 (47.9%) of doctors did not know where to send the form once the form was completed. Interestingly, only 113 (43.6%) knew that the reporting form was available at the hospitals where they practiced.

Eleven (64.7%) of the 17 doctors working in private hospitals in the Greater Accra Region had also never seen the reporting form in their practice.

There were four questions designed to measure the knowledge of the doctors about the reporting, system namely; awareness of the reporting system, having seen the reporting form, how to obtain the form and where to send the form once completed. Less than half 121 (46.9%) of the doctors answered all four questions correctly (Table 6) which represented excellent knowledge of the reporting system.

**Table 6: Knowledge of Doctors about the Reporting System in Ghana (N=258)**

Knowledge	Frequency	Percent
None	21	8.1
Poor	54	20.9
Average	30	11.6
Good	32	12.4
Excellent	121	46.9

Knowledge of the doctors about the reporting system was widespread amongst doctors who worked in government [OR=1.63, 95%CI (0.34-7.83)] and quasi-government hospitals [OR=1.91, 95%CI (0.29-12.61)] than doctors working in private hospitals. Doctors working in government hospitals are about twice likely to be knowledgeable about the reporting system than those working in private hospital [OR=1.91, 95%CI (0.29-12.61)]. Knowledge of the doctor about the reporting system is also significantly related to the rank, with medical officers about twice knowledgeable [OR=1.99, 95%CI (0.60-6.57)] than other ranks.

Doctors within the age category of 30 to 34 years were also about three times more likely to have knowledge of the ADR reporting system than (OR=2.67, 95% CI (0.72-9.97) doctors who were less than 29 years old.

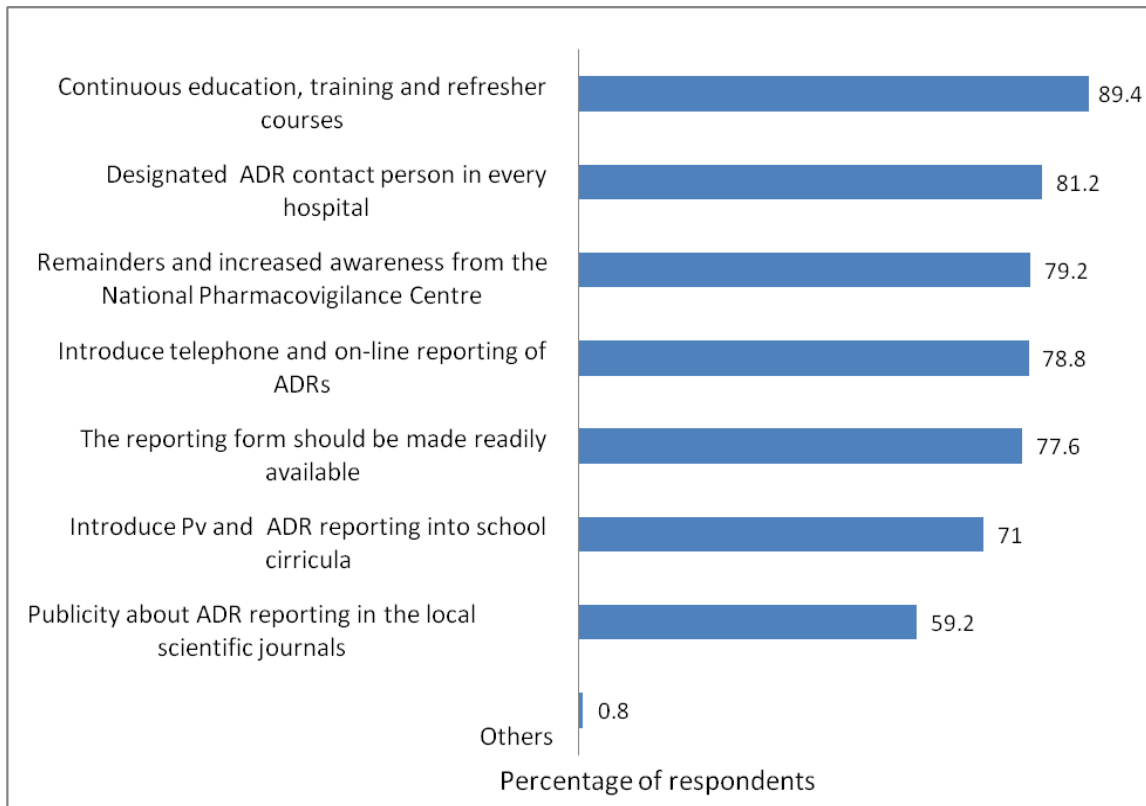
Twenty-nine (93.6%) of the 31 doctors who reported ADRs had excellent knowledge of the reporting system by answering all the four knowledge questions correctly. Therefore, knowledge of the reporting system suggested a strong determinant for adverse drug reaction reporting. However, there was no significant correlation between the knowledge of doctors about the reporting system and the age of the doctor or the number of years the doctor had been in practice.

#### **4.4 Strategies to Improve Spontaneous Reporting**

The results showed that many more doctors would report if appropriate rewards or motivation schemes were considered to encourage ADR reporting. Most doctors 161 (62.2%) considered a letter acknowledging receipt of each report submitted as motivating enough to encourage more ADR reporting.

Also about 59 (22.8%) of doctors in the study reported that if ADRs submitted by doctors would earn them credits for continuous professional development as well as names of doctors who reported ADRs published in the local scientific journals 45 (17.4%), these non-monetary incentives would encourage more ADR reporting by doctors. However, twenty-three (79.3%) of the 29 doctors who provided open responses to the reward or motivation required to report ADRs, wanted feedback from the National Pharmacovigilance Centre on actions taken on the reports submitted. Only 2 (6.9%) wanted monetary rewards for reporting adverse drug reactions.

Two hundred and twenty-eight (89.4%) of the doctors agreed that providing continuous education and refresher courses on ADR reporting could improve the ADR reporting system in Ghana (Figure 3).

**Figure 3: Suggested Methods to Improve the ADR Reporting System**

Twenty-eight (90.3%) of the doctors who reported suspected ADRs also reported that continuous medical education and training could improve the system. Other suggestions like patients should be trained to report ADRs directly to the National Pharmacovigilance Centre and including drug safety and ADR reporting as a compulsory component during the Continuous Medical Development Programs were also stated by doctors who answered the open ended questions as strategies that could improve ADR reporting by the doctors.

Seventy-four (37.4%) of the doctors who agreed that making the reporting forms readily available could improve the system suggested that the forms should be available in the wards and consulting rooms similar to the system used for distributing stationeries like prescription forms and laboratory request forms to the doctors.

Two hundred and twenty-five (96.4%) of the doctors agreed that it was their professional responsibility to report ADRs. Other healthcare professionals doctors stated should report ADRs as well, were pharmacists, nurses and medical assistants with about 160 (70.0%) of doctors wanting pharmacists to report suspected ADRs, 146 (61.1%) nurses and 141 (59.0%) medical assistants.

## CHAPTER FIVE

### DISCUSSION

The general objective of this study was to reveal the position of spontaneous adverse drug reaction reporting system in the Greater Accra region of Ghana and the specific objectives were;

- i. To determine adverse drug reaction reporting rate by doctors in the Greater Accra Region.
- ii. To assess the knowledge of doctors about the ADR reporting system.
- iii. To identify factors contributing to underreporting of suspected ADRs by doctors in the Greater Accra Region.

The response rate of 86.3% in this study is higher than in other studies reported by Lopez-Gonzalez, Herdeiro and Figueiras (2009) in which only 6 of the 45 studies (13.3%) had a response rate of greater than 86%. The high response rate obtained in this study is most likely due to the methodology adopted to deliver the questionnaire to the doctors during their clinical meetings where almost all are completed for immediate collection.

Although the probability of reporting adverse drug reaction did not differ significantly amongst the two sexes the study shows that female doctors are more likely to report adverse drug reactions than their male counterparts (OR=1.42, p-value=0.688). Other studies have also found differences between gender and adverse drug reaction reporting by doctors and pharmacists [Enwere, & Fawole, (2008); Herdeiro, Figueiras, Polonia, &

Gestal-Otero, (2006); Herdeiro, Figueiras, Polónia, & Gestal-Otero, (2005)] with the odd ratios reported in these studies between 1.23 to 2.56.

Of doctors reporting adverse drug reactions, over 58% had been trained on drug safety and adverse drug reaction reporting and training a doctor significantly improves adverse drug reaction reporting ( $X^2=11.6$ ,  $p\text{-value}<0.001$ ) as the study shows. Thus, doctors receiving training on drug safety and adverse drug reaction reporting are more likely to report suspected adverse drug reactions than those who do not receive any training. Training had been found in other studies to improve reporting of adverse drug reactions as well. In a Portuguese study, Figueiras et al. (2006) found that providing an hour long training for doctors increase the adverse drug reaction reporting rate by 10-fold within the first twelve months following the intervention (95%CI, 3.81-27.51). Similarly, Green et al. (2001) in the United Kingdom, found that pharmacists who received training were more likely to report suspected adverse drug reactions compared to those without training ( $p<0.0001$ , 95% CI , 15.4-36.7). Doctors trained on drug safety and adverse drug reaction reporting also have a better knowledge of the reporting system and they are therefore more likely to report adverse drug reactions they see in their practice.

Knowledge of the doctors about the reporting system was higher amongst doctors in government and quasi-government hospitals and this is not surprising since training and pharmacovigilance awareness activities organized by the National Pharmacovigilance Centre to educate healthcare professionals on adverse drug reaction reporting most of the time took place in the government and quasi-government hospitals. From January to

December, 2010 the National Pharmacovigilance Centre organized training and pharmacovigilance sensitization lectures in fourteen hospitals for which only one was a private hospital (FDB, 2010).

Underreporting of adverse drug reactions can therefore be reduced amongst doctors by providing training and refresher courses on pharmacovigilance and adverse drug reaction reporting.

The rank of the doctor is also an important determinant of adverse drug reaction reporting with medical officers most likely to report ADRs than other ranks. This is because the average number of patients seen per day was greater for medical officers than other rank of doctors. This is similar to results found by Robins et al. (1998) in South Africa where about 85% of adverse drug reaction reports submitted to the Medicines Safety Centre were by general practitioners than medical and surgical specialist. Enwere et al. (2008) in Nigeria also found that resident doctors were twice as likely to report suspected adverse drug reactions than their surgical counterparts [OR=2.2, 95% CI (1.2-4.3), p-value=0.015].

On the contrary, this study shows that the age and number of years practiced as a doctor does not improve adverse drug reaction reporting. This finding is inconsistent with similar studies reported by Lopez-Gonzalez, Herdeiro, & Figueiras, (2009) where they found age to have influence in 9 of the 27 (37.5%) studies reviewed.

Adverse drug reactions reporting rate is 21% among doctors in this study, this means that almost 80% of patients who suffer adverse drug reactions that are seen by doctors do not

have these adverse drug reactions reported. The reporting rate of this study is similar to studies in Nigeria, where the reporting rate ranges between 2% to 32% (Bello, & Umar, 2011; Oshikoya, & Awobusuyi, 2009; Enwere, & Fawole, 2008). The adverse reactions reporting rate in this study is however, less than reporting rates found in European countries with well established adverse drug reaction reporting systems where the reporting rates varied from 47% to 77% (Belton, et al. 1997). The low reporting rate of adverse drug reaction by doctors significantly acts as a barrier to accessing information needed by the National Pharmacovigilance Centre to evaluate the risk benefit analysis of drugs on the Ghanaian market. Greater proportions (80%) of safety concerns with drugs will therefore go undetected and this negatively affects patient safety and public health.

The two main reasons given by the doctors for not reporting adverse drug reactions were unavailability of the reporting form and lack of knowledge about the reporting procedures. This finding is similar to what was obtained by Enwere et al. (2008) in Nigeria where 70.9% and 69% of the 117 doctors stated unawareness of the reporting form and ignorance of the reporting procedure respectively as the factors responsible for non-reporting of suspected adverse drug reactions.

The perception of doctors about the factors contributing to underreporting were different from what actually resulted in inability of the doctors in the study to complete the reporting form. Whereas the major reason for the failure to complete the form was unavailability of the form, doctors' perception of underreporting was due to lack of time

and heavy workload. Other factors doctors in this study perceived as contributors of underreporting are the lack of confidence in the reporting system 91 (36%) and lack of recognition and reward for doctors who report adverse drug reactions 87 (15.8%)

Continuous education, training and refresher courses (89.4%) is a strategy this study observes can improve adverse drug reaction reporting among doctors. This suggestion is tenable because training has been found to improve adverse drug reaction reporting rate by about 10-fold in Portugal by Figueiras, et al. (2006).

## CHAPTER SIX

### CONCLUSION AND RECOMMENDATIONS

#### 6.1 Conclusion

Doctors in the Greater Accra Region have a good knowledge of the adverse drug reaction reporting system; however, this is not translated to the number of adverse drug reactions reported. The reporting rate of adverse drug reactions is only 21%. This means that about 80% of drug safety problems including substandard and counterfeit drugs will not be reported to the National Pharmacovigilance Centre for appropriate regulatory action to be taken including the withdrawal of the drug. The presence of these drugs on the market negatively affect public health and patient safety. The failure to report ADRs is attributed to unavailability of the reporting form and lack of knowledge about the reporting procedure.

#### 6.2 Recommendations

Based on the results of the study the following recommendations are made;

1. The reporting forms should be made available in the consulting rooms and wards as part of the general stationery received by the doctors.
2. Every report submitted by a doctor should be acknowledged and a feedback provided on the actions taken.
3. Training, continuous education and refresher courses in pharmacovigilance and adverse drug reaction reporting is needed to improve the knowledge of the doctors about the reporting system and on adverse drug reactions reporting. This training

could be incorporated into the Continuous Professional Development program for the doctors.

4. Further studies on factors contributing to underreporting of adverse drug reactions amongst other healthcare professionals like pharmacists, nurses and medical assistants is needed.

## REFERENCES

- Aagaard, L., Stenver, D. I., & Hansen, E. H. (2008). Structures and processes in spontaneous ADR reporting systems: a comparative study of Australia and Denmark. *Pharmacy World Science*, 30, 563–570.
- Bartlett II, J. E., Kotrlik, J. W., & Higgins, C. C. (2001). Organizational research: Determining appropriate sample size in survey research. *International Technology Learning and Performance Journal*, 19, 1.
- Beijer, . J. M. & de Blaey. C. J. (2002). Hospitalisations caused by adverse drug reactions (ADR): A meta-analysis of observational studies. *Pharmacy World Science*, 24(2), 46-54.
- Bello, S. O., & Umar, M. T. (2011). Knowledge and attitudes of physicians relating to reporting of adverse drug reactions in Sokoto, north-western Nigeria. *Annals of African Medicine*, 10, 13-8.
- Belton K. J, et al. (1997). Attitude survey of adverse drug-reaction reporting by health care professionals across the European Union. *European Journal of Clinical Pharmacology*, 52, 423-427.
- Dodoo, A. (2002, July). Pharmacovigilance in West Africa, *Uppsala Reports*, 19, 8-9.
- Edwards, I. R., & Aronson, J. K. (2000). Adverse drug reactions: Definitions, diagnosis, and management. *The Lancet*, 356, 1255–59.
- Enwere O. O., & Fawole O.I. (2008). Adverse drug reactions reporting by physicians in Ibadan, Nigeria. *Pharmacoepidemiology and Drug Safety*, 17, 517–522.
- Fadare, J. O., Enwere, O. O., Afolabi, A.O., Chedi, B.A.Z., & Musa, A. (2011). Knowledge, Attitude and practice of adverse drug reaction reporting among healthcare workers in a tertiary centre in northern Nigeria. *Tropical Journal of Pharmaceutical Research* , 10(3), 235.
- Figueiras, A., Herdeiro M. T., Polonia, J., & Gestal-Otero, J. J. (2006). An educational intervention to improve physician reporting of adverse drug reactions: A cluster-randomized controlled trial. *Journal of American Medical Association*, 296: 1086-93

- Food and Drugs Board (FDB). (2011). *Guidelines for Safety Monitoring of Products*. Retrieved December 29, 2011, from <http://www.fdbghana.gov.gh/images/pdf/guidelines/drugs/Guideline%20for%20Safety%20Monitoring.pdf>
- Food and Drugs Board (FDB). (2010). *2010 Annual Report for the National Pharmacovigilance Centre*. Obtained from the Food and Drugs Board.
- Food and Drugs Board (FDB). (2011). *Manual for detecting and reporting adverse drug reactions*. FDB, Accra
- Ghana Medical and Dental Council (GMDC). (2011). *List of medical and dental practitioners registered in Ghana for 2011, Standing register (Registered under section 28 of the Medical and Dental Decree, 1972 (N.R.C.D. 91)*. Retrieved January 12, 2012, from <http://www.mdcghana.org/pdfs/STANDING%20REGISTER%202011.pdf>
- Ghana Statistical Service (GSS). (2012). *2010 Population and Housing Census, Population by Region and Sex*. Retrieved July 2, 2012, from [http://www.statsghana.gov.gh/docfiles/2010phc/2010\\_population\\_and\\_housing\\_census%28view\\_population\\_by\\_sex\\_regional\\_and\\_district%29.pdf](http://www.statsghana.gov.gh/docfiles/2010phc/2010_population_and_housing_census%28view_population_by_sex_regional_and_district%29.pdf)
- Green, C. F., Mottram, D. R., Rowe, P. H., & Pirmohamed, M. (2001). Attitudes and knowledge of hospital pharmacists to adverse drug reaction reporting. *British Journal Clinical Pharmacology*, 51, 81-86.
- Hazell, L. & Shakir, S. A. (2006). Under-reporting of adverse drug reactions: A systematic review. *Drug Safety*, 29, 385-6.
- Herdeiro, M. T., Figueiras, A., Polonia, J., Gestal-Otero, J. J. (2006). Influence of Pharmacists' Attitudes on Adverse Drug Reaction Reporting A Case-Control Study in Portugal. *Drug Safety* 29(4), 331-340.
- Herdeiro, M.T., Figueiras, A., Polónia, J., & Gestal-Otero, J.J. (2005). Physicians' attitudes and adverse drug reaction reporting: A case-control study in Portugal. *Drug Safety*, 28, 825-33.
- Irujo, M., Beitia, G., Bes-Rastrollo, M., Figueiras, A., Hernández-Díaz, S., & Lasheras, B. (2007). Factors that influence underreporting of suspected adverse drug reactions among community pharmacists in a Spanish region. *Drug Safety*, 30(11), 1073-1082.
- Snodin, D. J. (2004). Toxicology and ADRs. In John, T., & Walker, P., (Eds.). *Stephen's detection and evaluation of adverse drug reactions: Principles and practice*. (5<sup>th</sup> ed, pp. 151-153), London. John Wiley & Sons Ltd.

- Kopecna, E., Descikova, V., Vlcek, J., & Mlada, J. (2011). Adverse drug reaction reporting in the Czech Republic 2005–2009. *International Journal of Clinical Pharmacy*, 33,683–689.
- Lazarou, J., Pomeranz, B. H., & Corey, P. N. (1998). Incidence of adverse drug reactions in hospitalized patients—a meta-analysis of prospective studies. *Journal of American Medical Association*, 279, 1200-5.
- Lopez-Gonzalez, L., Herdeiro, M. T. & Figueiras, A. (2009). Determinants of Under-Reporting of Adverse Drug Reactions: A Systematic Review. *Drug Safety*, 32(1), 19-31.
- Macfarlane, S.B. (1997). Conducting a descriptive survey: Choosing a sampling strategy. *Tropical Doctor*, 27(1), 14-21.
- Ministry of Health (MOH), Ghana. (2009). *Independent review of the health sector programme of work 2008*. Retrieved February 14, 2012, from <http://www.moh-ghana.org/UploadFiles/Publications/ANNUALREVIEWREPORT2008090825071054.pdf>
- Nwokike, J., & Eghan, K. (2010). *Pharmacovigilance in Ghana: A Systems Analysis*. Retrieved February 23, 2012, from [http://www.msh.org/projects/sps/SPS-Documents/upload/ghana\\_pharmacovigilence\\_april2010.pdf](http://www.msh.org/projects/sps/SPS-Documents/upload/ghana_pharmacovigilence_april2010.pdf)
- Olsson, S., Pal, S., Stergachis A., & Couper M. (2010). Pharmacovigilance activities in 55 low- and middle-income countries a questionnaire-based analysis. *Drug Safety*, 33(8), 689-703.
- Oshikoya, K. A., & Awobusuyi, J. O. (2009). Perceptions of doctors to adverse drug Reaction reporting in a teaching hospital in Lagos, Nigeria. *BMC Clinical Pharmacology*, 9, 14.
- Pal, S., Dodoo, A., Mantel, A., & Olsson, S. (2011). *The world medicines situation 2011: Pharmacovigilance and safety of medicines*. Geneva: Geneva, WHO Press.
- Pirmohamed, M., James, S., Meakin, S., Green, C., Scott, A. K., Walley, T. J., & Breckenridge, A. M. (2004). Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. *British Medical Journal*, 329, 15-19.
- Robins, A. H., Weir, M., & Biersteker, E. M. (1987). Attitudes to adverse drug reactions and their reporting among medical practitioners. *South African Medical Journal*, 72, 131-134.

- Sweis, D., & Wong, C. K. (2000). A Survey on factors that could affect adverse drug reaction reporting according to hospital pharmacists in Great Britain. *Drug Safety*, 23(2), 165-172.
- Vallano, A., Cereza, G., Pedròs, C., Agustí, A., Danés, I., Aguilera, C., & Arnau, J. M. (2005). Obstacles and solutions for spontaneous reporting of adverse drug reactions in the hospital. *British Journal of Clinical Pharmacology*, 60(6), 653–658.
- Venulet, J., & Helling-Borda, M. (2010). WHO's international drug monitoring, The formative years, 1968–1975, Preparatory, pilot and early operational phases. *Drug Safety*, 33(7), e1-e23.
- Wester, K., Jönsson, A. K., Spigset, O., Druid, H., & Hägg, S. (2008). Incidence of fatal adverse drug reactions: A population based study. *British Journal of Clinical Pharmacology*, 65(4), 573–579.
- World Health Organization (WHO). (2002). *The Importance of pharmacovigilance, safety monitoring of medicinal products*. Retrieved January 19, 2012, from <http://apps.who.int/medicinedocs/documents/s16559f/s16559f.pdf>
- World Health Organization (WHO). (2009). *A practical handbook on the pharmacovigilance of antiretroviral medicines*. Retrieved February 16, 2012, from <http://apps.who.int/medicinedocs/documents/s16882e/s16882e.pdf>
- World Health Organization (WHO). (2012). *Reporting Trends*. Retrieved June 6, 2012, from <http://who-umc.org/DynPage.aspx?id=108476&mn1=7347&mn2=7252&mn3=7322&mn4=7558>

## APPENDICES

**Appendix 1: Questionnaire on Adverse Drug Reactions Reporting by Doctors in the  
Greater Accra Region**

**Section A: Demographic characteristics**

**Gender:** Male  Female

**Age:** ..... (years)      **Years of Practice:** .....

**Marital Status:** Married  Single  Divorced       **Children:** Yes  No

**Position:** House Officer       Medical Officer       Snr. Medical Officer

Prin. Medical Officer       Specialist       Consultant

**Additional Qualifications obtained** (if any): .....

**Place of Work/Practice:** Private       Government       Quasi-government

**Level:** Teaching hospital       Regional hospital       District hospital

**Average Number of Patients per day:** ..... (in the past 1 year)

**Are you involved in any clinical research?** Yes  No

**Have you ever been trained on drug safety and reporting ADRs?** Yes  No

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

1. **Have you heard about adverse drug reaction reporting in Ghana?** Yes  No

2. **Have you ever seen the form for reporting ADRs?** Yes  No

3. **Which of the following represents how the form can be obtained?**

(Check all that applies)

- Contact Person in the hospital
- From the FDB office
- Download on the Internet
- I don't have an idea

4. **Do you have the reporting form in your hospital?** Yes  No  I don't know
5. **Do you know where to send the reporting form after completion?** Yes  No
6. **Have you seen a patient with an ADR in the past one year?** Yes  No

If NO, proceed to SECTION C

7. **If “YES”, did you report the ADR by completing the form?** Yes  No

If YES, proceed to SECTION C

8. **If “NO” why didn't you report?**

(Check all that applies)

- I did not know I was supposed to report
- The reporting form was not available
- I do not know the reporting procedure
- I did not have time to report
- I did not think it was important/serious
- The reaction is very commonly reported with that medication so I considered it “normal”
- Others:.....

### **SECTION C: Factors contributing to under reporting in Ghana**

1. **What in your view are some of the factors that contributes to the under reporting of ADRs?** (Please, check all that applies)

- **Lack of time and heavy workload**
- **Unaware of the reporting procedure and how the form can be obtained**

- **No idea that ADRs are to be reported**
- **The reporting form is not available at the hospitals**
- **The occasional single case reported cannot contribute much to medical knowledge**
- **All ADRs are well documented before medicines are placed on the market**
- **Inability to recognize or diagnose ADRs**
- **Fear of being legally accused of administering the wrong drug**
- **Fear of the negative impact the report may have on the company that produces the drug**
- **Preference to publish such data rather than report to the FDB**
- **Lack of confidence in the reporting system**
- **It should be the responsibility of consumers who suffer an ADR to report**
- **No reward or recognition for the physician who report ADRs**
- **Which of the following rewards will you consider appropriate?**
  - Acknowledgement letter for every report submitted
  - Award credits for CPD
  - Publish Name in local Scientific Journal
  - Others, please, specify.....
- **It is not part of the professional responsibility to report ADRs**

- In your opinion, which group of healthcare professionals should be responsible for reporting ADRs: Doctor  Medical assistant   
Pharmacist  Nurse

#### **SECTION D: Which of the following can be done to improve ADR Reporting**

(Please, check all that applies)

- **Continuous medical education, training and refresher courses**
- **Introduce Pharmacovigilance and ADR reporting into the medical school curricula**
- **Reminders and increased awareness from the National Pharmacovigilance Centre**
- **Publicity about ADR reporting in the local scientific journals**
- **Designated ADR contact person in every hospital**
- **Introduce telephone and on-line reporting of ADRs**
- **The reporting form should be made readily available**   
(please, suggest how you'll want to obtain the reporting form if you agree to the point above).....
- **Others:** .....

## **Appendix II: Informed Consent Form**

**Project Title:** Adverse Drug Reactions Reporting by Doctors in the Greater Accra Region

**Institution:** School of Public Health, College of Health Sciences.

### **Background**

My name is George Sabblah a student from the School of Public Health, University of Ghana, Legon. I am conducting a study on the topic “Adverse Drug Reactions Reporting by Doctors in the Greater Accra Region”. The objective of this study is to assess the knowledge of doctors about ADR reporting, determine reporting rate of ADRs and factors contributing to underreporting of adverse drug reactions.

### **Procedures**

The study will involve answering questions from a four-page questionnaire about knowledge on ADR reporting system, factors that are perceived to contribute to the underreporting of adverse drug reactions and suggestions to improve reporting of ADRs. It will take about 10 minutes to complete the questionnaire.

It will be appreciated if you would be willing to participate in this study. This is purely academic research which 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 not cause any discomfort to you. The results of the study can be used to inform the Food and Drugs Board (FDB) on issues to be addressed to improve adverse drug reaction reporting by doctors.

**Right to Refuse**

Participation in this study is voluntary and you can choose not to answer any individual question or all the questions. You are at liberty to withdraw from the study at anytime. However, I will encourage you to fully participate in the study since your opinions are important to help assess knowledge level of doctors about ADR reporting and factors that may be affecting adverse drug reaction reporting by doctors in the Greater Accra Region of Ghana.

**Anonymity and Confidentiality**

You are assured that information provided on the questionnaire is strictly confidential and information submitted would not be shared with anybody who is not part of the study team.

**Dissemination of Results**

The results of this study will be sent to you by post or e-mail if you provide your addresses 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).....

.....

If you have any questions later please, contact **George Sabblah (Tel: 0266 171 661)**.

**Consent**

I ....., declare that the purpose, procedures as well as 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.....Date:.....

**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:**.....

**Appendix III: Introduction Letter from the Accra Metro Health Directorate**

*In case of reply the  
Number and date of this  
letter should be quoted.*

My Ref. :AM/65  
Your Ref. No.



Metro Health Directorate  
Ghana Health Service  
Private Mail BagTUPM 14  
TUC Post Office  
Accra

Tel: (Main Line) 233-21-665879  
(Direct Line) 233-21-687000  
(Fax) 233-21-680575  
Email:  
accrametrohealthdirectorate@yahoo.com

15<sup>th</sup> May 2012

All Health Facilities  
Accra

Dear Sir/Madam,

**LETTER OF INTRODUCTION**  
**GEORGE SABBLAH – STUDENT OF MPH PROGRAMME**

This is to introduce to you the above mentioned student of the Department of Health Policy Planning and Management (School of Public Health University of Ghana Legon, Accra).

He has been given permission to collect data for his research on the “Adverse Drug Reaction Reporting” to interview the Doctors in your facility.

Kindly give him the necessary assistance.

Thank you.

Yours faithfully



**DR. JOHN B. K. YABANI**  
(MDHS – ACCRA)

**Appendix IV: Letter of Introduction from the School of Public Health****SCHOOL OF PUBLIC HEALTH  
COLLEGE OF HEALTH SCIENCES  
UNIVERSITY OF GHANA**

Phone: +233-21-946087/946088  
028-9109000/9109001  
Fax/Phone  
Cable: UNIVGhana  
E-mail: [gamoah@ug.edu.gh](mailto:gamoah@ug.edu.gh)



P O Box LG13  
Legon-Accra  
GHANA

May 31, 2012

**TO WHOM IT MAY CONCERN**

Dear Sir/Madam,

**LETTER OF INTRODUCTION: MR. GEORGE SABBLAH**

I write to introduce to you Mr. George Sabblah, a Master of Public Health student of School of Public Health, College of Health Sciences, University of Ghana, Legon.

As part of his academic requirements, he is undertaking a research on the topic **“Factors Affecting Adverse Drug Reaction Reporting among Physicians in the Greater Accra Region”** and would therefore need your assistance.

Anticipation your usual cooperation.

Yours faithfully,

A handwritten signature in black ink, appearing to read 'Godfred Amoah', written over a horizontal line.

GodfredAmoah  
Assistant Registrar

## Appendix V: Approval Letter issued by the Ghana Health Service Ethical Review Committee

### GHANA HEALTH SERVICE ETHICAL REVIEW COMMITTEE

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

*My Ref. :GHS-ERC: 3  
Your Ref. No.*



Research & Development Division  
Ghana Health Service  
P. O. Box MB 190  
Accra  
Tel: +233-302-681109  
Fax + 233-302-685424  
Email: [Hannah.Frimpong@ghsmail.org](mailto:Hannah.Frimpong@ghsmail.org)

21 June, 2012

**GEORGE TSEY SABBLAH**, Principal Investigator  
School of Public Health  
College of Health Science  
University of Ghana

#### **ETHICAL CLEARANCE - ID NO: GHS-ERC: 45/03/12**

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

#### **“Factors Affecting Adverse Drug Reaction Reportin Amongst Physicians in the Greater Accra Region”**

This approval requires that you submit periodic review of the protocol to the Committee and a final full review to the Ethical Review Committee (ERC) on completion of the study. The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Please note that any modification of the project must be submitted to the ERC for review and approval before its implementation.

You are also required to report all serious adverse events related to this study to the ERC within seven days verbally and fourteen days in writing.

You are requested to submit a final report on the study to assure the ERC that the project was implemented as per approved protocol. You are also to inform the ERC and your mother organization before any publication of the research findings.

Please always quote the protocol identification number in all future correspondence in relation to this protocol

SIGNED.....  
PROFESSOR FRED BINKA  
(GHS-ERC CHAIRMAN)

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