KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY, KUMASI, GHANA

REPORTING OF ADVERSE DRUG REACTIONS: EVALUATION OF KNOWLEDGE, ATTITUDE AND PRACTICE AMONG HOSPITAL PHARMACISTS IN ASHANTI REGION

BY

RICHARD DELALI AGBEKO

A Thesis submitted to the Department of Clinical and Social Pharmacy, Faculty of Pharmacy and Pharmaceutical Sciences, College of Health Sciences in partial fulfilment of the requirement for the degree

MASTER OF SCIENCE CLINICAL PHARMACY

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Supervisor: Dr Berko Panyin Anto

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DECLARATION

I, Richard Delali Agbeko, declare that this submission is my own work towards the award of Master of Science Clinical Pharmacy and that to the best of my knowledge, it contains no material previously published by another person nor material which has been accepted for the award of any other degree of the University, except where due acknowledgement has been made in the text.

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Certified by:		
Dr. Berko Panyin Anto	Signature	Date
(Thesis Supervisor)		
	……	……
Head of Department:	Signature	Date
Prof. (Mrs) F. Owusu-Daaku	……	……

ABSTRACT

Background: Spontaneous adverse drug reaction (ADR) reporting helps in the detection of serious, unexpected and unusual ADRs. Healthcare professionals play an integral part in the success of every pharmacovigilance programme. Even though the pharmacovigilance programme of Ghana was launched in 2001, under-reporting of ADRs by pharmacists and other health professionals has been the bane of the programme. Data on factors that contribute to the low reporting rate in Ghana is however limited.

Objective: The main objective of this study was to assess the knowledge, attitudes, and practice of pharmacovigilance among hospital pharmacists in Ashanti Region of Ghana.

Methods: The study was a cross-sectional survey of 120 hospital pharmacists across 38 hospitals; grouped as government (27), quasi-government (9) and private (2). The self-administered questionnaire was piloted and wordings rephrased to eliminate any ambiguity.

Information from the returned questionnaire was coded and entered into SPSS version 20 software. The results were presented as mean ± standard deviation, frequencies, and percentages. Charts were drawn with MS Excel, 2013.

The knowledge of the pharmacists in ADR reporting procedure was assessed by their answers to 12 specific knowledge questions. The score obtained by each respondent was graded as poor, average, good, very good or excellent.

The rate of ADR reporting was calculated by dividing the number of pharmacists that reported an ADR by the number that saw an ADR, and the result multiplied by 100.

Findings: The participant response rate in this study was 79.2%. Of the 95 pharmacists who completed the questionnaire, 43 (45.7%) had seen a patient with suspected ADR in the past one year prior to the study, however only 29 (69%) of them reported them by completing the ADR form. Reasons given for not reporting the ADRs included "*reaction commonly reported for the suspected drug"* (46.2%), "*reporting form not available in the hospital"* (38.5%), and "*I do not know the reporting procedure"* (38.5%). Over 80% of respondents have adequate knowledge of the reporting procedure, with tertiary hospital pharmacists having lesser knowledge than their counterparts in the primary and secondary hospitals in the reporting procedure [$p = 0.026$]. Overall, there was no statistically significant difference between age of respondents ($p = 0.534$), rank ($p =$

0.384), level of hospital ($p = 0.524$), or place of practice ($p = 0.732$) and ADR reporting. Refresher training on drug safety and ADR reporting, making available ADR forms, introducing electronic reporting of ADRs, and introducing pharmacovigilance as a major course into pharmacy education curriculum were some of the strategies suggested by respondents to improve ADR reporting.

Conclusion and Recommendation: The ADR reporting rate among the hospital pharmacists in Ashanti Region was 69%. Majority of pharmacists involved in this study had adequate knowledge in the reporting procedure. Lack of time or heavy workload, absence of ADR reporting form, and inability of some pharmacists to recognize and diagnose ADRs were some factors that contributed to under-reporting of ADRs in the Ashanti Region.

To further improve the reporting rate, refresher courses in drug safety and ADR reporting should be periodically conducted for hospital pharmacists. ADR reporting forms should also be made readily available in the wards, consulting rooms and pharmacies, and pharmacovigilance training in pharmacy schools should be intensified to equip the newly trained pharmacist to diagnose and report ADRs to align with FDA policy.

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LIST OF ACRONYMS

ADR:	Adverse Drug Reaction
CEM:	Cohort Event Monitoring
CTCPT:	Centre for Clinical Tropical Pharmacology and Therapeutics
FDA:	Food and Drugs Authority
GHS:	Ghana Health Service
GSS:	Ghana Statistical Service
KATH:	Komfo Anokye Teaching Hospital
UMC:	Uppsala Monitoring Centre
WHA:	World Health Assembly
WHO:	World Health Organization

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I would first of all like to express my sincere gratitude to God Almighty for guiding me successfully through this programme.

The completion of this dissertation will not have been possible without the help and support of the wonderful people around me. I am therefore grateful to my supervisor Dr. Berko Panyin Anto for his support, patience and understanding during this research.

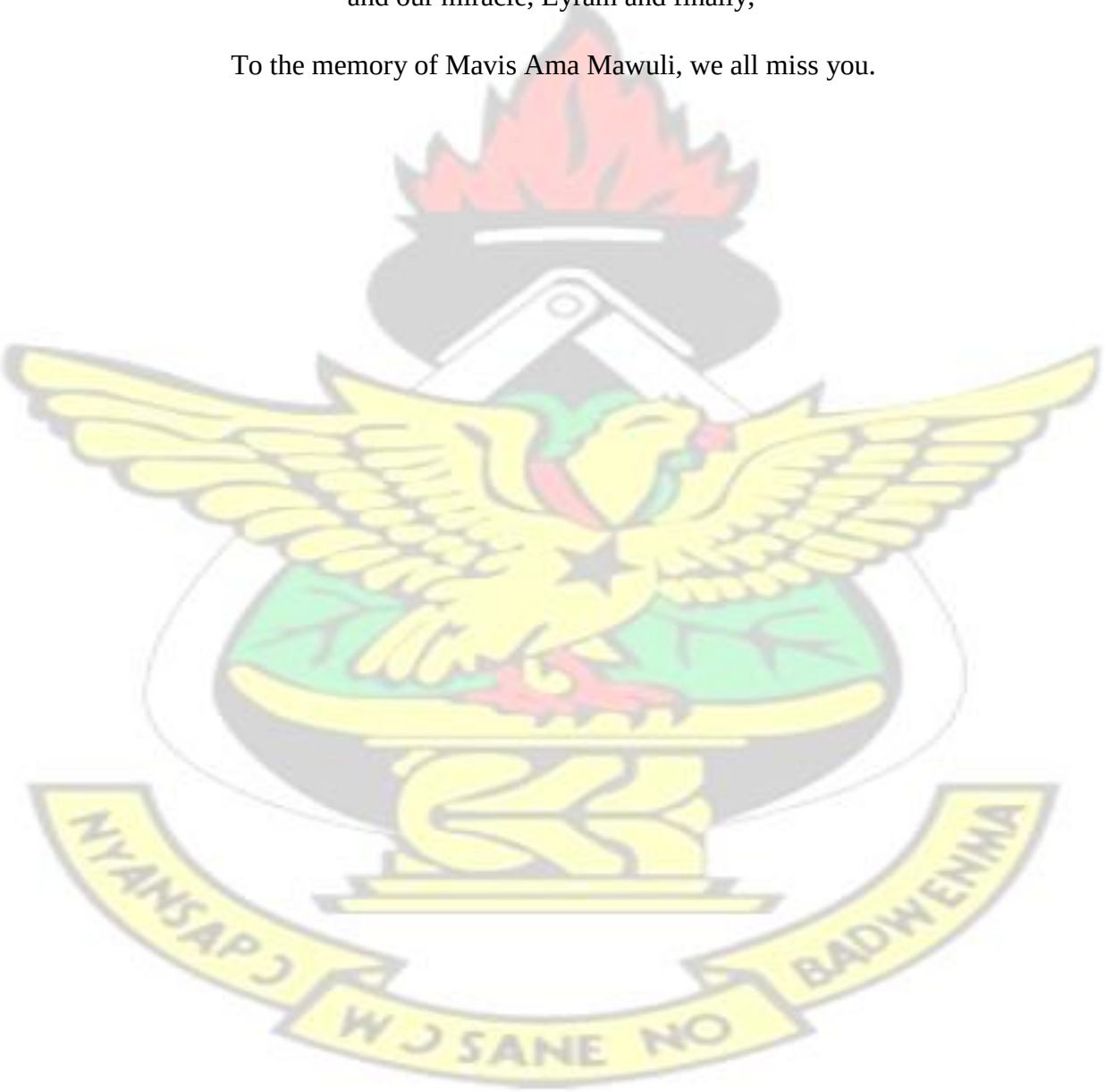
Special thanks to Pharm. Joseph Attakorah of KATH for his constructive criticisms throughout the period of my study under him.

Finally, a big thank you to all hospital pharmacists in Ashanti Region who willingly participated in this research, this study will be impossible without your participation, God bless you all.

DEDICATION

This dissertation is dedicated to my wonderful wife and best friend, Priscilla Afia Serwaa Duku, and our miracle, Eyram and finally,

To the memory of Mavis Ama Mawuli, we all miss you.



CHAPTER ONE

1.1 Introduction

Pharmacovigilance is the science and activities relating to detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. Such drug-related problems include adverse drug reactions (ADRs), unintended injuries or complications that arise from iatrogenic drug related cause or prolong hospital admission and result in disability or death (WHO, 2006).

Adverse drug reaction is defined by World Health Organization (WHO) as any noxious, unintended, and undesirable effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or cure of a disease (WHO, 2002). The risk of ADR is associated with all drug therapy and it is determined by myriad of factors, including dose and frequency of administration, genotype, and pharmacokinetic properties of special populations, such as paediatric and geriatric patients, and those with liver and kidney impairment. Due to the high prevalence rate and potentially serious outcomes, ADRs may have dramatic consequences in clinical practice both from economic and clinical perspectives.

A study from the United States of America projected that about 11.4-35.5% of all emergency department visits are due to drug-related causes (Budnitz, et al., 2007). It was similarly found that in Europe, up to 20% of ambulatory patients experience ADRs and approximately 10-20% of geriatric hospital admissions are due to drug-related issues. Another consequence of ADRs is the prolong hospital stay. A prospective study showed that the average number of days spent in hospitals due to ADRs was increased from 8 days for patients without ADRs, to 20 days if an ADR is involved (Davies, et al., 2009). Available data from the Food and Drug Authority show that 5%, 1% and 2.5% of 325 (2012), 260 (2013) and 436 (2014) ADR reports respectively submitted to the National Pharmacovigilance Centre of Ghana resulted in death.

Aside the human costs, such as morbidity and mortality, ADRs have an economic burden on the scarce health resources especially to poor countries (Ayani, et al., 1999). The United Kingdom's data on

incidence of hospitalizations and deaths resulting from ADRs exhibited an estimate of 6.5% and 0.15% respectively (Pirmohamed, et al., 2004). In 2007, the cost of emergency department visit due to ADR was estimated to be $333 per visit and $7,528 per hospitalization in Canada. (Wu, et al., 2012).

Efforts to document ADRs began internationally when the thalidomide tragedy was reported in 1961. Spontaneous ADR reporting became a safety tool in pharmacovigilance for monitoring ADRs (Waller, 2006). To this end, health professionals like pharmacists, doctors and nurses became the key players in spontaneous ADR reporting because they were directly involved in medicines use and well informed of the expected and unexpected effects of medicines.

In spite of being a cheap source of pharmacovigilance and the fact that it could be used throughout the lifespan of a drug to monitor its safety, the rate of spontaneous ADR reporting is still lower than expected, with only 6% of all ADRs being reported by healthcare professionals (Hazel & Shakir, 2006). This low rate of reporting of ADRs can delay signal detection and hence impact negatively on the health of the public.

A myriad of factors have been reported as the causes of underreporting of ADRs, among these are personal and professional characteristics of health carers, and their knowledge and attitudes to reporting (Lopez-Gonzalez, et al., 2009). Some studies carried out in Nigeria, India and United Arab Emirates, evaluating knowledge of doctors in adverse drug reaction reporting indicate among other factors, inadequate knowledge about reporting format, not knowing where reports should be sent to, busy schedule, unavailability of reporting forms, and lack of incentives as the reasons responsible for underreporting (Kamtane 2012, Oshikoya 2009, Lisha 2012, and Fadare 2011).

A study conducted among community pharmacists in Malaysia (Elkami, et al., 2011) showed that most respondent pharmacists had very little knowledge about the procedure for reporting ADRs. Another

study conducted among pharmacy students in South India (Reddy, et al., 2014) showed that an educational intervention was a positive factor in ADR reporting.

Ghana, officially, started pharmacovigilance and spontaneous adverse drug reaction monitoring activities in 2001 when she became the 65th nation to join the WHO Programme for International Drug Monitoring (Uppsala Report, 2001). The major challenge of the programme is under-reporting by healthcare professionals. Available data from WHO Ghana ADR Report (Nwokike & Eghan, 2010) showed that, using a standard of 100 reports per million population, expected reporting rate was 23 but only 1.55 was observed, despite wide spread availability of ADR forms in health facilities across the country. Studies on reasons for under-reporting of ADRs by health workers in Ghana are scarce. One such study (Sabblah, et al., 2014) conducted among doctors in the Greater Accra region in 2012 showed that even though 59.5% had seen a patient with an ADR in the past one year prior to that study, only 21% reported them by completing the ADR reporting form.

1.2 The Trend of ADR Reporting in Ghana

Data from the Food and Drugs Authority showed that ADR reporting has been on the rise. In 2012, a total of 325 suspected ADRs were reported by healthcare professionals amounting to 14 ADR reports per 1,000,000 population; while in the first nine months of 2013, two hundred and sixty (260) reports were sent to the national pharmacovigilance centre. However, in 2014, even though the number of reports increased to 436 the rate dropped to 12 ADR reports per 1,000,000 Ghanaians per year, which is significantly lower than the WHO recommendation of 200 per 1,000,000 population.

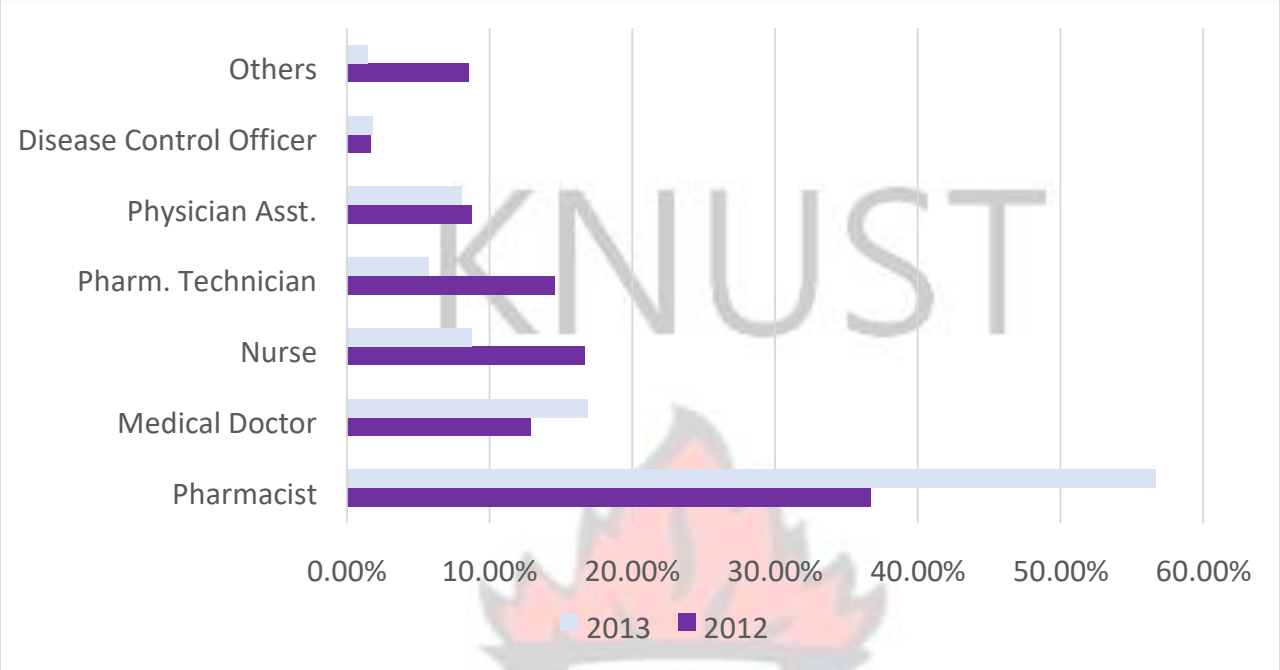


Figure 1 Percent ADR Reporting by health professionals (Source: FDA, DrugLens 2012 & 2013)

The number of ADR reports submitted to the National Pharmacovigilance Centre (Figure 2) has been on the rise over the past 5 years and as can be observed pharmacists are the most likely healthcare professionals to report a suspected ADR, having sent over 50% of the received ADR reports in 2013 as depicted by figure 1 above.

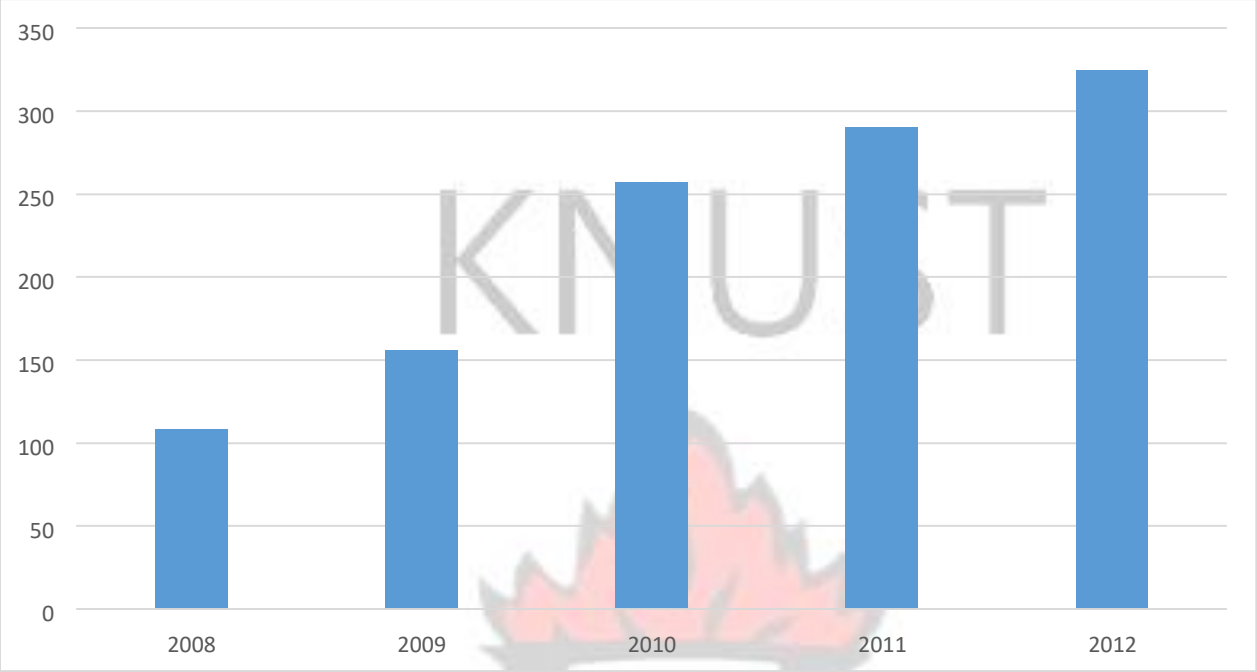


Figure 2 Five-year trend of number of ADR reports received by FDA, Ghana (Source: FDA, DrugLens 2013)

The report (Figure 3) also showed that Greater Accra Region leads in the number of reports generated annually with 27.7% followed by Upper East Region with 21.5%, while Ashanti and Volta regions were tied in the third position with 12.1% each. The Upper West Region failed to produce a single ADR report in 2012.

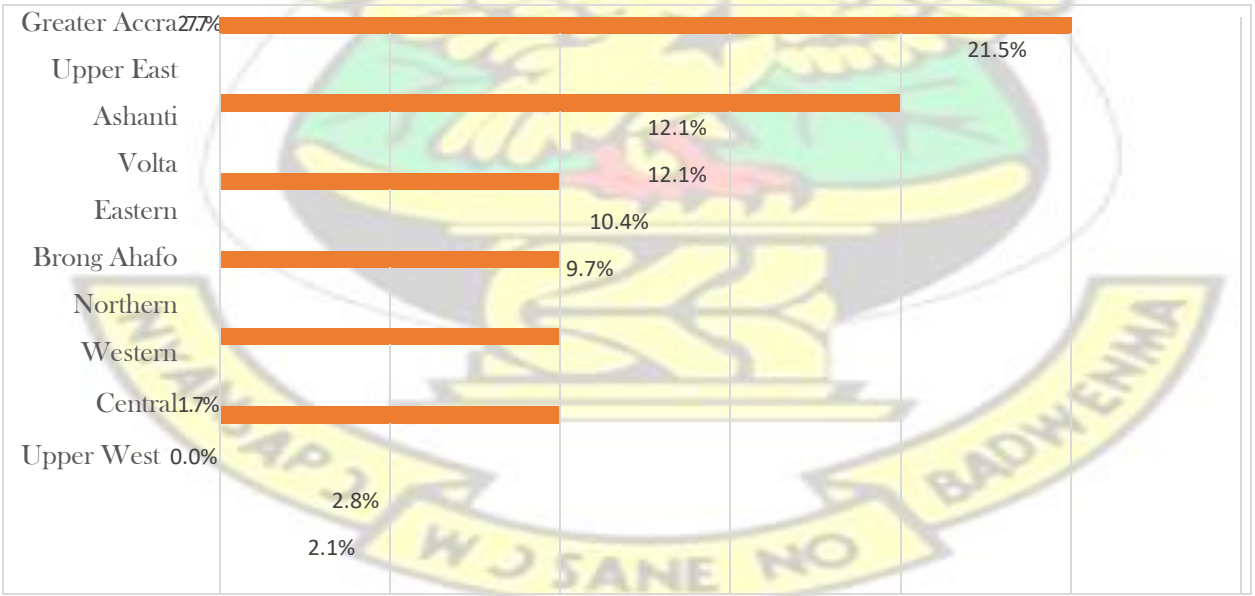


Figure 3 Percent ADR reporting per region (Source: FDA, DrugLens 2012)

From the data provided above, it can be observed that Ashanti Region's reporting rate is very low considering the fact that it is the most populous region in Ghana with over 19.4% of the total population (GSS, 2010). The ADR reporting, as can be observed in *Figure 1,* is being championed by pharmacists who see pharmacovigilance as a professional responsibility, hence contributing over 36% and 56% of the reports in 2012 and 2013 respectively. Therefore if the reporting rate in Ashanti Region will improve then hospital pharmacists' interest in pharmacovigilance in the region should be stimulated. It is therefore important to identify reasons why ADRs reporting in Ashanti Region is low and then measures put in place to improve ADR reporting among hospital pharmacists to ensure patient safety.

1.3 Problem Statement and Study Justification

Spontaneous reporting of adverse drug reactions by healthcare professionals help identify rare and unknown effects of drugs which may have been missed during pre-registration clinical trials. It is a very important and affordable means of pharmacovigilance in the general population which helps by identifying ADRs in particular populations of patients and hence the use of such drugs in those patients.

The ADR reporting rate in Ghana by healthcare professionals is 14 reports per 1,000 000 population (Darko, 2013) and pharmacists contributed about 56% of the report. The percent of the total reports that came from Ashanti Region was 12.1% of the national figure of 325 reports in 2012. This rate is low considering that Ashanti Region is the most populous region in Ghana. It also brings to the fore questions about the pharmacovigilance practice of healthcare professionals in the region. There is therefore the need to find out reasons for the low reporting rate in the region and measures instituted to improve spontaneous ADR reporting by hospital pharmacists in the region to improve patient safety.

1.4 Research Questions

i. What is the ADR reporting rate among hospital pharmacists in Ashanti Region? ii. What are the barriers to ADR reporting by hospital pharmacists in Ashanti Region?

iii. What is the level of knowledge of hospital pharmacists in Ashanti Region about the ADR reporting system?

iv. What methods can be used to improve ADR reporting among hospital pharmacists in Ashanti Region, and Ghana as a whole?

1.5 Objectives

1.5.1 General Objective

To evaluate pharmacovigilance among hospital pharmacists in Ashanti Region

1.5.2 Specific Objectives

i. To determine the rate of adverse drug reaction reporting by hospital pharmacists in the Ashanti Region. ii. To assess the knowledge of hospital pharmacists about the current ADR reporting procedure in Ghana.

iii. To identify barriers to ADRs reporting by hospital pharmacists in the Ashanti Region.

CHAPTER TWO

LITERATURE REVIEW

2.1 History of Spontaneous ADR Reporting

The thalidomide tragedy of 1961 stimulated international efforts at addressing drug safety issues. At the time most infants were exposed to medicines taken by pregnant women resulting in congenital malformations. In 1963, at the Sixteenth World Health Assembly, a resolution (WHA 16.36) was adopted that required the need for prompt action on dissemination of information on adverse drug reactions. This led to the WHO Pilot Research Project for International Drug Monitoring with ten countries in 1968 (Venulet & Helling-Borda, 2010). The purpose was to develop a system, applicable internationally, for detecting previously unknown or poorly understood adverse effects of medicines. The pilot project later developed into the WHO Programme for International Drug Monitoring (the Uppsala Monitoring Centre). From these beginnings emerged the science of pharmacovigilance. Systems were developed in member states for collection and evaluation of individual case reports of ADRs for marketed drugs where the spontaneous adverse drug reaction reporting programme began. As of 2010, there were 136 countries that have their own pharmacovigilance centres with the Uppsala Monitoring Centre co-ordinating their activities (Pal, et al., 2011)

The objective of the programme was to develop a comprehensive global drug safety strategy that responds to the healthcare needs of low- and middle-income countries by collating ADR reports into a central database to serve as a tool for national drug regulatory bodies, improve the safety profile of medicines, and help avoid future disasters (Venulet & Helling-Borda, 2010).

Within the last decade, the scope of pharmacovigilance has widened beyond the detection of new signals of safety concerns. The popularity of the internet usage in gaining access to medicinal products and information on such products has led to such new kinds of safety concerns as illegal sale of medicines and drugs of abuse over internet, increasing self-medication practices, irrational and potentially unsafe drug donation practices, widespread manufacture and sale of counterfeit and

substandard medicines, increasing use of traditional medicines outside the traditional culture of use, and increasing use of traditional/herbal medicines with other medicines with potential for ADRs.

The story of pharmacovigilance in Ghana started with the institution of the National Pharmacovigilance Centre at the University of Ghana Medical School at Korle Bu Teaching Hospital in June 2001 as a collaboration between the Food and Drugs Board (FDB) and the Centre for Clinical Tropical Pharmacology and Therapeutics (CTCPT) of the University of Ghana. The centre, in collaboration with the Uppsala Monitoring Centre (UMC) is involved in: collection and analysing case report of ADRs, distinguishing signals from background "noise", making regulatory decisions based on strengthened signals, and alerting healthcare professionals, manufacturers, and the public to new risks of adverse reactions.

The centre relies on health professionals who observe ADRs to report by filling the blue ADR reporting form which is made available at the various health facilities and downloadable from the FDA website. The FDA routinely sends reports to healthcare professionals on pharmacovigilance. Thess include analysis of submitted ADR reports, issues concerning safety of medicines available on the Ghanaian markets when necessary.

2.2 The Magnitude of the Global Problem of Adverse Drug Reactions

Adverse drug reactions have significant effects on mortality, morbidity and hospitalizations, and these affect patients' quality of life. Patients who suffer ADRs may lose confidence in the healthcare system.

ADRs also mimic certain diseases resulting in unwarranted investigations hence increase cost of patient care and delay in initiation of treatment (Pirmohamed, et al., 2004).

Studies done in the United Kingdom on the burden of ADRs on the health system showed that 1 in 16 admissions were due tor ADRs, occupying 4% of hospital bed capacity. In the same study it was shown that ADR occurs in 10-20% of admitted patients, out of which 2% died, accounting for 0.15% of all admitted patients and a projected cost of US$ 847 million to the National Health Service (Pirmohamed, et al., 2004). A similar study carried out in a tertiary hospital in India by Patel et al in 2005 found that in a period of six weeks, out of 2,046 patients admitted for various reasons, 6.89% were due to ADRs, causing a median duration of stay of 5 days and an average cost of US$ 150 per patient (Patel, et al., 2007).

The financial cost of ADRs also points to a huge loss to the healthcare system. A study conducted in hospitalized patients in the United States by Cullen et al found that US$ 2,262 was required to treat an ADR and this increases with severity of the ADR (Classen, et al., 1997). It was also found that the cost of treating ADRs in intensive care units was higher than general care units i.e. $US 19,685 vs. $US 13,994 (Cullen, et al., 1997). Aside from the direct financial cost to the healthcare system, there are also such indirect costs for patients and their care givers, as missed days from work and/or morbidity such as anxiety due to episodes of ADRs (Wu, 2003).

A Canadian study in 2007 by Wu et al showed that annually, 0.75% of patients aged 66 years and above reported to the emergency department with an ADR-related complaint and 21.6% of these patients were hospitalized costing the healthcare system in Canada an estimated US$ 35.7 million (Wu, et al., 2012).

Data on ADRs reported to the National Pharmacovigilance Centre of Ghana in 2013 shows that out of the 260 reports received for first nine months in Ghana, 1% resulted in deaths and 88% recovered with the rest lost to follow up. In 2014 however, 2.5% out of 436 reports submitted to the Center resulted in

deaths. (Darko, 2014). The trend is frightening because these are just the reported cases since ADR reporting in Ghana among health professionals is low. It is therefore important to have enough data on reactions towards medicines that are on the market so that deductions can be made from these reactions to avoid administering these drugs to the population of patients who are at greater risk.

2.3 Classifications of Adverse Drug Reactions

Adverse drug reaction as defined by WHO, is "a response to a drug that is noxious and unintended and occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for modification of physiological function".

Traditionally ADRs are classified into two categories – Type A and Type B reactions. Type A reactions are exacerbations of pharmacological effects of a drug and hence are dose-dependent. An example is insulin-induced hypoglycaemia. Such reactions are predictable because of the known pharmacology of the drug hence preventable. Because of the predictable nature of type A ADRs, mortality recorded as a result of such a reaction is low because reducing the dose or discontinuing the drug makes the ADR disappear, even though they are responsible for considerable morbidity.

Type B reactions are hypersensitivity reactions and are not dose-related. An example is penicillininduced hypersensitivity. Such reactions are not predictable and only preventable if the patient has a known history of this type of reaction. Type B adverse drug reactions are rare but often serious with a high rate of mortality (Krska & Cox, 2012)

Recently, newer classifications have been proposed based on the two broad categories above. These include:

- Type C or ‘continuing’ reactions – they persist for a relatively long time e.g. osteonecrosis of the jaw with biphosphonates. Type D or ‘delayed’ reactions, are observed some time after the drug has been used e.g. leucopaenia which can occur six weeks after a dose of lomustine.
- Type E or ‘end-of-use’ reactions are associated with withdrawal of the medicine e.g. insomnia and anxiety following the withdrawal of a benzodiazepine.

Other classification schemes have also been proposed, such as ‘DoTS’, which takes Dose-related, Time-related and Susceptibility factors into consideration. Another classification scheme based on severity is shown in *Table 1*.

Table 1 Classifications of ADRs based on severity

Severity	***Description***	***Example***
Mild	No antidote or treatment is needed; hospitalization (if any) is short	Opiods: Constipation
Moderate	A change in treatment (e.g., modified dosage, addition of a drug) but not necessarily discontinuation of the drug is required; hospitalization may be prolonged, or specific treatment may be required.	Hormonal contraceptives: DVT NSAIDs: Hypertesnsion and oedema
Severe	An ADR is potentially life threatening and requires discontinuation of the drug and specific treatment of the ADR.	ACE inhibitors: angioedema
Lethal	An ADR directly or indirectly contributes to a patient’s death.	Paracetamol overdosage: Liver failure Anticoagolants: Haemorrhage

2.4 Diagnosis and Treatment of ADRs

Diagnosis of an ADR can be very confusing, especially if the patient is taking other medicines for the same condition, or taking other medicines for multiple conditions. At this point the physician has to be sure that symptoms being experienced by the patient are as a result of the drug she is taking or another condition he/she may be suffering from. Some patients may be taking other medicines for other conditions, herbal/traditional medicines, contraceptives and recreational drugs which may interact with his/her current medications which may result in the symptoms being presented.

Symptoms that occur soon after the administration of a drug may easily be attributed to that particular drug. However diagnosis of a suspected ADR from a drug taken on a long-term basis by a patient for a chronic disease may be difficult and may require a significant level of suspicion and it is often complicated. Sometimes, stopping the drug may be necessary to confirm the ADR, but this may be difficult if the drug is essential and does not have a suitable alternative. When proof of the relationship between a drug and a symptom is important, re-challenge should be considered except in cases of serious allergic reactions.

For dose-related ADRs, modifying the dose or reducing the precipitating factors may be enough to resolve the problem. It is important to discontinue drugs which result in allergic and idiosyncratic reactions and the patient must be told to avoid such drugs in future (Coulter, 2003). There are situations which can also allow for switching between drug classes if allergic reactions occur e.g. switching to erythromycin (a macrolide) if a patient reacts to a penicillin.

2.5 Monitoring of Adverse Drug Reactions

The two most popular methods used in pharmacovigilance include spontaneous ADR reporting and cohort event monitoring (active surveillance) also called prescription event monitoring.

Spontaneous reporting is defined by WHO (2002) as "a system whereby case reports of adverse drug events are voluntarily submitted by health professionals to national regulatory authority". The pharmaceutical industry has the prime responsibility for the medicines they market. Manufacturers are in the most advantageous position to monitor medicines from the development stage, and thereafter throughout the lifetime of the drug. Spontaneous reporting provides the highest volume of data at lowest cost, and for many years has been of immense value in the detection of safety issues concerning medicines (Pal, et al., 2011).

The most important role played by spontaneous ADR reporting is early detection of signals (Harmark & van Grootheest, 2008) and deduction of hypotheses, which leads to further research to confirm the ADR or otherwise resulting in regulatory warnings and possible changes to product information leaflet. An example is the withdrawal of Rofecoxib from the market in 2004 because of evidence of increased risk of strokes and myocardial infarction. Advantages of spontaneous reporting include:

- Administratively simpler and less labour-intensive
- Less costly
- Identify very rare problems associated with a particular drug used in any health setting
- Provides pharmacovigilance for a drug throughout its lifetime (Pal, et al., 2013)

However with spontaneous reporting, because there are no follow-ups of patients and reporting is mainly left at the initiative and motivation of the health professionals this leads to under-reporting. Therefore it is difficult to calculate the actual number of individuals experiencing an adverse reaction to the drug. Together with the uncertainties around the number of patients who are administered the said medicine makes it difficult to estimate the rate and frequency of adverse drug reactions through spontaneous reporting (Hazel & Shakir, 2006).

Cohort Event Monitoring (CEM), is a prospective, observational, cohort study of adverse events associated with one or more drugs after marketing authorization has been issued (WHO, 2009). The CEM programme is essentially for safety monitoring of newly registered drugs in routine clinical use but can also be used for older drugs. Advantages of CEM over spontaneous reporting are:

- Ability to produce rates
- Ability to produce a near-complete ADR profile of medicines of interest
- Very effective in identifying signal at early stage
- Ability to associate reactions with risk factors
- Can detect reduced or failed therapeutic effect and raise suspicion of medication errors, interactions, emerging resistance or poor quality or counterfeit medicines.
- Ability to record and examine details of all deaths and provide rates of death (Pal, et al., 2013)

In Ghana, laws regarding the monitoring of ADRs do not exist and there are no laws that require marketing authorization holders to continuously monitor safety of their products and report to

the Food and Drugs Authority (FDA), which also serves as the national pharmacovigilance centre. The centre therefore relies on voluntary reports submitted by health professionals, pharmaceutical companies, and consumers. An official standardized form for reporting ADRs is issued by the FDA, downloadable at the FDA website and also made available in health facilities through institutional pharmacovigilance contact persons. Reports on ADRs resulting from routine clinical practice and health programmes such as Malaria, HIV/AIDS and Tuberculosis, sent to the centre are entered into a national database and also made available to the WHO monitoring centre in Uppsala. The FDA has a national ADR or pharmacovigilance advisory committee which provides technical assistance or causality assessment, risk assessment, risk management, case investigation, and where necessary crisis management. To enhance the quality of reports generated, the centre in collaboration with Uppsala Centre annually organises training causes in pharmacovigilance for health professionals on ADR reporting.

2.6 Factors Affecting Reporting of ADRs

A myriad of factors could possibly affect the attitude of health professionals in reporting adverse drug reactions of their patients. A lot of studies (Kamtane 2012, Oshikoya 2009, Lisha 2012, and Fadare 2011) have been conducted to identify such factors so as to improve spontaneous adverse drug reaction reporting among health care professionals. Reasons mostly given as the cause of low reporting among health professionals include lack of access to reporting form, inadequate knowledge about how to report, and heavy workload.

One such study conducted in hospital pharmacies in Western China found that having a higher professional title, better knowledge about reporting by having received training are independently

associated with adverse drug reaction reporting. This study also found that clinical pharmacists were more likely to report ADRs than dispensary pharmacists (Liu, et al., 2015)

Another study conducted in Spain among community pharmacists (Irujo, et al., 2007) revealed that age, years of work experience, participation in activities related to pharmacovigilance, having the basic knowledge required to report ADRs, and disagreement with the common belief among healthcare professionals that to report an ADR it is necessary to be sure that reaction is related to the use of a particular drug, are factors that were positively associated with ADR reporting. A similar study which was conducted among hospital pharmacists in Great Britain found that apart from lack of time, other factors that deter reporting are lack of confidence in recognizing ADRs and fear of breaching patient confidentiality (Sweis & Wong, 2000). In another study in Great Britain among hospital pharmacists, it was found that even though more than half of respondents felt that ADR reporting was their professional obligation, and agreed that it should be made compulsory for all pharmacists, they were unclear as to what should be reported (Green, et al., 2001).

A systematic review of a total of 45 papers by Lopez-Gonzalez, et al., 2009 also found that the professional characteristic most closely associated with under-reporting in 76% of studies involving physicians was medical specialty. Other factors that contributed to under-reporting were ignorance (the belief that only severe ADRs are to be reported) in 95%; diffidence (fear of being ridiculed for reporting merely suspected ADRs) in 72%; indifference (the belief that a single report could not contribute to medical knowledge) and insecurity (not sure that a particular drug is responsible for the reaction) in 67%; lethargy (proscrastination, lack of interest or time to find report card) in 77%; and complacency (the belief that only safe drugs are allowed on the market) in 47% of studies.

Even though studies are abound in Europe, Asia, and America about reasons for under-reporting of ADRs, same cannot be said about the situation in Africa because availability of such studies are limited.

It is also difficult to relate reasons for under-reporting in one country to another because the reasons vary. For example in the study conducted in Spain by Irujo et al , complacency was identified as the main reason for under-reporting whereas the study conducted in Nigeria (Fadare, et al., 2011), lack of knowledge of the forms for reporting (74.1%), ignorance of the reporting procedures (66.1%), and identifying what constituted ADRs (48.3%) were the major reasons for under-reporting.

In the study by Sabblah et al, 2012 which evaluated adverse drug reaction reporting among 259 doctors in Greater Accra region of Ghana, reporting rate was found to be 21%, and the main reasons for underreporting were unavailability of the reporting form (43.1%), and lack of knowledge of reporting procedure (28.5%). Since the Sabblah study is just one, it may not be enough to generalise this finding to other healthcare professionals in Ghana. In all of these studies it was realized that healthcare professionals see it necessary to report only unusual and serious reactions, neglecting reactions well recognized for particular agents.

This study will seek to find out reasons for under-reporting of ADRs among hospital pharmacists in Ashanti Region of Ghana and then compare the findings with previous studies from other parts of Africa.

CHAPTER THREE

METHODOLOGY

3.1 Study Design

The study was a cross sectional survey of hospital pharmacists who were involved in clinical pharmacy, dispensing and drug information. The respondents' hospitals were grouped into government, quasigovernment and private hospitals in the Ashanti Region.

Ashanti Region was chosen for the study because it is the most populous region, consisting of 19.4% of the population of Ghana (2010 Census). The region has 30 administrative districts which have at least one government hospital each. There are also 11 mission hospitals, one regional hospital, a tertiary hospital and a few private hospitals with pharmacists. In total, the region has an estimated population of 150 hospital pharmacists. Thirty-eight hospitals were visited and the questionnaire administered to pharmacists who were willing to take part in this study and signed a consent form. A total of 120 questionnaires were administered.

The questionnaire was adapted from similar studies which investigated the attitudes and practice of reporting ADRs among healthcare workers in Nigeria (Oshikoya & Awobusuyi, 2009), United Arab Emirates (Lisha, et al., 2012), India (Kamtane & Jayawardhani, 2012), Portugal (Herdeiro, et al., 2006) and UK (Green, et al., 2001). The questionnaire was designed to capture among other information, duration of practice, type of hospital, information about knowledge, and practice of ADR reporting and factors that may affect their willingness to report ADRs. The questionnaire was piloted and the necessary corrections made by way of rephrasing of sentences to eliminate ambiguities.

3.2 Study Population

3.2.1 Inclusion Criteria

The study population involved pharmacists in clinical practice with at least one year of practice experience. Hospital pharmacists were chosen for the study because they were likely to see ADRs since they are the category of healthcare professionals who will be notified in case of any adverse drug reaction, and also because the pharmacovigilance "contact persons" in the hospitals are mostly pharmacists hence they will be contacted if a reaction to a particular medicine is suspected.

3.2.2 Exclusion Criteria

Pharmacy interns, pharmacists involved in manufacturing and logistics management in hospitals. However if a pharmacist is alone in his hospital and is involved in both administrative and clinical duties, he or she is included.

3.3 Sampling

The hospitals were classified into government, quasi-government and private hospitals. Most of the district hospitals have one pharmacist hence that pharmacist was automatically selected. The teaching hospital has about 60 pharmacists of which about 45 were involved in dispensing and clinical activities, and every pharmacist who met the inclusion criteria was approached to take part in the study if he/she agreed. The eleven mission hospitals all have pharmacists but only 9 agreed to take part in the study.

3.4 Study Variables

The dependent variable for the study is the reporting of adverse drug reactions. The independent variables such as knowledge of ADR reporting system, training on pharmacovigilance are used in this study to establish the determinants of ADR reporting by hospital pharmacists.

3.5 Data Collection

A total of 120 questionnaires *(Appendix A)* were distributed to 120 pharmacists in 38 hospitals, made up of thirty-one (31) government hospitals, five (5) mission hospitals, and two (2) private hospitals.

The data collection took place between 15th March and 15th June, 2015. A time frame of 2 weeks was allowed for the collection of the filled questionnaires. If a pharmacist did not fill the questionnaire after 2 weeks, three more attempts were made to retrieve the filled form. A fresh questionnaire was made available to respondents who misplaced theirs. However after three unsuccessful attempts at retrieval of the filled forms, the pharmacist was declared non-respondent.

The questionnaire was made up of four (4) sections: Section A sought to collect the demographic data of respondents, section B, about their knowledge in the ADR reporting system in Ghana, section C looked at the attitudes of the respondents, and section D sought to find out the perception of the respondents on possible ways of improving the ADR reporting rates in Ghana. The questionnaire was personally delivered to some respondents in their various hospitals, and others at their quarterly meetings. A brief explanation of study objectives, and overview of questionnaire was explained to them. They were assured of their confidentiality, and each of them signed a consent form before they took part in the study.

3.6 Data Processing and Analysis

Information from the returned questionnaire was coded and entered into SPSS version 20 software. The results are presented as mean ± standard deviation, counts, and percentages. Charts were drawn with MS Excel, 2013. Descriptive statistics was used to describe the background characteristics of the respondents.

Twelve questions namely; Q3 (knowledge of colour of reporting form), Q6 (which tend to illicit multiple choice answers from respondents about their knowledge of the purpose of reporting ADRs, 6 answers in all), Q7 (how the ADR form can be obtained) Q10 and Q11 were used to assess the basic knowledge of respondents about the reporting system in Ghana. The responses were coded on a scale of 0 (for wrong answer) or 1 (for a correct answer). Based on the total score, a respondent's level of knowledge was graded as Excellent for a score of 70% and above, Very Good for 60-69%, Good for 59-50%, Average for 40-49% and Poor for marks below 40%, based on the KNUST grading system.

The rate of ADR reporting among hospital pharmacists was calculated by dividing the number of respondents who had seen and reported a suspected ADR in the past one year prior to the study by the total number of pharmacists who saw an ADR within the same period.

The factors perceived by the respondents as contributing to under-reporting of ADR was determined by multiple response to questions.

3.7 Ethical Consideration

Ethical approval *(Appendix B)* was obtained from the Committee on Human Research, Publications and Ethics (CHRPE), Kwame Nkrumah University of Science and Technology, for the conduct of the study. Permission was sought from the Ghana Health Service and Komfo Anokye Teaching Hospital for their pharmacists to participate in the research.

The identities of respondents were kept confidential, and this was explained to them. They were then made to sign a consent form before participating in the research.

There was minimal or no risk associated with their participation in the study and no compensation was paid to participants.

3.8 Limitations of the Research

Because the questionnaire was self-administered, factors associated with such studies which include accuracy of recall and personal bias may affect the study. Some pharmacists may find it difficult to recollect seeing a patient with an ADR during their practice, however this was minimized by the use of one year period prior to the study.

In addition to that, it is possible some pharmacists may give socially acceptable responses such as having reported an adverse drug reaction in the past one year. The likelihood of this occurring was

minimized by allowing the respondent to fill the form in the absence of the researcher, and the fact that confidentiality was assured.

CHAPTER FOUR

RESULTS

4.1 Background Information of Respondents

Ninety-five pharmacists from 38 hospitals completed the questionnaire giving a response rate of 79.2%. Out of this number 88.4% (*n*=84) came from government hospitals, 9.5% (*n*=9) came from quasigovernment (mission) hospitals and 2.1% (*n*=2) work in private hospitals. About 32% of the

respondents came from the teaching hospital, 4% from the regional hospital and 64% came from district hospitals. All mission hospitals were classified as district hospitals.

Majority (67.4%, *n*=62) of respondents were males. The modal age group was 31-35 (26.7%, n=24). The average number of years of practice of the pharmacists who participated in the study was 8.9 (SD=5.2). Even though respondents include pharmacists from the various ranks, senior pharmacists constitute the highest proportion (46.2%, *n*=43), principal pharmacists and pharmacists constitute 23.7% (*n*=22) each and deputy directors constitute 6.5% (*n*=6). The other characteristic features are shown in the *Table 2*.

Table 2 Demographics of respondent pharmacists

Characteristics		***Number of respondents***	***Percentage***
Gender	Male	62	67.4
	Female	30	32.6
Age (years)	26-30	13	14.4
	31-35	24	26.7
	36-40	16	17.8
	41-45	19	21.1
	46-50	9	10.0
	>50	9	10.0
Rank of Respondents	Pharmacist	22	23.7
	Snr. Pharmacist	43	46.2

	Prin. Pharmacist	22	23.7
	Deputy Director of Pharmaceutical Services	6	6.5
Place of Work	Private Hospital	2	2.1
	Government Hospital	84	88.4
	Quasi-government (Mission) Hospital	9	9.5
Level of Work	Teaching Hospital	30	31.6
	Regional Hospital	4	4.2
	District Hospital	61	64.2
Trained on Drug Safety & ADR Reporting, n=52	Teaching Hospital	14	26.9
	Regional Hospital	4	7.7
	District Hospital	34	65.4

4.2 Rate of ADR Reporting among Hospital Pharmacists in Ashanti Region

The number of respondents who said they had seen an ADR in the past one year prior to the study was 43 (45.7%) but only 29 of this number reported the ADR by completing and submitting the ADR reporting form. This gave a perceived ADR reporting rate of 69% among hospital pharmacists in Ashanti Region.

For those respondents (n=13) who saw a suspected ADR but did not report, the three major reasons for not reporting were "*Reaction commonly reported so considered normal*" (46.2%), "*Reporting form not available*" (38.5%), and "*Did not know the reporting format*" (38.5%) as depicted in *Figure 4*.

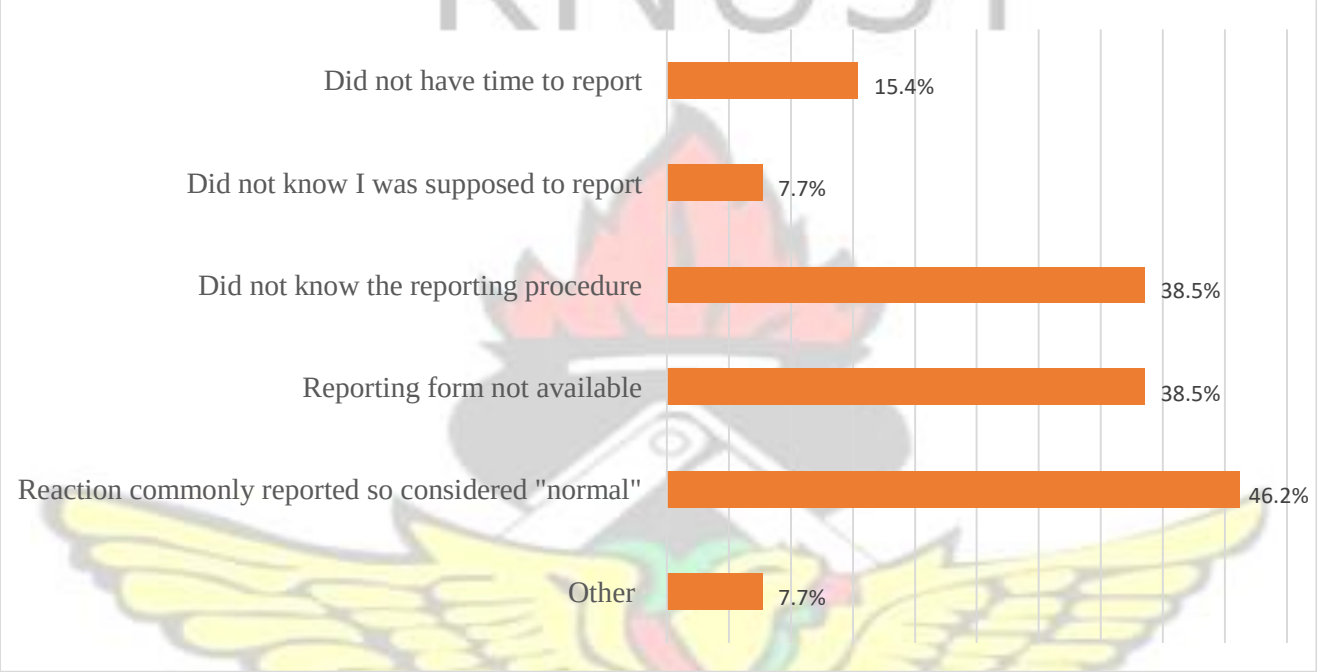


Figure 4 Pharmacists' reasons for not reporting suspected ADR

4.3 Knowledge of Adverse Drug Reaction Reporting

Ninety-four out of the 95 respondents answered positive to the question of whether respondents had heard of ADR reporting in Ghana, and 91.4% said they had seen the ADR reporting form in their hospital in the past one year prior to the study. However 79.5% (*n*=62) of those who claimed to have seen the ADR form correctly identified it by its blue colour.

Fifty-two respondents (57.8%) said they have had training in drug safety and adverse drug reaction reporting. All the respondents acknowledged that ADR reporting would be beneficial to the patient. The top 3 benefits of ADR reporting as perceived by respondents are information resource on ADR

characteristics, to identify unrecognized ADRs and to calculate incidence of ADRs among others, as depicted in *Figure 5*.

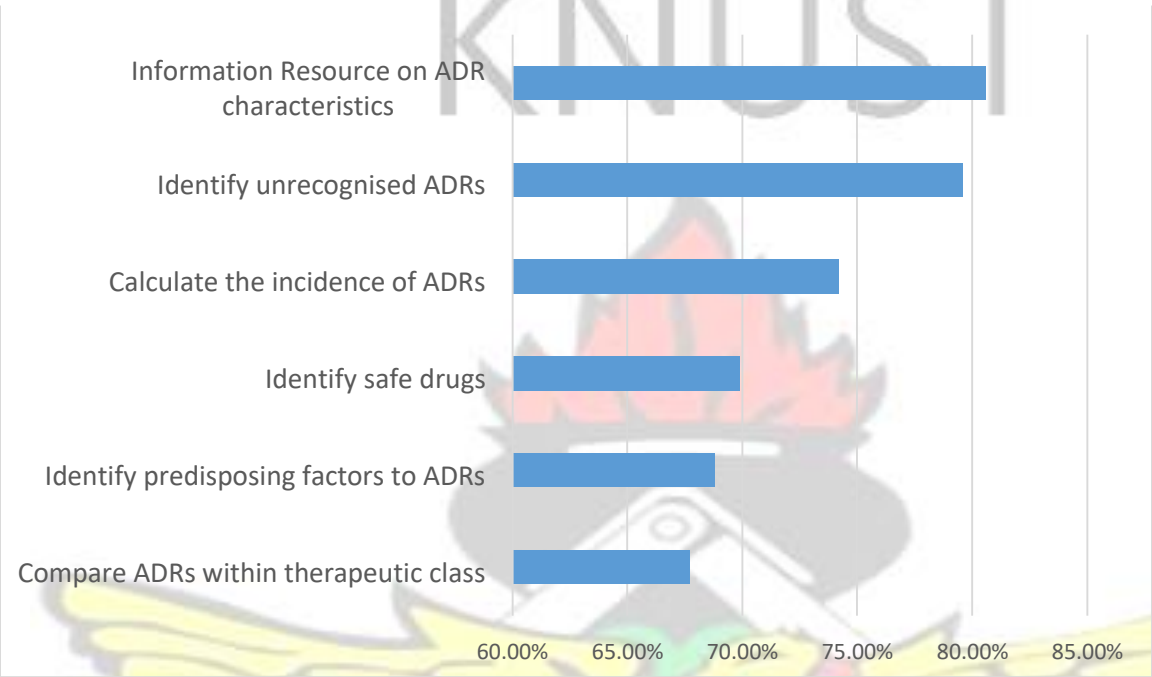


Figure 5 Respondents' knowledge of purpose of ADR reporting

On the question of where to obtain the ADR reporting form, 84% of respondents knew that the reporting form was present in the hospital but only 66.3% knew the pharmacovigilance contact person in the hospital can provide them with ADR forms. Other means by which the ADR forms can be obtained are as shown in *Figure 6*.

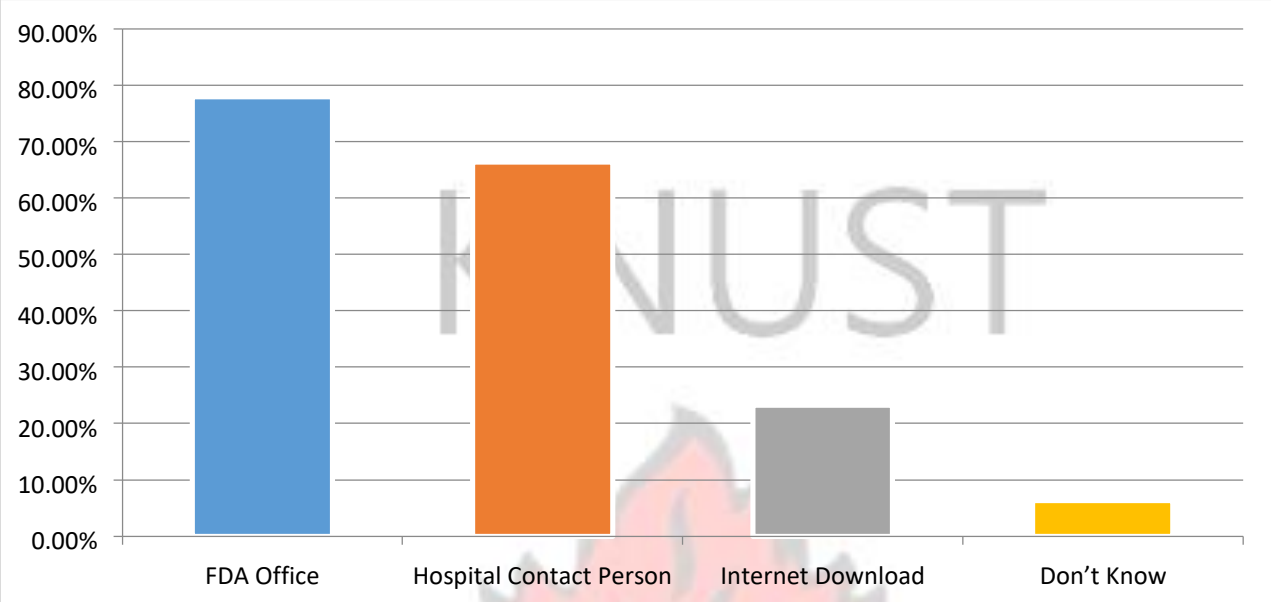


Figure 6 How respondents obtain ADR forms

To assess the overall knowledge of respondents in the reporting procedure objectively, the total score obtained by answering correctly 12 questions, namely Q3, Q6, Q7, Q10 and Q11 was used. A total score of 12 was expected if a participant answered all questions correctly. Based on the total score, a respondent's knowledge was graded as Excellent, Good, Average and Poor using KNUST grading system of Excellent for >70%. The result is as shown in *Table 3* below.

Table 3 Pharmacists' level of knowledge in ADR reporting system in Ghana

Marks (%)	***Remarks***	***Number of respondents***	***Percentage of respondents***

70 – 100	Excellent	47	49.5
60 – 69	Very Good	21	22.1
50 – 59	Good	14	14.7
40 – 49	Average	6	6.3
≤39	Poor	7	7.4
Total		**95**	**100.0**

The mean aggregate knowledge score also showed that the mean score (7.83 ±2.32) of respondents from the tertiary hospital was significantly different [$t(93) = -2.268$, $p = 0.026$)] from the mean aggregate score (8.85 ±1.87) from other (regional and district) hospitals.

4.4 Attitudes of Respondents to ADR Reporting

A vast majority (n=91) of the respondents agreed that ADR reporting is a professional obligation of the pharmacist with only two of them disagreeing, and one declining to comment. One pharmacist however said he does not know if reporting ADR is his professional obligation.

According to respondents, the major factor that will encourage them to report an ADR is when the reaction is serious, and unusual. Only 56.5% of the hospital pharmacists are likely to report a wellrecognized ADR. Only 3.5% (n=3) of respondents erroneously believed that reporting one ADR will not make any significant contribution to pharmacovigilance. About 92.1% (n=82) of respondents say they will want ADR reporting to be made compulsory for all pharmacists.

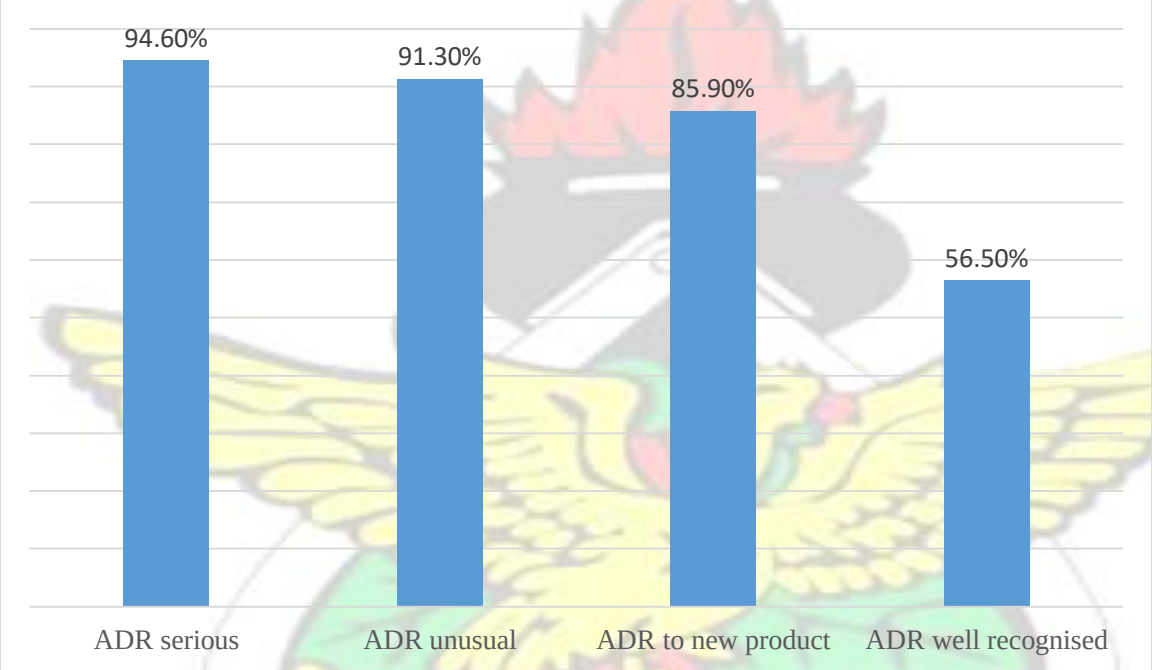


Figure 7 Factors encouraging ADR reporting

Table 4 below shows the top five factors that will discourage respondents from reporting an ADR. i.e. Lack of time or heavy workload (57.8%), ADR form not available (47%), unaware of reporting procedure or how the form can be obtained (45.8%), no reward or recognition for pharmacists who report (36.1%), and inability to recognize or diagnose ADRs (31.3%).

Table 4 Factors discouraging ADR reporting

Factors Discouraging ADR Reporting	***Responses*** ***N***	***Percent of Cases***
Lack of time or heavy workload	48	57.8
ADR form not available in the hospital	39	47.0
Unaware of reporting procedure	38	45.8
No reward or recognition for pharmacists who report	30	36.1
Inability to recognize or diagnose ADRs	26	31.3
Lack of confidence in the reporting system	20	24.1
Concern report may be wrong	19	22.9
No idea that ADRs are to be reported	12	14.5
Fear of being legally accused of administering wrong drug	10	12.0

Single case reported cannot contribute to medical knowledge	7	8.4
Negative impact of ADR report on drug producing company	6	7.2
All ADRs documented before medicines go on the market	5	6.0

On which health professionals are responsible for ADR reporting, all respondents who answered (*n*=91) agreed that it is the professional responsibility of pharmacists. However, only 58.2%, 52.7% and 49.5% of respondents agreed that doctors, nurses and medical assistants respectively, are equally professionally responsible for reporting ADRs.

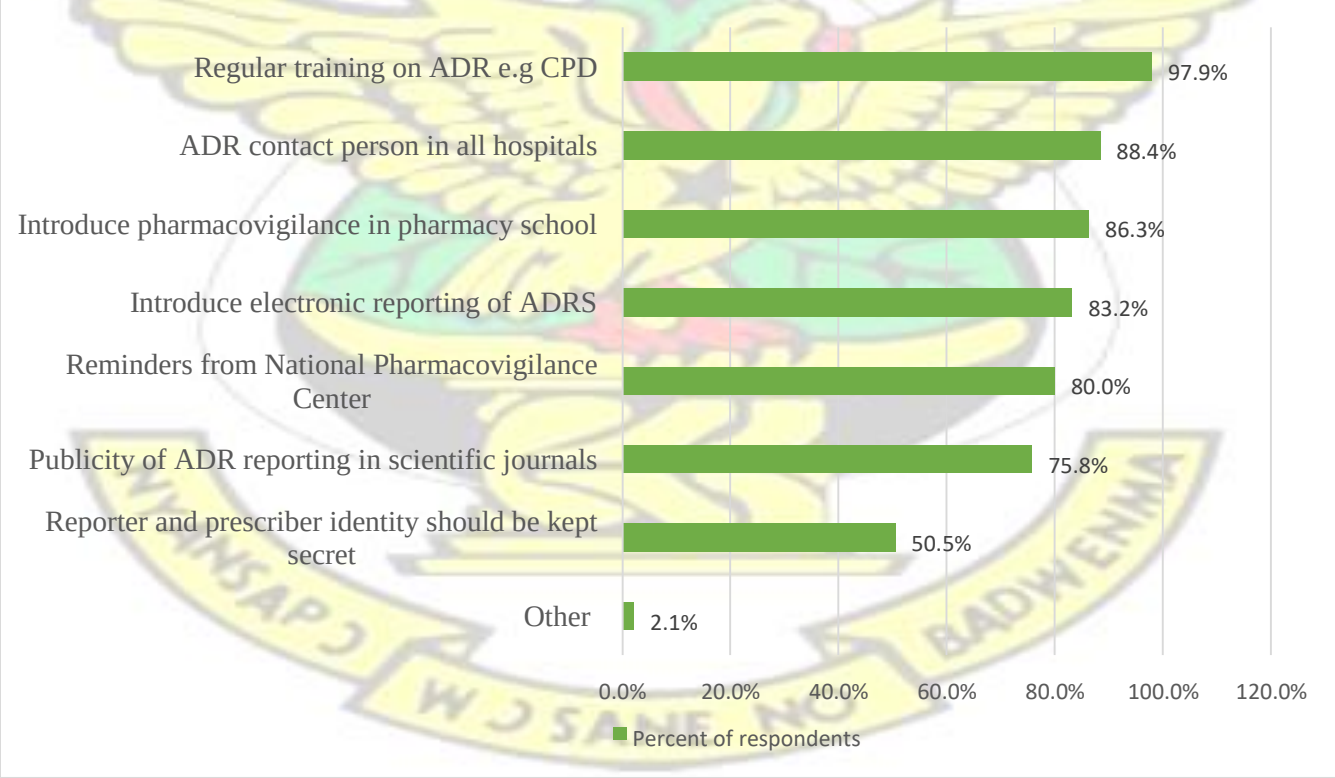


Figure 8 Respondents' perception of strategies to improve ADR reporting

The chart from *Figure 8* above shows that many pharmacists will report ADRs if a refresher course in the form of continuous professional development (CPD) is conducted routinely to train pharmacists in the reporting procedure. Many also agreed that introducing pharmacovigilance into the curriculum of pharmacy education as a course (86.3%), identifying pharmacovigilance contact persons in the various hospitals (88.4%), routine reminders from the national pharmacovigilance centre can equally improve ADR reporting rate. Seventy-nine respondents (83.2%) also identified the use of electronic reporting of ADRs i.e. mobile and online reporting, as convenient means of increasing the reporting rate.

The appropriate rewards for reporting ADRs as suggested by respondents included credits for CPD (79.4%, *n*=54), publishing the name of the reporters in a journal (61.8%, *n*=42). Nine (9) others gave open ended answers such as financial reward, and prompt feedback from the national pharmacovigilance centre on actions taken on submitted reports.

CHAPTER FIVE

DISCUSSION

The rate of adverse drug reaction reporting among the hospital pharmacists studied in Ashanti region was 69%; higher than the 42.5% found in the study carried out in Northern Nigeria (Fadare, et al., 2011), the 41% found in medical practitioners in India (Ramesh & Parthasarathi, 2009), the 21% found among doctors in Greater Accra Region of Ghana (Sabblah, 2012) , and 14.7% among pharmacists in Hong Kong (Lee, et al., 1994).

The top four reasons given by pharmacists who failed to report suspected ADRs were complacency i.e. the believe that the reaction was commonly reported so considered normal (46.2%), lack of knowledge in the reporting procedure (38.5%), absence of the reporting form in the hospital (38.5%), and 15.4%

said lack of time prevented them from reporting. This finding was similar to the observation in a similar study among physicians in Ibadan, Nigeria where it was found that unawareness of the presence of ADR form and ignorance of the reporting procedure prevented reporting among doctors (Enwere & Fawole, 2008).

These findings suggest that training, and availability of reporting forms, have the potential to increase ADR reporting. Interestingly, 90.7% of the forty-three respondents who said they saw an ADR were trained in drug safety and ADR reporting. Of this number, only 51.3% (n=20) actually reported an ADR in the year prior to the study. However there was no statistically significant difference between training and ADR reporting (X^2=2.167, p=0.141) in this study. Training was found in other studies (Figueiras, et al., 2006) to be a positive determinant of ADR reporting. Figueiras, et al., 2006 found that an hour long training for physicians increase ADR reporting by ten-folds within the first twelve months following the training (95% CI 3.81-27.51). Another study in Great Britain (Green, et al., 2001) evaluating attitudes and knowledge of hospital pharmacists in reporting adverse drug reactions also found that pharmacists who are trained in ADR reporting were more likely to report than those not trained (p=0.0001, 95% CI, 15.4-36.7%).

It was also observed from this study that even though senior pharmacists reported more ADRs than other ranks, there was no statistically significant difference in ranks and ADR reporting (X^2 = 3.049, p = 0.384). Again, there did not appear to be a relationship between ADR reporting and level of practice (X^2 = 1.292, p = 0.524), or place of practice (X^2 = 0.624, p = 0.732), or age (X^2 = 4.106, p = 0.534), contrary to findings by the study of Irujo, et al., 2007 who observed that factors which were positively associated with ADR reporting were age, years of work experience as a pharmacist, and participation in educational activities related to drug safety.

The knowledge of respondents about the reporting system was good, with over 86% (n=82) having excellent to good level of knowledge from the knowledge score. The level of knowledge obtained from this study was however higher than what was found by Sabblah et al in their study, where 59.3% of doctors in the Greater Accra Region had either excellent or good knowledge of the reporting system in Ghana. It can be observed that knowing what to report, and how to report it is a positive factor in reporting ADRs because in the Sabblah study, 59.3% of respondents who had at least a good knowledge of the reporting system produced a reporting rate of 21%, while 86.3% of respondents in this study with at least a good knowledge produced a reporting rate of 69%. Therefore refresher courses in pharmacovigilance and ADR reporting system could improve the reporting rate among pharmacists.

The perception of pharmacists about the benefits of adverse drug reaction reporting is positive, with all of them agreeing that ADR reporting could be beneficial to patient drug safety, 96.8% (n=91) agreeing that it is their professional responsibility to report ADRs, and 92.1% (n=82) believe ADR reporting should be made compulsory for all pharmacists. Other health professionals whom respondents believed should also report ADRs are doctors, nurses and medical assistants in that order. It was found in the Lisha, 2012 study that only 31% of doctors in the United Arab Emirates see ADR reporting as their professional responsibility and only 57% of them agree that ADR reporting should be compulsory. Kamtane, 2012 also found that 93.61% of physicians in India agree that ADR reporting and monitoring system would benefit the patient, with 85.1% of them agreeing that ADR reporting should be made mandatory. In the study by Green et al, 2001, only 50% of hospital pharmacists in Great Britain felt ADR reporting should be made compulsory, even though 75% agreed that reporting ADRs is their professional responsibility. The Sabblah study found that only 3.6% of doctors felt ADR reporting was their professional responsibility, with 70% preferring pharmacists to report instead. It can therefore be observed in this study that the high sense of responsibility among the respondents was evident in the reporting rate that was found, which is higher than those found in the studies earlier mentioned.

The major factors that would encourage a pharmacist to report a suspected ADR were if the ADR is serious (94.6%) and unusual (91.3%). Only 56.5% of the pharmacists will report a well-known ADR by a particular drug. This finding was similar to those observed in the Green study, Lisha study, and the Lee study, in Great Britain, United Arab Emirates, and Hong Kong respectively. This finding was also consistent with reasons given by respondents who did not report a suspected ADR in this study, highest being that the reaction was commonly reported for that medicine hence they did not report. This belief is in contrast with the guidelines from the FDA on ADR reporting, which directs health professionals to report even if the reaction is known to be associated with the suspected drug, and even if the reporter is not sure the reaction is caused by the suspected medicine. The fact that some respondents did not know means more training is required if more gains are to be made in the area of pharmacovigilance in the region.

Top three factors found from this study that may deter a pharmacist from reporting an ADR were lack of time or heavy workload (57.8% of cases), absence of ADR reporting form in the hospital (47% of cases), and unawareness of the reporting procedure (45.8% of cases). Similar findings were observed in the Sabblah study, where lack of time and heavy workload was the main barrier to ADR reporting. However, "*lack of confidence in the reporting system"* was mentioned more frequently by respondents than *absence of reporting form* in the Sabblah study as barriers to ADR reporting. In the Lisha study however, the top three factors that discouraged doctors from reporting were found to be respondents not knowing how to report, non-remuneration for reporting, and lack of time to actively look for ADRs. In another study among hospital pharmacists in Great Britain (Sweis & Wong, 2000), it was found that being busy at work, lack of confidence in recognising ADRs and fear of breaching patient confidentiality were deterring factors to reporting ADRs. It can therefore be observed from the study that factors that discouraged ADR reporting differs from one country to the other.

The respondents' perception of how reporting can be improved included mainly through training and sending periodic reminders to health professionals about ADR reporting from the national pharmacovigilance centre. They also believed that dedicating more teaching hours to pharmacovigilance in pharmacy schools across the country will improve the confidence of the pharmacist in recognizing, and hence reporting suspected ADRs. This finding is similar to that observed by Ramesh et al in India, Sabblah et al in Ghana, Herdeiro et al in Portugal, Sweis et al and Green et al both in Great Britain who all find training as the best means of improving the rate of reporting ADRs.

Majority (83.2%) of respondents also agreed that introduction of electronic reporting of ADRs, e.g. cell phone text messaging, email, and telephone call reporting can also improve the reporting rate. This finding was consistent with a study by Lynn et al, in comparing the traditional yellow card system to a piloted email system, observed that ADRs in 67 children were reported by email compared to only 8 children whose ADRs were reported using the MHRA yellow card system, and respondents in that study were more willing to use the electronic reporting system (Lynn, et al., 2010).

The pharmacists in this study also believed that rewarding reporters of ADRs can motivate them to do more. This, they believed can be done through giving (CPD) credits for each ADR report submitted (79.4%), by publishing the name of the reporter in journals and periodicals of pharmacovigilance (61.8%), and then financial reward for reporters. The Food and Drug Authority already has a newsletter called the *DrugLens* which is published once a year, in which pharmacovigilance activities and a summary of ADR reporting trends and patient outcomes from drug reactions are shared with healthcare professionals. Persons who contribute immensely to the success of the programme are acknowledged in this newsletter. The fact that most respondents do not know this already means the coverage of *DrugLens* is not adequate. Therefore if the circulation of the FDA periodical on pharmacovigilance is increased then more awareness could be created among healthcare professionals.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

4.5 Conclusion

The ADR reporting rate among hospital pharmacists studied in Ashanti Region was 69%.

Hospital pharmacists in Ashanti Region had adequate knowledge of the ADR reporting procedure.

Lack of time or heavy workload, absence of ADR reporting form, and inability of some pharmacists to recognize and diagnose ADRs were some factors that contributed to under-reporting of ADRs in the Ashanti Region.

4.6 Recommendations

- ADR reporting forms must be readily available in the hospitals and scheduled reporting by pharmacists must be clearly instituted and monitored.
- The FDA should increase the number of trainings in pharmacovigilance for hospital pharmacists to improve their capacity in diagnosing and reporting ADRs.
- Pharmacovigilance training in pharmacy schools should be intensified to align with the FDA policy.
- Other forms of ADR reporting, like smart phone Apps, could also be implemented.

- Because this study involves just one region out of ten, it will be necessary to conduct this study among pharmacists in other regions and results compared before findings can be generalised.

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APPENDICES

APPENDIX A: QUESTIONNAIRE

Questionnaire on Evaluation of Knowledge, Attitude, and Practice among Hospital Pharmacists in Ashanti Region on Reporting Adverse Drug Reactions

SECTION A: *Demographic characteristics*

Gender: Male ☐ Female ☐

Age(years): 20-25 ☐ 26-30 ☐ ☐ 31-35 36-40 ☐ 41-45 ☐ 46-50 >50 ☐

Rank: Pharmacist ☐ Snr. Pharmacist ☐ Prin. Pharmacist ☐ DDPS ☐

Additional Qualification obtained (if any): …… **Years of practice:** ……

Place of work/practice: Private ☐ Government ☐ Quasi-government ☐

Level: Teaching hospital ☐ Regional hospital ☐ District hospital ☐

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. **What is the colour of the ADR reporting form?** Yellow ☐ Pink ☐ Blue ☐ 4. **Have you ever been trained on drug safety and reporting ADRs?** Yes ☐ No ☐ 5. **Do you think that ADR reporting would benefit the patient?** Yes ☐ No ☐ Don't know ☐ 6. **The purpose of reporting ADRs is** (please check all that apply)

a) To identify safe drugs ☐
b) To calculate incidence of ADRs ☐
c) To identify predisposing factors to ADRs ☐
d) To identify previously unrecognized ADRs ☐
e) To serve as an information resource about characteristics of the ADR ☐
f) For comparison ADRs of drugs within the same therapeutic class ☐

7. **Which of the following represents how the form can be obtained?** (Check all that apply)

a) Contact person in the hospital ☐
b) Download from the internet ☐
c) From the FDA office
d) I don't know ☐

8. **Do you have the reporting form in your hospital?** Yes ☐ No ☐ I don't know ☐
9. **Do you know where to send the reporting form after completion?** Yes ☐ No ☐
10. **Should all ADRs be reported for newly marketed agents?** Yes ☐ No ☐ 11. **Serious reactions should be reported for established products.** Yes ☐ No ☐
12. **Have you seen a patient with an ADR in the past one year?** Yes ☐ If No ☐ No, proceed to SECTION C

13. **If "YES", did you report the ADR by completing the form?** Yes ☐ If YES, proceed to SECTION C

14. **If "NO", why didn't you report?** (Check all that apply)

a) I did not know I was supposed to report ☐
b) The reporting form was not available ☐
c) I do not know the reporting procedure ☐
d) I did not have time to report ☐
e) I did not think it was important/serious ☐
f) The reaction is very commonly reported with that medication so I considered it "normal" ☐
g) Others:

……

……

SECTION C: Attitudes to reporting ADRs

1. **ADR reporting is a professional obligation of a pharmacist** Yes ☐ No ☐ Don't know ☐
2. **Factors that may encourage you to report an ADR include**
   a) if the reaction was serious ☐
   b) if the reaction was unusual ☐
   c) if the reaction was to a new product ☐
   d) if the reaction was well recognized for a particular drug ☐
3. **Reporting of only one ADR makes no significant contribution to pharmacovigilance**
   a) Yes ☐ b) No ☐ c) Don't know
4. **ADR reporting should be** a) compulsory ☐ b) voluntary ☐

5. **Which of the following factors may discourage you from reporting an ADR?** (please check all that apply)

a) Concern that the report may be wrong ☐
b) Lack of time and heavy workload ☐
c) Unaware of the reporting procedure and how the form can be obtained ☐
d) No idea that ADRs are to be reported
e) The reporting form is not available in the hospitals ☐
f) The occasional single case reported cannot contribute much to medical knowledge
g) All ADRs are well documented before medicines are placed on the market
h) Inability to recognize or diagnose ADRs
i) Fear of being legally accused of administering the wrong drug ☐
j) Fear of negative impact the report may have on the company that produces the drug
k) Lack of confidence in the reporting system
l) No reward or recognition for the pharmacist who report ADRs
m) Which of the following rewards will you consider appropriate?
   - Award credits for Continuous Professional Development ☐
   - Publish name of pharmacist in a local scientific journal
   - Others, please specify

   ……

6. **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 apply)

1. Continuous professional education, training and refresher courses ☐
2. Introduce pharmacovigilance and ADR reporting into pharmacy school curriculum ☐
3. Reminders and increase awareness from the National Pharmacovigilance Centre ☐
4. Publicity about ADR reporting in the local scientific journals
5. Designated ADR contact person in every hospital ☐
6. Introduce mobile apps and on-line reporting of ADRs ☐

7. The identity of reporter and prescriber should be kept a secret ☐
8. Others:

……
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Thank you for your time.

APPENDIX B: ETHICAL CLEARANCE

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY
COLLEGE OF HEALTH SCIENCES

SCHOOL OF MEDICAL SCIENCES / KOMFO ANOKYE TEACHING HOSPITAL
COMMITTEE ON HUMAN RESEARCH, PUBLICATION AND ETHICS

Our Ref: CHRPE/AP/384/14 — 8th December, 2014.

Mr. Richard Delali Agbeko
Nkenkaasu Government Hospital
Post Office Box 37
Nkenkaasu- Ashanti.

Dear Sir,

LETTER OF APPROVAL

Protocol Title: "Reporting Adverse Drug Reactions: Evaluation of Knowledge, Attitude and Practice of Hospital Pharmacists in Ashanti Region."

Proposed Site: All Hospitals in Ashanti Region with Pharmacists.

Sponsor: Principal Investigator.

Your submission to the Committee on Human Research, Publications and Ethics on the above named protocol refers.

The Committee reviewed the following documents:

- A notification letter of 22nd October, 2014 from the Komfo Anokye Teaching Hospital (study site) indicating approval for the conduct of the study in the Hospital.
- A notification letter of 17th November, 2014 from the Ashanti Regional Health Directorate (study site) indicating approval for the conduct of the study in the Region.
- A Completed CHRPE Application Form.
- Participant Information Leaflet and Consent Form.
- Research Proposal.
- Questionnaire.

The Committee has considered the ethical merit of your submission and approved the protocol. The approval is for a fixed period of one year, renewable annually thereafter. The Committee may however, suspend or withdraw ethical approval at anytime if your study is found to contravene the approved protocol.

Data gathered for the study should be used for the approved purposes only. Permission should be sought from the Committee if any amendment to the protocol or use, other than submitted, is made of your research data.

The Committee should be notified of the actual start date of the project and would expect a report on your study, annually or at the close of the project, whichever one comes first. It should also be informed of any publication arising from the study.

Thank you Sir, for your application.

Yours faithfully,

Osomfuor Prof. Sir J. W. Acheampong MD, FWACP
Chairman

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