UNIVERSITY OF CAPE COAST

ADVERSE DRUG REACTION REPORTING AMONG NURSES AND MIDWIVES IN THE SEKONDI -TAKORADI METROPOLIS

BY

SARAH ESI BILSON

Thesis submitted to the Department of Health, Physical Education and Recreation of the Faculty of Science and Technology Education, College of Education Studies, University of Cape Coast, in partial fulfilment of the requirements for the award of Masters of Philosophy degree in Health Education.

OCTOBER 2023

DECLARATION

Candidate's Declaration

I hereby declare that this thesis is the result of my own original research and that no part of it has been presented for another degree in this university or elsewhere.

Candidate's Signature ……Date ……...

Name: Sarah Esi Bilson

Supervisors' Declaration

We hereby declare that the preparation and presentation of the thesis were supervised in accordance with the guidelines on supervision of thesis laid down by the University of Cape Coast.

Principal Supervisor's Signature ……Date ……....

Name: Prof Joseph Mintah

Co-Supervisor's Signature …… Date ……

Name: Dr. Nancy Ebu Enyan

ABSTRACT

Drugs administered in hospitals for the treatment of diseases can also produce adverse effects in patients. Therefore, health care professionals should monitor and report adverse reactions when they occur to ensure the safety of patients. This study was conducted to assess Sekondi – Takoradi nurses and midwives knowledge and attitude on the ADR reporting system, ADR reporting rate and barriers to ADR reporting. A quantitative descriptive survey design was used to collect in four Government hospitals in the Sekondi-Takoradi Metropolis. A census was employed as the sampling procedure and 529 respondents (328 nurses and 201 midwives) were used. Results from this study revealed that nurses and midwives in the Sekondi-Takoradi Metropolis have moderate knowledge on pharmacovigilance and a negative attitude towards the reporting of adverse drug reaction. ADR reporting among nurses and midwives in the Sekondi-Takoradi Metropolis was low and majority of the respondents had not received training on ADR reporting. The three top perceived barriers by nurses and midwives to ADR reporting were unawareness of the ADR reporting system, not knowing how to fill an ADR form and not receiving feedback after reporting an ADR. The findings of this study suggests that regular training of nurses and midwives on the ADR reporting system is needed to improve ADR reporting and pharmacovigilance.

KEYWORDS

Adverse Drug Reaction (ADR)

Adverse Drug Reaction (ADR) reporting

Midwives

Nurses

Pharmacovigilance

ACKNOWLEDGMENTS

My thanks go to the nurses and midwives in the Sekondi-Takoradi metropolis who participated in my study and everyone who played a vital role in the research process. I also express my gratitude to my supervisors, Professor Joseph Mintah and Dr Nancy Ebu Enyan for their able guidance and direction which led to the success of this work. Additionally, I appreciate all members of the faculty of Department of HPER UCC for their valuable inputs to this study. Again, I would like to appreciate Mrs Pearl Oteng, Mrs Sabina Bilson and Mr Anthony Addiaba for their immense support. To my family and friends, I am truly grateful for your support and encouragement. I am blessed to have you in my corner.

DEDICATION

To my children, Daniella, Jadyn and Sabina Addiaba.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER ONE

INTRODUCTION

Background to the Study

Adverse drug reactions (ADRs) are issues of global concern as they result in diseases, death, and an increase in the economic burden of the medical sector (Coleman & Pontefract, 2016). ADRs are untoward and harmful reactions that occur after taking drugs under normal conditions (WHO, 2002). ADR reporting by health care providers is vital to safeguard the life of patients. Spontaneous reporting of ADRs has led to cases where unsafe drugs have been removed from the market. Serious ADRs are usually noticed when drugs are used in real life situations. The European Commission (2008) attributed 3 - 10% of hospital admissions and 197,000 deaths annually to ADRs. These reactions have led to an increment in the expenses of the health sector. America spends about 30.1 billion dollars yearly on adverse drug reactions (Sultana, Cutroneo, & Gianluca, 2013). It is therefore important that health care professionals spontaneously report ADRs when they occur. ADR is a critical reason for hospitalization and death worldwide (Patel & Patel, 2018).

ADR reporting is one of the activities under pharmacovigilance. Pharmacovigilance is "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem" (WHO, 2002, p. 7). The concept of drug safety monitoring became of international concern when the drug thalidomide caused havoc in 1960s. The drug was administered to pregnant women to reduce morning

sickness; it however led to the birth of babies with fetal abnormalities (WHO, 2002). Subsequently, in 1968, the WHO created a Collaborating Centre for International Drug Monitoring (Uppsala Monitoring Centre or UMC), which became fully functional in 1978. The aim of the UMC is to gather data about adverse effects of medicines from around the globe and to recognize potential harms from drugs in a timely manner (UMC, 2018). The UMC receives ADR reports from member countries. Ghana joined the UMC in 2001. The Ghana Food and Drugs Authority (FDA) coordinates pharmacovigilance activities in the country, providing the necessary information based the UMC requirements.

The FDA receives ADR reports from healthcare professionals working in health care facilities and take regulatory actions where necessary. In 2012, the FDA received 325 adverse drug reaction reports (FDA, 2013). This figure is equivalent to approximately seven ADR reports per 1,000,000 population which falls low below the WHO recommended amount of 200 - 250 ADR report for every 1,000,000 population (FDA, 2015). Over the years, the number of spontaneous reports received by the FDA has increased from the initial 325 reports received in 2012 to 3729 reports in 2018 (FDA, 2019). However, Ghana has still not been able to meet the recommended number; with the population of Ghana being 29.6 million (World Bank, 2019), the 3729 reports received by the FDA is approximately equivalent to 63 reports per 1,000,000.

Several theories and models have been used to study behaviour of health workers in health settings. These theories and models have been useful in explaining behaviour, identifying challenges to behaviour change, and detecting

ways to improve behaviour (Shalviri et al., 2018). For example, the Knowledge, Attitude and Practice (KAP) survey model have been used by researchers to examine ADR reporting and activities of pharmacovigilance Practice. The KAP model helps in identifying barriers to activities or plan programmes. For instance, Amedome and Dadson (2017) used a KAP survey model based on Bennett's change model to assess pharmacovigilance practice among healthcare professionals in the Volta Region of Ghana. Results of their study showed that high knowledge of pharmacovigilance did not correspond to ADR reporting by participants.

Studies have been carried out worldwide to review ADR reporting practices by healthcare professionals. For example, De Angelis et al. (2015) study, involving 570 nurses in Italy found out that nurses were not aware of the ADR reporting system, 11 % of the respondents of the study reported ADRs. Alshammari and Almoslem (2018), examined the knowledge, attitudes, practices of healthcare professionals towards ADR reporting in Saudi Arabia. Findings from the study revealed that 6% of physicians and 26 % of nurses submitted an ADR report although 73% of the healthcare professionals had knowledge on the ADR reporting system in their facility. The low ADR reporting rate was attributed to time constraints, difficulties in completing the ADR reporting form and concerns that the report might be wrong.

In the African context, a study carried out in Nigeria by Oshikoya and Awobusuyi (2009), involving doctors stationed at a teaching hospital, showed that over 50 % of the respondents were not aware of the ADR reporting system and

just 16% of the doctors had reported an ADR. A similar study conducted by Sabblah et al. (2014), to assess ADR reporting among doctors in the capital of Ghana, revealed that more than 90% of the respondents felt they were obligated to report ADRs but only 21% actually reported an ADR. Some of the reasons attributed to under reporting of ADR were unawareness of the ADR reporting system, unavailability of the ADR reporting form and a conviction that the said ADR was a common one.

A recent study in the Volta Regional Hospital of Ghana to assess pharmacovigilance practices among healthcare professionals showed that the healthcare professionals (pharmacists 92.2 %, doctors 88 %, and nurses 78 %) had a high level of awareness of pharmacovigilance (Amedome & Dadson, 2017). However, this did not translate into the reporting of ADR they had encountered during practice. In Ghana, not enough studies have focused on assessing pharmacovigilance practices among nurses and midwives. Even though this group of healthcare professionals spend a lot of time with patients in the clinical setting and as such have a critical role to play in ADR monitoring and reporting.

Statement of the Problem

Studies have shown that there is under reporting of ADR by health care providers worldwide (Hazell & Shakir, 2006; Santosh, Tragulpiankit, Gorsanan, & Edwards, 2013; Toklu et al., 2016; Nisa et al., 2018; Gidey et al., 2020). Data from the VigiBase showed that the ADR reports from Africa amounted to 0.88% of the global reports (Ampadu et al., 2016). In Ghana, research on adverse reporting by doctors revealed recording rates of 20% among doctors in the

Greater Accra Region (Sabblah et al., 2014). Osei (2016), found a 16 % ADR reporting rate among Community Pharmacists in the Greater Accra Region. In 2017, Amedome and Dadson's research in the Volta Region of Ghana showed that healthcare professionals had high awareness on pharmacovigilance but it did not correspond to ADR reporting. Reports from the FDA indicate that the Western Region of Ghana generated the lowest number of ADR reports in 2018 (FDA, 2019).

From the above studies, it appears that not much has been done to assess adverse drug reporting among nurses and midwives even though nurses and midwives in a clinical setting are responsible for administering drugs and monitoring for adverse effects of medications. This study is therefore aimed at assessing ADR reporting practices among nurses and midwives in hospitals within the Sekondi – Takoradi Metropolis.

Purpose of the Study

This study was conducted to assess Sekondi – Takoradi nurses and midwives knowledge and attitude on the ADR reporting system, ADR reporting rate and barriers to ADR reporting

Research Questions

The study was guided by the following research questions:

1. What level of knowledge do nurses and midwives in the Sekondi - Takoradi Metropolis have on pharmacovigilance?
2. What is the attitude of nurses and midwives towards spontaneous ADR reporting in the Sekondi -Takoradi Metropolis?

3. What proportion of nurses and midwives in the Sekondi - Takoradi Metropolis report ADR?
4. What are the barriers to ADR reporting by nurses and midwives in the Sekondi – Takoradi Metropolis?
5. What is the extent to which knowledge, training and demographic characteristics of nurses and midwives predict reporting of ADR in Sekondi – Takoradi Metropolis?

Significance of the Study

The results of the study will provide information on adverse drug reaction reporting rate among nurses and midwives in hospitals in the Sekondi – Takoradi Metropolis. Findings from this study will be beneficial to the FDA of Ghana who coordinates pharmacovigilance activities in the country, the Ghana Health Service and the nursing administration of the four Government Hospitals in the Sekondi – Takoradi Metropolis. This will enable the stated stake holders to improve upon structures and interventions to enhance adverse drug reaction reporting practices of nurses and midwives and ultimately enhance patient safety. Ultimately, the study will augment the strife for the attainment of the sustainable development gaols on health specifically Goal 3: which seeks to ensure healthy lives and promote well-being for all at all ages.

Delimitations

This study was delimited to:

1. Registered General Nurses and midwives working at the four Government Hospitals in the Sekondi Takoradi; Effia-Nkwanta Regional Hospital, Kwesimintsim Hospital, Takoradi Hospital and Essikado Hospital.
2. Adverse drug reaction reports on patients who have been nursed on the ward.

Limitations

A census was used as sampling method for this study. The participants of the study were nurses and midwives. Hence, the researcher was unable to meet them at a particular time and this was a limitation to the study. Data collection was done during the COVID 19 pandemic and as such most hospitals were running a week shift system, making it difficult to reach the participants of the study. Additionally, some of the participants were not at post due to annual leave or study leave. The data collection period was therefore prolonged in a bid to reach majority of the participants of the study.

Definition of Terms

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

A Drug or Medicine - is a pharmaceutical product, used in or on the human body intended for the prevention, diagnosis, or treatment of disease, or for the modification of physiological function. (WHO, 2000).

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

Pharmacovigilance Reporting System - The core data - generating system of pharmacovigilance, relying on health care professionals and patients to identify and report any suspected adverse events from medicines to their local System whereby case reports of adverse drug events are voluntarily submitted from health professionals and pharmaceutical manufactures to the national regulatory authority (WHO, 2002).

Signal - Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. (WHO, 2002)

Spontaneous reporting – is a system whereby case reports of adverse drug events are voluntarily submitted from health professionals and pharmaceutical manufactures to the national regulatory authority (WHO, 2002).

Organization of the Study

The study comprised five chapters. Chapter one provided a background to the study, statement of the problem, purpose of the study, research questions,

significance of the study, delimitations of the study and definition of terms. Chapter two reviewed related literature from empirical and theoretical perspectives. Chapter three focused on the methodology of the study, research design, study population, sampling technique and procedure, sources of data, instrumentation, ethical principles, and methods of data analysis. Chapter four presented the results and discussion of the study. Chapter five focused on summary, conclusions, and recommendations.

CHAPTER TWO

LITERATURE REVIEW

The purpose of this study was to assess Sekondi-Takoradi nurses and midwives knowledge and attitude on the ADR reporting system, ADR reporting rate and barriers to ADR reporting.

This chapter dealt with related literature. Literature for the study was obtained from journals on pharmacovigilance, pharmaceutical research, medicine, and nursing, WHO publications on pharmacovigilance and ADR reporting, as well as FDA publications on pharmacovigilance. Some databases that were accessed include google scholar, Pubmed, research gate and JSTOR. The literature review focused on the types and effects of ADRs, the history and scope of pharmacovigilance (PV), the ADR reporting system, factors affecting ADR reporting, theoretical and conceptual framework of the study.

Adverse Drug Reactions

Adverse drug reactions (ADRs) are untoward and harmful side effects that occur after taking drugs under normal conditions (WHO, 2002). ADRs can occur because of the drug's pharmacological properties, drug interactions, the presence of other diseases or health condition of the patient, errors of drug presentation and administration and inherent anomalies in patient response. However, the causes of some ADR(s) are unknown. An ADR is termed as serious when one of the following occurs: death, hospitalization/prolongation of hospitalization, congenital anomaly/birth defect, persistent or significant disability or incapacity, or a life-threatening condition (Edwards & Aronson, 2000). ADR is a critical

reason for hospitalization and death worldwide (Patel & Patel, 2018). Some ADRs results from unknown causes. There are however four causative factors linked with the development of ADRs. These include pharmacological properties of the drug, inherent anomalies in patient response, comorbidity, and errors in drug presentation and administration (Shibbiru & Tadesse, 2016).

Classification of ADR(s)

Previously, ADRs were classified into only two; Type A and B. These types did not fully cover all the ADRs. Hence, additional classifications have been added. There are six types of ADRs; Type A, B, C, D, E and F (Edwards, & Aronson, 2000; Kaufman, 2016). Type A (Augmented) reactions are frequently drug-related, dose-dependent, and predictable (Schatz & Weber, 2018). They are usually identified before the drug is released unto the market or before it is approved (Iasella, Johnson, & Dunn, 2017). Bleeding after taken a high dose of anticoagulants is an example of a Type A reaction. Type A reactions are generally prevented with care. They are more common than Type B reactions.

Type B (Bizarre) reactions are out of the ordinary and unexpected. Type B reactions are distinct from Type A reactions in that they are not linked to the drug's pharmacological activity or characteristics (Shibbiru & Tadesse, 2016). Type B reactions are rare and usually serious and are also called allergic reactions (Kaufman, 2016; Costa et al., 2018). They might occur as a result of a genetic anomaly of an individual and are unpredictable. Type B reactions are mostly identified after the drug has been released to the general populace; an example is anaphylaxis with the intake of penicillin. Type C (Chronic) reactions are related

to long term treatment; the cumulative dose received by the patient over an extended period tends to be toxic (Rohilla & Yadav, 2013). For instance, an individual can develop analgesic nephropathy after being on NSAIDS (example ibuprofen) for a long time. Type D (Delayed) reactions become evident after using the medication for a while (Rohilla & Yadav, 2013). For instance, Leukopenia can develop six weeks after a patient has taken a dose of Lomustine; a type of chemotherapy drug.

Type E (end of Use) reactions are apparent after a drug is discontinued (Schatz & Weber, 2018). A clear example is when a patient experiences anxiety and insomnia after withdrawal of a benzodiazepine. Type F (failure of efficacy) reactions refer to situations where there is a failure of therapy. It can be as a result of inadequate dosage of the drug, lack of an active ingredient, wrong diagnosis and drug interactions (Edwards & Aronson, 2000). An example is resistance to antimicrobial treatment. The DoTS is another classification system of ADRs based on Dosage of the drug, Timing of the ADR, and the Susceptibility of the patient (Aronson, & Ferner, 2003). The DoTS can enable health workers to understand, envisage and avert the occurrence of ADRs (National Medicines Information Centre, 2019). Table 1 shows the DoTS classification system of ADRs.

Table 1: DoTS Classification System of ADRs

Relation of adverse drug reaction to dose

- Toxic reactions – reactions that occur at supratherapeutic doses
- Collateral reactions – reactions that occur at standard therapeutic doses
- Hyper susceptibility reactions – reactions that occur at subtherapeutic doses in susceptible patients

Timing of ADR

- Time independent reactions - reactions that occur anytime during drug therapy
- Time dependent reactions – There are 6 types; rapid, first dose, early, intermediate, late, and delayed.

Susceptibility – factors include genetics, age, gender, food and drug interactions, pregnancy, medical conditions such as renal and liver diseases.

SOURCE: National Medicines Information Centre, (2019)

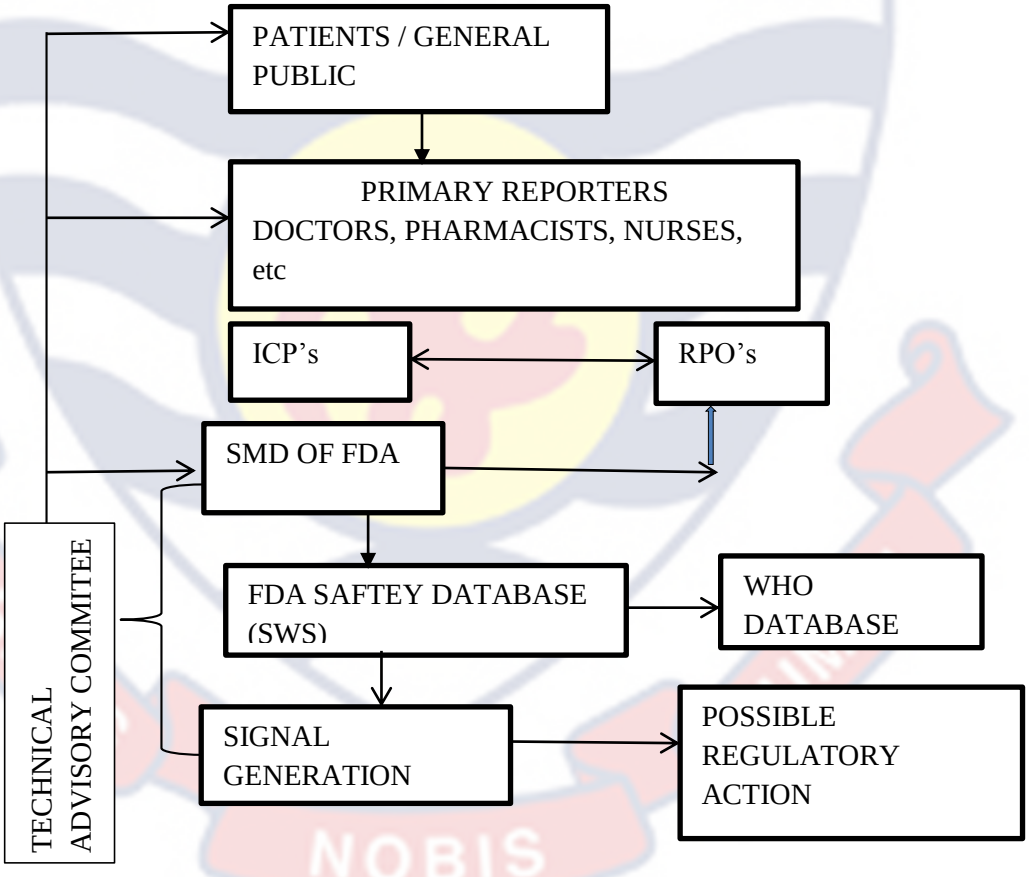
Pharmacovigilance (PV)

Pharmacovigilance (PV) is a combination of the Greek term Pharmakon (drug) and the Latin word Vigilare (watch). PV is "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem" (WHO, 2002, p. 7). The purpose of pharmacovigilance is therefore to reduce risk associated with medicinal products while ensuring patient safety. The scope of pharmacovigilance goes beyond prescribed drugs but include irrational drug use, drug abuse, medication errors, traditional and herbal medicines, lack of efficacy, substandard and counterfeit medicines, blood and blood products, cosmetics, and medical devices.

In the past, ADRs report only became known when clinicians wrote about it in well recognized scientific Journals; now there are electronic registers available (Fornasier, Francescon, Leone, &· Baldo, 2018). The concept of monitoring for the safety of drugs became of international concern when the drug thalidomide caused havoc in 1961. The drug was administered to pregnant women to reduce morning sickness; it however led to the birth of babies with fetal abnormalities (WHO, 2002). Subsequently, in 1962 the US Food and Drug Administration revised the law requiring the proof of safety in addition to quality and efficacy before issuing marketing authorisation (Santosh & Tragulpiankit, 2011; Beninger, 2018). In 1964, the United Kingdom also introduced the Yellow Card system to monitor and report ADRs (Fornasier, Francescon, Leone, &· Baldo, 2018).

Europe response to the thalidomide disaster was the development of a legislation to promote drug safety in 1965 (Permanand, Mossialos, & Mckee, 2006; Fornasier, Francescon, Leone, & Baldo, 2018). A global approach to the thalidomide disaster occurred in 1968 when the WHO created a Collaborating Centre for International Drug Monitoring (Uppsala Monitoring Centre or UMC) which became fully functional in 1978 (WHO, 2002). The aim of the UMC is to gather data about adverse effects of medicines from around the globe and to recognize potential harms from drugs in a timely manner (UMC, 2018). As at 2019, the VigiBase; the WHO global database had received over 20 million reports and there are 136 member countries of the UMC.

Ghana joined the UMC in 2001 and the FDA coordinates pharmacovigilance activities in the country. The Public Health Act, 2012, Act 851, Section – 125 gives the FDA a legal basis for pharmacovigilance (FDA, 2012). The FDA receives ADR reports from healthcare professionals working in health care facilities and take regulatory actions where necessary. There are Institutional contact Persons (ICPs) in almost all the health care facilities. The ICPs forward ADRs reports from health care professionals to FDA through regional Pharmacovigilance officers. Figure 1 below shows the spontaneous ADR reporting system of Ghana.



- ICPs-Institutional Contact Person
- RPOs-Regional PV Officers
- SWS-Safety Watch System
- SMD-Safety Monitoring Department

Figure 1: Spontaneous ADR Reporting System of Ghana (FDA, 2015)

There is an ADR reporting form that is filled by healthcare professionals when they encounter an ADR, see Appendix A for an ADR reporting form. In 2017, the FDA created an online platform where healthcare professionals and patients can report ADR on medication (FDA, 2018). The online system serves as an additional tool to the previous paper-based reporting system and has an added advantage of timely reporting of ADRs and the needed regulatory action. Another electronic tool; the Med Safety Mobile App was launched in 2018 to enhance ADR reporting by the populace (FDA, 2019). The Med Safety APP can be easily downloaded by anyone who has an android phone. It provides an alternative to paper and online reporting tools.

In 2012, the FDA received 325 adverse drug reaction reports (FDA, 2013). This figure is equivalent to approximately 7 ADR reports per 1,000,000 population which falls way below the WHO recommended amount of 200 - 250 ADR report for every 1,000,000 population (FDA, 2015). There has been a rise in spontaneous reports to the FDA, but Ghana has yet to meet the recommended number. Figure 2 below shows ADR reports received by the FDA from 2013 to 2018.

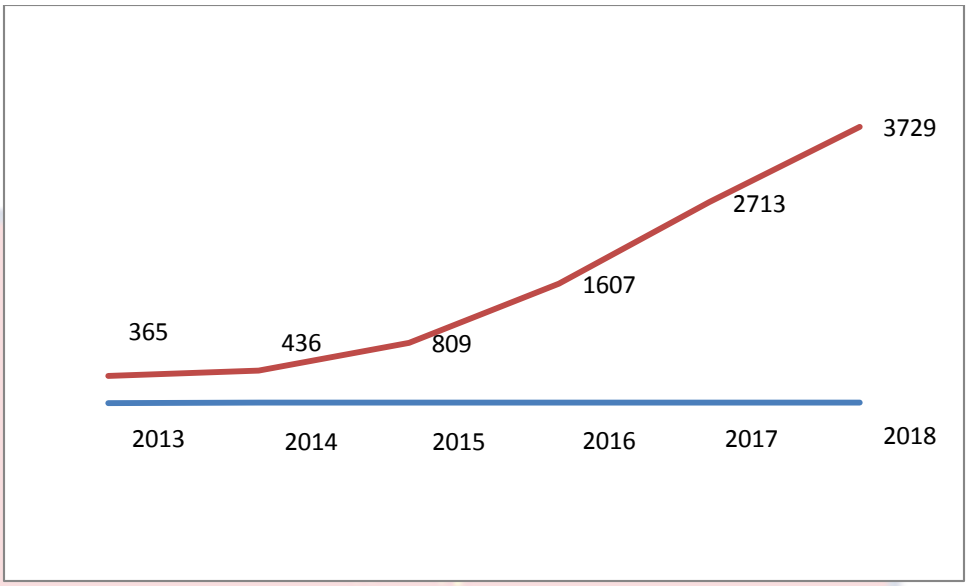


Figure 2: Number of ADR reports received by the FDA from 2013 to 2018 (FDA, 2019)

The FDA received the most reports in 2018 with 3729 (FDA, 2019). This amounts to 63 reports per 1,000,000 which falls below the WHO recommended number of 200 – 250 ADR reports per 1,000,000. In 2018, the Upper West Region of Ghana submitted the highest number of spontaneous ADR reports; 5.6 per 10,000 population while the western Region submitted the lowest number of Spontaneous ADR reports 0.35 per 10,000 population (FDA, 2019).

Reporting of Adverse Drug Reactions

Pharmaceutical companies are required to report ADRs that occur during clinical trials of drugs, however there are some constraints. For instance, the number of patients used for clinical trials are just a handful of the population, the time period for the trial is short, the aged, pregnant women and babies are usually excluded from clinical trials and other treatments are excluded during clinical trials (Gurmesa & Dedefo, 2016).

In contrast, a larger population receives medications in the clinical setting. In addition, some patients take drugs for their whole life time and may also be on other treatments. Furthermore, the drug might be served to pregnant women, geriatric, and pediatric patients. As such there are some serious ADR that can only be noticed when the drug is used in real life. Spontaneous reporting of ADRs by all healthcare workers is therefore vital to keep patients and the entire populace safe. Spontaneous reporting of ADRs is a system in which health practitioners and pharmaceutical companies voluntarily submit reports of adverse drug events to the national regulatory body (WHO, 2002). Spontaneous ADR reporting is considered as an important pillar in pharmacovigilance because it ensures prompt detection of drug related problems (De Angelis et al, 2015). It is also economical when compared to other ways of identifying ADR such as cohort event monitoring and Post-Authorization Safety Studies.

When ADR reports are sent to the National Pharmacovigilance center of a country, a causality assessment is carried on the reports. A causality assessment is a method used to verify if there is a relationship between a drug and an observed ADR (Parida, 2013). The result of the causality assessment enables the FDA to establish a causal link and to take appropriate regulatory action to prevent future occurrence. The WHO-UMC causality Categories of ADR and the Naranjo Probability scale are some of the common causality assessments used. The result of a causality assessment of an ADR report may be described in one of the following terms; Certain, Probable, Possible, Unlikely, Conditional and

Unclassified (UMC, 2018). Table 2 shows the various categories and its corresponding assessment criteria.

Table 2: WHO-UMC Causality Categories

Causality term	Assessment Criteria
Certain	•Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probably/Likely	•Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	•Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	•Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional/unclassified	•Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable/ Unclassifiable	•Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

The Naranjo Probability scale is made up of 10 weighted questions, a total score is given after the assessment. The obtained score reflects the causal

relationship between the ADR and the medication. A score of nine and above indicates that the ADR is certain; five to eight is termed as probable, one to four is termed as possible; and a score of zero shows an unlikely link between the drug and ADR (WHO, 2012). See Appendix B for the Naranjo scale.

ADR Reporting Rate by Healthcare Professionals

Spontaneous reporting of ADR is beneficial; however, there is evidence of under reporting of ADR by healthcare professionals (Santosh, Tragulpiankit, Gorsanan, & Edwards, 2013; Toklu et al., 2016). Some studies have shown an ADR reporting rate of between 3 to 8 % among nurses (Hanafi et al., 2012; Vural, Ciftc, & Vural, 2014). In Ghana, research on adverse reporting by doctors revealed recording rates of 20% among physicians in the capital of Ghana (Sabblah et al., 2014). According to Osei (2016), Community Pharmacists in the Greater Accra Region had a 16 % ADR reporting rate. Amedome and Dadson (2017), discovered an ADR reporting rate of 16.7% and 24% among doctors and the nurses, respectively.

Knowledge on the ADR Reporting System and Reporting of ADR by healthcare Professionals

Studies have shown that there seems to be a relationship between healthcare workers knowledge on the ADR reporting system and PV practices. For example, De Angelis et al. (2015) study, involving 570 nurses in Italy found out that 58 % of nurses were unfamiliar with the ADR reporting system and 70% of them did not know how to fill an ADR reporting form. Their level of knowledge influenced their practice as only 11 % of the respondents of the study reported ADRs. Gurmesa and Dedefo (2016)'s study investigated factors that

affect ADR reporting among healthcare professionals (19 doctors, 70 nurses, 25 health officers and 19 pharmacists) in Ethiopia. This study revealed that unawareness of the pharmacovigilance system (41 %) was a key factor that discouraged ADR reporting by healthcare professionals. Amin et al (2016)'s study involving Bangladesh's community pharmacists (203) revealed that more than 50% had no knowledge on the PV system. Although the community pharmacist (98.1%) had knowledge that ADR reporting improved drug safety, none of them reported ADRs they encountered (Amin et al., 2016).

Nisa, Zafar, and Sher (2018) assessed ADR reporting among 333 physicians and 34 pharmacists in hospitals in Pakistan's capital. Most respondents (83%) had limited knowledge of the ADR reporting system, which led to underreporting (11.7 %). In an Indian study on the knowledge and attitude of nurses towards reporting adverse drug reactions, 40% of respondents were unaware they were obligated to report ADRs (Ahsan, & Mallick, 2017). In contrast, there are some studies which have shown that a good knowledge or awareness in the ADR reporting system does not necessarily translate into the practice of ADR reporting. For instance, Amedome and Dadson (2017), study in the Volta Regional Hospital of Ghana to assess pharmacovigilance practices among healthcare professionals showed that the healthcare professionals (pharmacists 92.2 %, doctors 88 %, and nurses 78 %) had a high level of awareness of pharmacovigilance. However, the study revealed a low ADR reporting rate of 16.7% and 24% respectively among doctors and the nurses.

In addition, Bahekar and Patil (2018) study, evaluated the knowledge, attitude, and practice of ADR reporting among doctors and nurses in a tertiary care teaching hospital in India. Findings from the study showed that although doctors had more knowledge on PV and ADR reporting system than nurses; only about 50% of the doctors reported ADR encountered. Some healthcare professionals have had the opportunity to partake in training workshops on PV and ADR reporting while others have not. This could be the reason for the discrepancies in knowledge level on ADR reporting among healthcare professionals. Notwithstanding, knowledge on the ADR reporting system seems to be a key factor affecting ADR reporting. A healthcare professional will require adequate knowledge on ADR reporting to know what to report and how to report.

Attitude of Healthcare Professionals towards ADR Reporting

The attitude of healthcare professionals is a factor that influences ADR reporting. Professional obligation to report ADRs is one of the attitudes which affect the reporting of ADRs. For instance, a study that was conducted by Hanafi et al. (2012), revealed that 82% of nurses did not consider ADR reporting as their professional obligation. Findings from Toklu et al., (2016) study, revealed that pharmacists and nurses did not see ADR reporting as a natural part of their jobs. Doctors usually prescribe medications so some nurses might feel that it is the responsibility of doctors to report ADR when they occur. For instance, 87% of nurses reported ADRs to doctors and did not report it through the ADR reporting system (Hanafi et al., 2012).

Additionally, lack of time is one of the negative attitudes that affect the reporting of ADRs. Chopra, Wardhan and Rehan (2011), study assessed doctors' knowledge, attitudes, and practices in relation to ADR reporting. According to the findings, 20% of doctors attributed their inability to report ADRs to lack of time. Toklu et al. (2016) studied Northern Cyprus healthcare professionals' knowledge of pharmacovigilance and ADR reporting. The study showed that 34.6% doctors and 41.8% nurses who were part of the studies attributed underreporting of ADRs to lack of time. A study carried out in the Volta Region of Ghana also revealed that time constraints was one of the primary factors discouraging over 60 percent of physicians and nurses from reporting adverse drug reactions (Amedome & Dadson, 2017). Similar studies carried out in India revealed that lack of time was seen as a factor that prevented 70% of the nurses from reporting ADRs, and 60% of nurses considered ADR reporting as time consuming activity (Ahsan & Mallick, 2017; Rajalakshmi et al., 2017).

Factors that predict ADR Reporting

Studies have shown that factors such knowledge, training on ADR reporting and demographic characteristics of health care professionals predict ADR reporting. Gidey, et al. (2020) studied Ethiopian healthcare professional's knowledge, attitude and practice of adverse drug reactions reporting. The study showed that knowledge on ADR reporting, training on ADR reporting and years of experience of health workers predict ADR reporting. Similar studies carried out in Uganda revealed that there is significant association between age and years of experience and ADR reporting (Katusiime, Semakula, & Lubinga, 2015).

Barriers to ADR Reporting

It can be clearly seen that some barriers to ADR reporting include Knowledge on the ADR reporting system and attitude of healthcare professionals towards ADR reporting. Another factor that serves as a barrier to ADR reporting is unavailability of reporting forms. Chopra, Wardhan and Rehan (2011) showed that lack of reporting forms (20%) was a contributing factor to under reporting. The intent of study was to assess the knowledge, attitudes, and reporting behaviors of clinicians in India's teaching hospitals about ADRs. Sabblah et al. (2014) carried out a study to determine the ADR reporting rate by doctors in the capital of Ghana. The survey found that 43% of respondents attributed their inability to report ADRs to unavailability of reporting forms. Agbeko (2016) investigated the knowledge, attitudes, and practice of pharmacovigilance among hospital pharmacists (95) in Ashanti Region of Ghana. The study revealed that unavailability of reporting forms (35%) was one of the reasons why some respondents did not report ADRs. The unavailability of forms reported from these studies could indicate that the health facilities lacked a robust PV system or the healthcare workers were not sensitized on the PV system present in their facilities

Theoretical Framework

This study's theoretical foundation was derived from elements of Bennett's Hierarchy Logic Model (Bennett, 1975). Claude Bennett developed the model to plan and evaluate extension programs. The model is made up of seven stages that occur in sequence: inputs, activities, participation, reaction, knowledge, attitude, skills, aspirations (KASA), practice change and End results (Bennett, 1975).

Inputs referred to the resources needed for the program; it includes funds, human resource, and time (Radharkrishina & Bowen, 2010). Per the activities, the next stage involves the doings of the program such as training, demonstration, meetings, the use of mass media and correspondence (Bennet, 1975; Onkka, 2018; Radharkrishina & Bowen, 2010). The participation level describes the people involved in the programme and the frequency of the programme. Reaction is the fourth stage; it describes the participant's reaction to the programme. The fifth stage is KASA change; here there are changes in participants' knowledge, attitude, skill, and aspiration. These changes pave way for the next stage in the hierarchy. The practice change stage is the sixth change. This study's theoretical framework was mainly based on the KASA change stage (knowledge and attitude) and the practice change stage. As a result of the KASA change people who were involved in the program now adopt a new practice or behaviour. The final stage is the result. The practice change of participants of the program should have a positive impact on the society (Onkka, 2018).

Conceptual Framework

The conceptual framework of this study was adapted from Amedome and Dadson (2017) study. It was based on Bennett's change model. Figure 3 depicts the conceptual framework for this study. The conceptual framework shows that a healthcare professional requires good knowledge and a positive attitude towards pharmacovigilance (PV) to be able to practice the reporting ADRs. This implies that a nurse or midwife must have knowledge of the PV system of the country; they must be aware and know how to use and access the PV tools such as ADR

reporting form and online reporting platform to be able to report ADRs. This knowledge is obtained from PV sensitization and training. Again, a nurse or midwife who monitors patients for ADRs and can identify ADRs will be able to report ADRs. In addition, the nurse or midwife should have a positive attitude towards ADR reporting to spontaneously report ADRs. The ability to perceive that every report can help improve patient safety and accept that reporting ADRs is a professional obligation are key components of a positive attitude toward ADR reporting

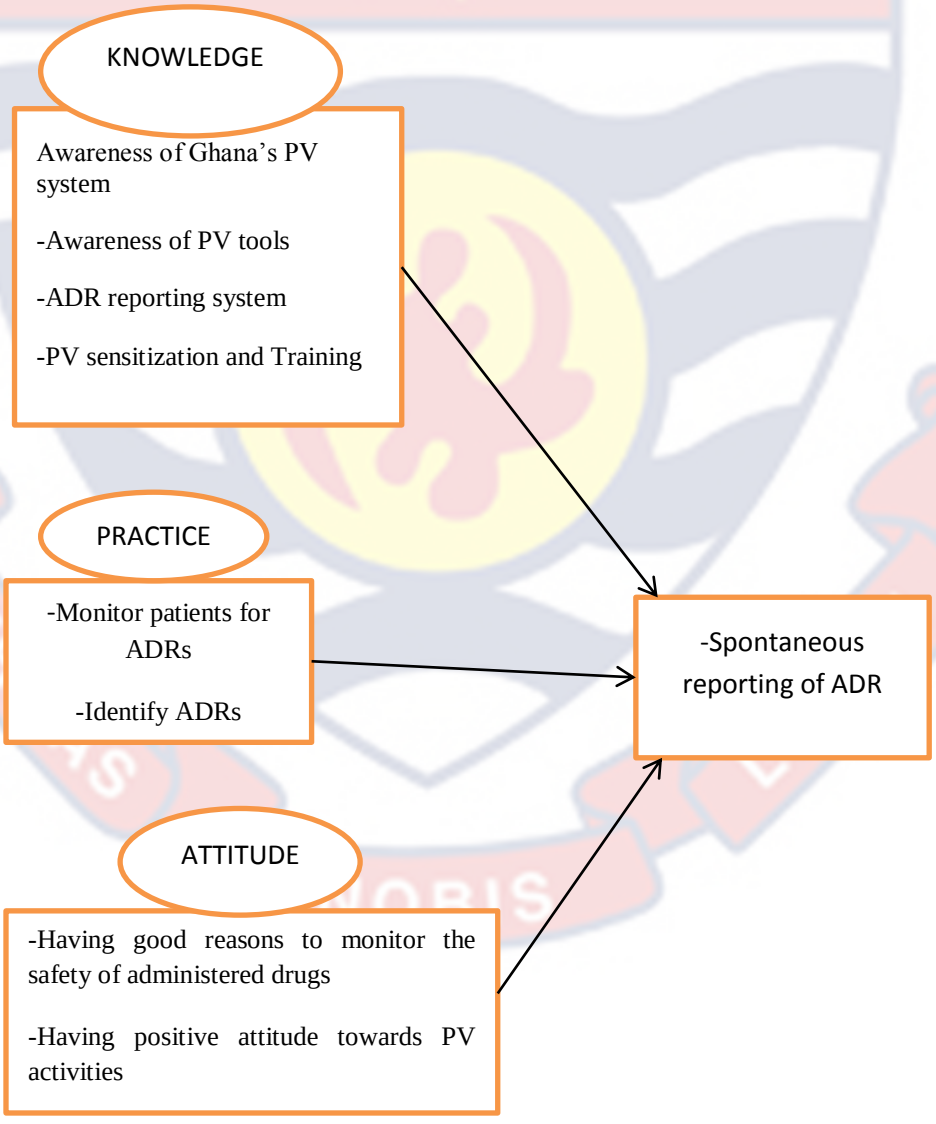


Figure 3: Conceptual framework for the study (Amedome & Dadson, 2017).

Summary

This chapter reviewed related literature on pharmacovigilance, the knowledge and attitude of Healthcare professionals towards ADR reporting, ADR reporting practices and the barriers to ADR reporting. The conceptual framework which was based on the Bennett's change model was adapted from Amedome and Dadson (2017). Overall, this chapter literature provided an adequate literature review and showed the importance of the current study.

CHAPTER THREE

RESEARCH METHODOLOGY

This study sought to assess Sekondi – Takoradi nurses and midwives knowledge and attitude on the ADR reporting system, ADR reporting rate and barriers to ADR reporting. This chapter was organized under the following headings: research design, population, sampling procedure, data collection instrument, data collection procedures and data processing and analysis.

Research Design

A quantitative descriptive survey design was used to assess adverse drug reaction reporting practices among nurses and midwives in the four Government Hospitals in Sekondi-Takoradi Metropolis. This design enables the researcher to describe a population, situation, or phenomenon that is being studied and it employs survey as a means of data collection. An advantage of descriptive survey is that it provides sufficient information on the population under study (Fox & Bayat, 2007). Furthermore, it can serve as a basis for further research. A descriptive survey, on the other hand makes it difficult to demonstrate a cause-and-effect relationship.

Study Area

The study was conducted at the four Government Hospitals in the Sekondi-Takoradi metropolis of the Western Region. The Western Region was chosen for the study because it reported the lowest number ADRs per 10,000 in 2018 (FDA, 2019). The four Government Hospitals used were; Effia-Nkwanta Regional Hospital, Takoradi Government Hospital, Kwesimintsim Government

Hospital and Essikado Government Hospital. These hospitals are the main health facilities which serve the Sekondi-Takoradi Metropolis and thus were chosen for the study. The Sekondi-Takoradi Metropolis is situated at the south-eastern part of the Western Region. The Ahanta-West District borders on the west, and the Shama District borders on the east of the metropolis. The Atlantic Ocean lies to the south of the Metropolis and to the north lies Wassa East.

The land size coverage is 191.7 km^2. Sekondi-Takoradi is the region's most urbanized district (Ghana Statistical Service, 2012). The population of Sekondi-Takoradi Metropolis is 559,548 which constitute 23% of the region's total population. (Ghana Statistical Service, 2012). The Effia-Nkwanta Regional Hospital was founded in 1938 as a military hospital by the then-Takoradi-based British West African Royal Force. After the Second World War, it was handed over to the British Colonial Administration in 1945. The hospital has been developed over the years to its present state. ENRH is located on a land which is about 202 hectares and it is about 500 hectares from the sea. It has a bed compliment of 329 and staff strength of about 849 (ENRH, 2019).

The Takoradi Government hospital also known as European Hospital was built in 1929 to provide medical care for the Europeans who were in Gold Coast to construct the Takoradi Harbour. Currently, it is a district hospital and is managed by Ghana Health Service, the hospital has a staff strength of 344 and has a bed state of 86. (Takoradi Government Hospital, 2019).

The Essikado Government hospital was established in 1964. It is a district hospital located within the Essikado-Ketan Constituency and serves Essikado and

its surrounding communities such as Kojokrom, Ngyiresia, Mpintsin, Sofokrom, Essipong, Inchaban and Ahinkofi. The hospital renders services to an estimated number of 82,200 people. It has a bed state of 55 and a staff strength of 325 (Essikado Government Hospital, 2019).

The Kwesimintsim Government Hospital was established in 1977 as a polyclinic. It was upgraded to a hospital in 2000 for the Effia-Kwesimintsim Municipal Assembly serving an estimated population of 58,030. In addition, it serves communities from Ahanta West, Mpohor, Wassa East and Tarkwa-Nsuaem. The Kwesimintsim Hospital has six wards with a bed compliment of 77 and staff strength of 463. (Kwesimintsim Government Hospital, 2019).

Population

This study was designed to cover Registered General Nurses and Midwives stationed at Effia Nkwanta Regional Hospital, Takoradi Government Hospital, Essikado Government Hospital and Kwesimintsim Government Hospital. The inclusion criteria for the study were Registered General Nurses and Midwives who meet the following criteria:

- A Registered General Nurse or Midwife that has clinically practiced continuously for not less than a year at the time of the study.
- Registered General Nurse or Midwife that directly interacts with patients in relation to medicine use and is in a position to detect and report ADRs.

The exclusion criteria for the study were based on the following:

- A Registered General Nurse or Midwife that has not clinically practiced continuously for up to a year in his or her profession.

- A Registered General Nurse or Midwife who is on study or maternity leave.

Table 3 shows the various hospitals with its corresponding number of Registered General Nurses and Midwives.

Table 3: Hospitals with Corresponding Registered General Nurses and Midwives

Hospital	Nurses	Midwives	Total
Effia Nkwanta Regional Hospital	141	107	248
Takoradi Hospital	44	32	76
Kwesimintsim Hospital	87	36	123
Essikado Hospital	74	61	135
Total	346	236	582

SOURCE: Effia Nkwanta Regional Hospital, 2019; Essikado Government Hospital, 2019, Kwesimntitsim, 2019¸ Takoradi Government Hospital, 2019.

The population of nurses and midwives in the four Government Hospitals was 582.

Sampling Procedure

This study used a census. A census method uses everyone in the population It was appropriate to use a census because the respondents for the study were easily identified and reached (Cantwell, 2008). In addition, data from census could be used as a yardstick for further studies.

Data Collection Instrument

A researcher generated questionnaire was used to collect data. It was constructed using items from similar previous studies on the knowledge, attitudes and practices of healthcare professionals on ADR reporting (Lohit, Vidya, &

Manjunath, 2016; Nisa, Zafar, & Sher, 2018; Haines, Meyer, Summers, & Godman, 2020). The questionnaire was made of 40 items and was organised into five sections. Section A (items 1-5) was on the demographic data of participants (gender, age, specialty, and years of practice), Section B included 12 items and focused on the knowledge on pharmacovigilance and ADR reporting. It elicited information on the definition, scope, and purpose of pharmacovigilance and the ADR reporting system of Ghana. Section C was on attitude of nurses and midwives towards ADR reporting and a five-point Likert scale was used to measure these eight items. Section D comprising six items elicited information on the practice of ADR reporting. Section E focused on barriers to ADR reporting and it had nine items. See Appendix B for the questionnaire.

Validity and reliability of the instrument

The instrument was pretested at SDA hospital in Takoradi using 30 nurses and midwives, prior to the commencement of the main study to test the validity and reliability of the instrument. The SDA Hospital was used as the site for pretesting because it had similar characteristics with the study area. Additionally, the Registered General Nurses and Midwives have received the same standard of training as their counterpart in the government Hospital. Reliability of Section A and C of the instrument used for data collection was checked with Cronbach Alpha, a reliability value of was 0.72 was obtained indicating that the items on the questionnaire were highly reliable. With items in section B, D and E the individual items were assessed by the researcher's supervisors and experts reviewing the entire questions to ensure that each one of the questions target the

exact characteristics that the instrument was designed to cover. The questions therefore were taken through processes to compare it against the goals of the study and the theoretical properties of the construct. At the end of these processes parts B, D and E of the questionnaire was also found to be reliable.

Data Collection Procedure

Prior to commencing the entire data collection procedure, approval was given from the Institutional Review Board of the University of Cape Coast (UCCIRB/CES/2021/01). An Introductory letter was also obtained from the Department of Health, Physical Education and Recreation to gain permission from the nursing administration of the four hospitals used for the study. Furthermore, to obtain permission from the nursing administration of the four hospitals used for the study, an introductory letter was obtained from the Department of Health, Physical Education, and Recreation. Data was collected over a two-month period, from April 1st to June 1st, 2021. Two trained research assistants helped with data collection. The nurses and midwives were identified, an informed consent was obtained and then the questionnaire was administered to them at the nurse's station.

Questionnaires which were completed on time by participants were retrieved on the spot whereas those who were occupied at the time had their questionnaires collected two days later. To safeguard participants' confidentiality, they were not obliged to indicate their identities. A few challenges were encountered during the data collection process. As a result of the COVID pandemic, nurses and midwives were running a one-week shift system and as

such the research team had to make several visits to the hospitals to be able to effectively collect data.

Data Processing and Analysis

The data were analysed using the Statistical package for Social Sciences (SPSS) version 20.0. Research question one (What level of knowledge do nurses and midwives in the Sekondi -Takoradi Metropolis have on pharmacovigilance?) was analysed using frequencies and percentages. In this study, knowledge of participants on pharmacovigilance and ADR reporting was assessed using 12 questions. Each correct answer had a score of 1 and each wrong answer had a score of 0. The maximum possible score a participant could obtain was 12. A composite score percentage was used for categorization of knowledge. It was calculated by taking each person's score, dividing it by the highest possible score, and then multiplying that result by 100. The composite score was divided into three groups. A composite score of more than 66% was considered as high knowledge, 34 to 66% was considered as moderate knowledge while a component score of less than 34% was considered as poor knowledge (Lohit, Vidya, & Manjunath, 2016).

Research question two (What is the attitude of nurses and midwives towards spontaneous ADR reporting?) was analysed using frequencies and percentages. The attitude of participants towards ADR reporting was assessed using 8 items with 5-points Likert scale response option. The positive statements received ranked scores as follows: a score of 5 for ‘strongly agree’, a score of 4 for ‘agree’, a score of 3 for ‘not sure’, a score of 2 for ‘disagree’, and a score of 1

for 'strongly disagree'. Reversed scoring was used for negative statements. The maximum obtainable score was 40. A composite score with two groups was used for categorization of attitude. A composite score of more than 80% was considered as positive attitude while a composite score of less than 80% was seen as negative attitude (Adisa & Omitogun, 2019).

Research question three (What proportion of nurses and midwives in the Sekondi -Takoradi Metropolis report ADR?) was analysed using frequencies and percentages. Research question four (What are the barriers to ADR reporting by nurses and midwives in the Sekondi – Takoradi Metropolis?) was analysed using frequencies and percentages. Research question five (What is the extent to which knowledge, training and demographic characteristics of nurses and midwives predict reporting of ADR in Sekondi –Takoradi Metropolis?) was analysed using multiple regression. The dependent variable was ADR reporting while the independent variables were knowledge and training on ADR reporting and the demographic characteristics of the participants.

CHAPTER FOUR

RESULTS AND DISCUSSION

This study was undertaken to assess Sekondi – Takoradi nurses and midwives knowledge and attitude on the ADR reporting system, ADR reporting rate and barriers to ADR reporting. A quantitative descriptive survey design was used for this study and a census was employed as the sampling method. The results and discussion are presented in this chapter.

As presented in Table 4, a total of 529 (328 nurses and 201 midwives) took part in the study. Most of the respondents were females 386 (73%) while the males 143 (27%) were in the minority. Majority of the respondents 336 (63.5%) fell within the age range of 20 to 30, the rest within the age range of 31 – 40 (158, 29.9%) and 41 to 50 (35, 6.6%). Regarding years of practice, 444 (83.3%) had worked below 10 years, while 74 (14%) had worked for 11 to 20 years, 4 (0.85%) had worked for 21 to 30 years and 7 (1.3%) had worked for above 30 years.

Table 4: Demographic Characteristics of the Respondents

Demographic Characteristics	Frequency	Percentage (%)
Gender		
Male	143	27
Female	386	73
Age distribution		
20 – 30	336	63.5
31- 40	158	29.9
41- 50	35	6.6
Distribution of health care professionals		
Nurses	328	62
Midwives	201	38
Years of Practice		
Below 10	444	83.9
11 – 20	74	14
21 – 30	4	0.8
Above 30	7	1.3

SOURCE: Field Data, Bilson (2022)

Research Question One: What level of knowledge do nurses and midwives in the Sekondi -Takoradi Metropolis have on pharmacovigilance?

The purpose of this research question was to assess nurses and midwives' knowledge on pharmacovigilance. Analysis of this question was done using frequencies and percentages. Twelve items elicited information on

pharmacovigilance. Each correct answer had a score of one (1) and each wrong answer had a score of zero (0). A composite score percentage was used for categorization of knowledge. The composite score was divided into three groups. A composite score of more than 66% was considered as high knowledge, while a score of 34 to 66% and a score of less than 34% was considered as moderate knowledge and low knowledge respectively.

Frequency data on participants' responses showed that 213 (40.3 %) of the respondents gave the correct definition of pharmacovigilance and 285 (53. 9%) of them also chose the correct definition of ADR. More than half of the respondents 333 (62. 9%) knew the main purpose of pharmacovigilance. Only 263 (49.7 %) of the respondents knew that the FDA was the institution responsible for receiving and taking regulatory action of ADR reports in Ghana.

On the types of ADRs to report, majority of the respondents 336 (63.5 %) answered that all ADRs should be reported while 130 (24.6%) of them said only serious ADR should be reported. Most 418 (79%) of the respondents rightly chose that patients and health care professionals can report an ADR. With the modes of reporting ADR in Ghana, just about half of the participants 271 (51. 2%) chose ADR reporting form, while 20 (3.8%) of them chose the online reporting form, 10 (1.9%) picked the med safety App and 160 (30.2 %) picked the 'all of the above' option which referred to ADR reporting form, online reporting form and med safety App.

On the Types of ADRs, only 146 (27.6%) of the respondents knew the types of ADR. With regards to major risk factor for the occurrence of maximum

adverse drug reactions only 181 (34.2%) participants chose the correct option which was renal failure. On the item on constituents of a serious adverse reaction; just around half 281 (53%) of the participants answered correctly that birth defects, prolonged hospitalization, disability, and death were all serious ADRs. Regarding the statement "All ADRs are known before a medicine is marketed," 231 (43. 7 %) of the participants appropriately responded no. The last item on knowledge was on the presence of an institutional contact person for pharmacovigilance in the hospital. Just about half 295 (55.8%) of the nurses and midwives correctly reported Yes. Overall, the composite score percentage for knowledge for nurses and midwives in the Sekondi-Takoradi Metropolis was 49.5%, which depicts that they have moderate knowledge on pharmacovigilance. Table 6 shows the knowledge level of participants on pharmacovigilance.

Table 5: Knowledge Level of Participants on Pharmacovigilance (N = 529)

Items on knowledge	Correct responses	Number	Percentage %
What is pharmacovigilance?	The detection, assessment, understanding and prevention of adverse effects	213	40.3
Which of the following defines an Adverse Drug Reaction (ADR) correctly?	Noxious and unintended response to drug and occurs at doses normally used in man or animal for prophylaxis, diagnosis, or therapy of disease	285	53.9
What is the main purpose of pharmacovigilance?	Improve patient care and safety in relation to medicine use	333	62.9
Which institution in Ghana receives ADR reports and takes regulatory action where necessary?	Food and Drugs board	263	49.7
Which type of ADR should be reported?	All ADRs	336	63.5
Who can report an ADR?	All the above	418	79
What are the modes of reporting an ADR in Ghana?	All the above	160	30.2
Identify the types of ADR's	Type A, B, C, D, E, and F	146	27.6
Which of the following is a major risk factor for the occurrence of maximum adverse drug reactions?	Renal failure	181	34.2
Which of the following constitutes a serious adverse reaction?	All of the above	281	53.1
All ADRs are known before a medicine is marketed.	N0	231	43.7
Does your hospital have an institutional contact person for pharmacovigilance?	Yes	295	55.8
Average % of correct response = 49. 53%			

SOURCE: Field Data, Bilson (2022)

For a healthcare professional to appropriately report an ADR there is a need for adequate knowledge on ADR reporting process and pharmacovigilance.

Findings from this study showed that nurses and midwives in the Sekondi-Takoradi have a moderate knowledge (49.5%) on pharmacovigilance. One possible reason for this finding could be that, some of the participants might have received training on pharmacovigilance. Additionally, pharmacovigilance as a course was added to the nursing and midwifery curriculum in 2015; as such participants of the study who completed their education before the said year might have a knowledge gap on pharmacovigilance.

The findings of this research are consistent with other studies that showed fair or moderate knowledge among healthcare workers (Katusiime, Semakula, & Lubinga, 2015; Alwhaibi & Al Aloola, 2020). In contrast, other studies showed that healthcare workers had a high knowledge on pharmacovigilance (Amedome & Dadson, 2017; Bahekar & Patil, 2018; Hussain et al., 2021). Yet, other studies have revealed a low level of knowledge among health care workers (Suyagh, Farah, & Farha, 2015: Nisa, Zafar, & Sher 2018; Prashar, Jere & Kalungia, 2019). The differences in the knowledge levels among health workers could be as a result of the varied levels of categorization used in assessing knowledge. In addition, some healthcare workers might have received training on pharmacovigilance hence the different knowledge levels.

Research Question Two: What is the Attitude of Nurses and Midwives towards Spontaneous ADR Reporting in the Sekondi – Takoradi Metropolis?

A five-point Likert scale was used to assess participant's attitude towards spontaneous ADR reporting. This question was analysed using frequencies and percentages. The positive statements received ranked scores as follows; a score of 5 for 'strongly agree', a score of 4 for 'agree', a score of 3 for 'not sure', a score

of 2 for 'disagree', and a score of 1 for 'strongly disagree'. Reversed scoring was used for negative statements. A composite score with two groups was used for categorization of attitude. A composite score of more than 80% was considered as positive attitude while a composite score of less than 80% was seen as negative attitude. Table 6 below shows the attitude of nurses and midwives towards ADR reporting.

Table 6: Attitude of Nurses and Midwives towards ADR Reporting (N = 529)

Attitude related items	Strongly agree N (%)	Agree N (%)	Not sure N (%)	Disagree N (%)	Strongly disagree N (%)
ADR reporting is a professional obligation	252 (47.6)	187 (35.3)	25 (4.7)	36 (6.8)	29 (5.5)
ADR reporting in the hospital by healthcare professionals should be voluntary	83 (15.7)	192 (36.3)	28 (5.3)	147 (27.8)	79 (14.9)
ADR reporting should be mandatory for all healthcare professionals	256 (48.4)	142 (26.8)	31 (5.9)	86 (16.3)	14 (2.6)
ADR reporting by one person can make a significant difference to the community	219 (41.4)	172 (32.5)	85 (16.1)	41 (7.8)	12 (2.3)
ADR reporting creates additional workload	70 (13.2)	100 (30.2)	124(23.4)	124(23.4)	51 (9.6)
ADR reporting is time consuming	68 (12.9)	151 (28.5)	98 (18.5)	146 (27.6)	66 (12.5)
ADR reporting in the hospital should be financially rewarded	157 (29.7)	141 (26.7)	45 (8.5)	128 (24.2)	58 (11)
I am willing to implement ADR reporting in my practice	217 (41)	207 (39.1)	45 (8.5)	23 (4.3)	37 (7.0)

SOURCE: Field Data, Bilson (2022)

About the statement that ADR reporting is a professional obligation, 252 (47.6%) of the respondents strongly agreed that ADR reporting is a professional obligation while 187 (35.3%) of the participants agreed to this statement. Just 25 (4.7%) of them were not sure that ADR reporting is a professional obligation. On the contrary, 36 (6.8%) of the nurses and midwives disagreed that ADR reporting is a professional obligation while 29 (5.5%) strongly disagreed that ADR reporting is a professional obligation.

Almost half of the respondents 256, (48.4 %), strongly agreed that ADR reporting by healthcare should be mandatory. Additionally, 142 (26.8 %) respondents agreed on mandatory reporting of ADR and 31 (5.9%) of them were not sure on mandatory reporting of ADR. Conversely, 86 (16.3%) and 14 (16.3%) participants of the study disagreed and strongly disagreed respectively on mandatory reporting of ADR by healthcare professionals. Regarding the statement that ADR reporting by one person can bring a significant difference to the community; almost half of the participants 219 (41.4%) of the study strongly agreed while 172, (32.5%) agreed. 85 (16.1%) of the participants were unsure of the significance of the ADR report by one person. However, just a few of the respondents had an opposing view on the significance of ADR reporting by one person; 41(7.8%) and 12 (2.3%) disagreed and strongly disagreed, respectively.

On ADR reporting creating additional workload, 70 (13.2%) of the participants agreed to this statement while 160 (30%) of them strongly agreed. 124 (23.4%) of them did not take a stand on this statement while 124 (23.4%) and 51 (9.6%) disagreed and strongly disagreed respectively that ADR reporting creates an

additional workload. On ADR reporting being time consuming, 68 (12.9%) and 151 (28.5%) of the participants of the study strongly agreed and agreed respectively to this assertion. The data showed that less than half of the respondents opposed this view as 146 (27.6%) and 66 (12.5%) of them disagreed and strongly disagreed respectively that ADR reporting was not time consuming. More than half of the respondents mentioned that they were willing to report ADR as 217 (41.0%) and 201 (39.1%) of them strongly agreed and agreed respectively to the statement that they were willing to report ADR in their practice. Less than 12% of the respondent were not willing to report ADR as 23 (4.3%) and 37 (7%) of them disagreed and strongly disagreed respectively to the statement that they were willing to report ADR in the practice.

Data from this study revealed that 58.4% of the participants had a positive attitude towards ADR reporting while 41.6% of them had a negative attitude towards ADR reporting. In general, the attitude of nurses and midwives in this study towards ADR reporting was negative as the data showed a composite score of 58.4% which is below the 80% mark. A possible reason for this finding could be that the categorization for positive knowledge used in this study was high.

The finding of this study on attitude is congruent to a study carried by Adisa and Omitogun, (2019), where most of the participants held a negative attitude towards ADR reporting. Other studies have also exhibited a negative attitude of healthcare personnel toward ADR reporting (Gurmesa & Dedefo, 2016). However, other studies showed that healthcare personnel had a favourable attitude toward the reporting of adverse drug reactions (Amedome & Dadson,

2017; Alwhaibi et al., 2021). A positive attitude towards ADR reporting could enhance ADR reporting.

Although the general attitude of nurses and midwives in this study was negative, there were some encouraging attitudes exhibited by participants of this study. This current study revealed that most 439, (83%) of the nurses and midwives in the Sekondi-Takoradi metropolis felt that ADR reporting was their professional obligation. This finding is in line with studies carried out in Kuwait, Nigeria, and Pakistan where healthcare professionals saw ADR reporting as their professional obligation (Lemay et al., 2017; Hussain et al., 2021). Another encouraging attitude among nurses and midwives in this study was their view that a single ADR report was significant (391, 73.9%). This is consistent with a study on knowledge and attitude of nurses on ADR reporting by Ahsan and Mallick (2017).

Research Question Three: What Proportion of Nurses and Midwives in the Sekondi -Takoradi Metropolis Report ADR?

The purpose of this question was to determine the proportion of nurses and midwives who reported ADRs they had encountered through the appropriate channel. The analysis of the data involved the use of frequencies and percentages. The data revealed that more than half of the respondents had encountered ADRs in clinical practice in the last 12 months; 321 (60.7%) of them made this assertion while 208 (39.3%) of the participants had not encountered an ADR in the last 12 months of their practice.

On ADR reporting, 273 (51.6%) of the respondents said they had reported an ADR before, while the rest (256, 48.4%) responded in the negative. Most of them (316, 59.7%) reported to the nurse in charge, 90 (17.0%) of them reported to the physician in charge while 80 (15.1%) documented the ADR in the nurses note. It was however noticed that only 43 (8.1%) of them reported through the appropriate means by using an ADR reporting form. It can therefore be said that ADR reporting among nurses and midwives in the Sekondi Takoradi metropolis is low. Figure 4 shows how participants responded to an ADR.

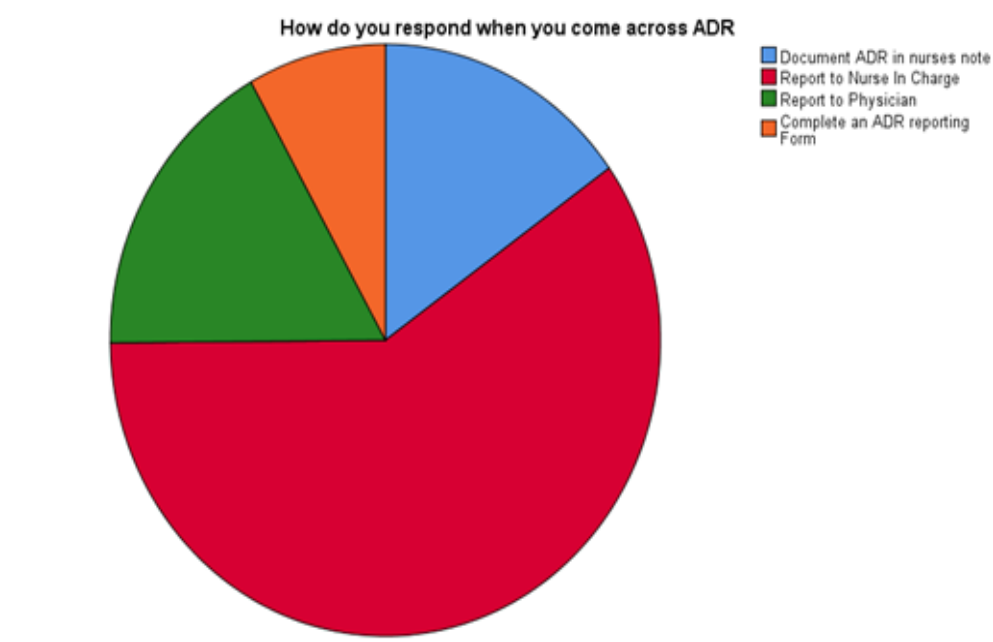


Figure 4: Response to ADR by Nurses and Midwives
SOURCE: Field Data, Bilson (2022)

In addition, most participants surveyed in this study had not been trained in the reporting of ADR. It was found in this study that 434 (82%) of the participants had not received any training on ADR reporting, only 95 (18%) had received training on ADR reporting.

Among 321 (60.7%) of participants who came across an ADR only 8.1% of them went ahead to appropriately report an ADR through the ADR reporting form. This low ADR reporting rate among nurses and midwives could be because of lack of training on the ADR reporting process as results from this study show that 82% of the respondents had not received any form of training on ADR reporting. In addition, pharmacovigilance as a subject was added to Registered General Nursing and Midwifery curriculum in the year 2015, so the concept of pharmacovigilance might be new to practicing nurses and midwives and this could be a contributory factor to the low ADR reporting rate among nurses and midwives in the Sekondi-Takoradi metropolis. Similar studies on nurses and other healthcare professionals have revealed low ADR reporting rates (below 20%) (Katusiime, Semakula, & Lubinga, 2015; Torwane et. al, 2015; Alsaleh et. al, 2017; Güner & Ekmekci, 2019). The reasons for underreporting in the studies were a lack of knowledge on the ADR reporting system by healthcare workers. This present research found same.

Research question four: What are the Barriers to ADR Reporting by Nurses and Midwives in the Sekondi – Takoradi Metropolis?

The barriers to ADR reporting among nurses and midwives in the Sekondi-Takoradi Metropolis was explored. Majority of the respondents 431 (81.5%) refuted the claim that not knowing that it was their duty to report was a barrier to ADR reporting while the rest 98 (18.5%) agreed that not knowing that it was their duty to report ADR was a barrier. More than half of the participants 299 (56.5%) agreed that unawareness of the ADR reporting procedure was a barrier to

ADR reporting however, the rest 230 (43.5%) disagreed that unawareness of the ADR reporting procedure was a barrier to ADR reporting.

Lack of ADR reporting form was seen as a barrier to ADR reporting by 256 (48.4%) of the respondents while 273 (51.6%) of them did not consider it as a barrier. More than half of the respondents 296 (56%) admitted that they did not know how to fill an ADR reporting form and as such this was a barrier to ADR reporting. On the other hand, 233 (44%) refuted the claim that not knowing how to fill an ADR reporting form was a barrier to ADR reporting. Majority of the participants of the study 443 (83.7%) disagreed that not knowing how to detect an ADR was a preventive factor in ADR reporting. However, 86 (16.3%) of them agreed that not knowing how to detect an ADR was a barrier to ADR reporting.

Less than half of the respondents 205 (38.8%) agreed that a heavy work load prevented them from reporting an ADR. However, most of them 324 (61.2%) disagreed that a heavy work load prevented them from reporting an ADR. More than half of the respondents 349 (66%) disagreed that lack of time hindered them from reporting ADR while 180 (34%) of them saw lack of time as a preventive factor in ADR reporting. Less than half of the respondents 147 (27.8%) agreed that their facility does not encourage reporting of ADR while majority of the respondents 383, (73.2%) refuted this claim. In all, 267 (52.2%) agreed that not receiving feedback after reporting an ADR was a barrier to ADR reporting while 253 (47.8%) of them did not agree that lack of feedback was a barrier to ADR reporting. Figure 5 shows the barriers to ADR reporting.

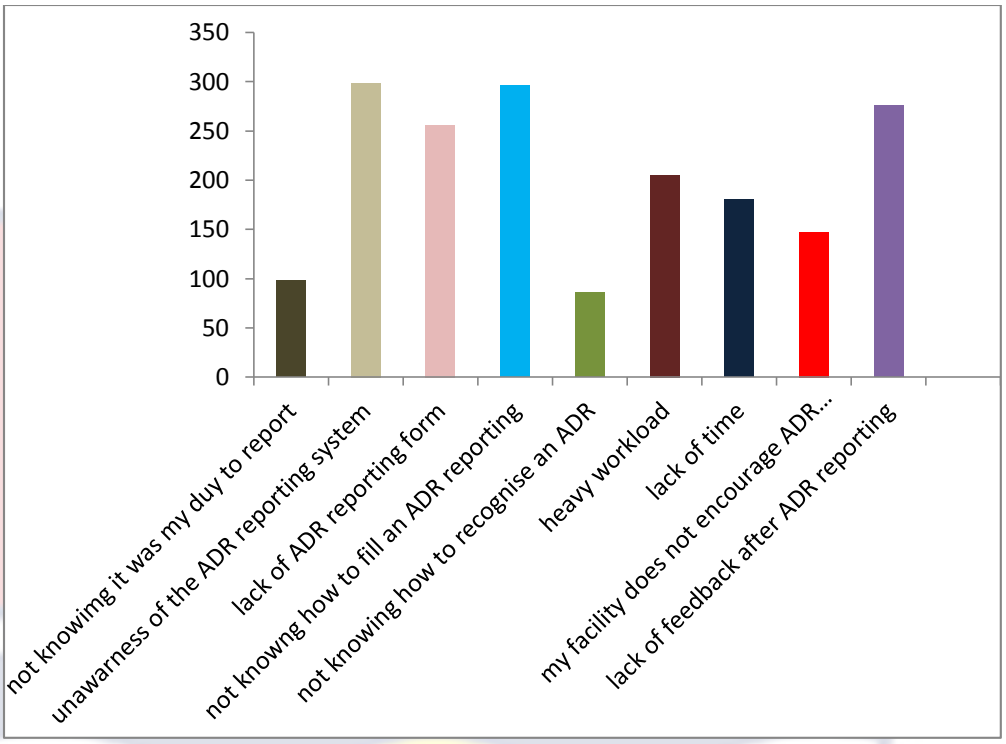


Figure 5: Barriers to ADR Reporting
SOURCE: Field Data, Bilson (2022)

The top three barriers that became known in this study were unawareness of the ADR reporting system 299 (56.5%), not knowing how to fill an ADR form 296 (56%) and not receiving feedback after reporting an ADR 267 (52.2%). These findings collaborates a study carried out in Italy by De Angelis et al. (2015), which revealed that 58 % of nurses were not aware of the ADR reporting system and 70% of them did not know how to fill an ADR reporting form. Additionally, other studies show that a major barrier to ADR reporting by healthcare workers is unawareness of the ADR reporting system (Kunnoor et al., 2017; Bahekar & Patil, 2018). Contrary views from other studies showed that 60 to 85% of healthcare workers consider lack of time as a major barrier to ADR reporting

(Torwane et. al, 2015; Amedome & Dadson, 2017; Rajalaksmi et al., 2017; Ahsan & Mallick, 2017).

Research Question Five: What is the Extent to which Knowledge, Training and Demographic Characteristics of Nurses and Midwives Predict Reporting of ADR in Sekondi –Takoradi Metropolis?

This research question sought to explore the extent to which knowledge (types of ADR to be reported, modes of reporting ADR), training on ADR reporting and demographic characteristics (specialty and age) of nurses and midwives in the Sekondi- Takoradi metropolis would predict reporting of ADR. . A hierarchical multiple regression analysis was used to identify the best predictor of ADR reporting. Age of the respondents was statistically significant (F (1, 528) =120.38, $p<.001$, $R^2=0.33$. Types of ADR to be reported was also statistically significant at (F (2, 527) =14.36, $p<.001$, $R^2=0.37$. Meanwhile, specialty was not statistically significant (F (3, 526) = 110.52, $p<.061$, $R^2=0.20$. Training on ADR was also not statistically significant (F (4, 525) =108.73, $p<.082$, $R^2=0.14$. Based on the results, the best predictor for ADR reporting was Age ($\beta=0.49$, $p <.001$), followed by Types of ADR to be reported ($\beta=0.24$, $p <.001$)

Table 7: Hierarchical Multiple Regression Analysis Showing How Specialty, Training, Age and Types of ADR Determine ADR Reporting (N=529)

Predictor Variables	Regression	Regression	Regression	Regression
Specialty	0.75	0.73	0.30	0.27
Mode of Training		0.23	0.26	0.24
Age of Respondents			0.39***	0.10***
Type of ADR reported				0.49***
R^2	0.33	0.37	0.57	0.70
R^2Change		0.37	0.20	0.14

Note ***=P<0.001.
SOURCE: Field Data, Bilson (2022)

Similar studies in Ethiopia revealed that training of healthcare personnel and knowledge about reporting ADRs were found to be significant determinants of ADR reporting (Gidey, et al., 2020). Additionally, other studies have established an association between poor knowledge on ADR reporting, training on ADR reporting and reporting of ADR (Hazell & Shakir, 2006; Elnour, et al., 2009). In contrast, a similar study carried out in Uganda showed that healthcare professionals within the age range of 36-65 years were more likely to report an ADR than younger healthcare professionals (Katusiime, Semakula, & Lubinga, 2015). However, in this study age and types of ADR reported were seen as significant predictors to the reporting of ADR.

Summary

The findings of this study revealed that nurses and midwives in the Sekondi – Takoradi metropolis have moderate knowledge on pharmacovigilance and have a negative attitude towards ADR reporting. Most of them have not received training on the ADR reporting process. The three top perceived barriers by the nurses and midwives to ADR reporting were unawareness of the ADR reporting system, not knowing how to fill an ADR form, and not receiving feedback after reporting an ADR. These findings depict that nurses and midwives need sensitization on pharmacovigilance and training on the ADR reporting process. This will go a long way to increase ADR reports in the Sekondi-Takoradi metropolis and hence promote the safety of patients in relation to drug use.

CHAPTER FIVE

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

This chapter deals with a summary of the entire work, conclusions drawn and recommendations made. The intent of this study was to assess Sekondi-Takoradi nurses and midwives knowledge and attitude on the ADR reporting system, ADR reporting rate and barriers to ADR reporting. A quantitative descriptive survey design was used to collect data for this study. The study was carried out in the four Government hospitals in the Sekondi-Takoradi metropolis. A census was employed as the sampling procedure and 529 (328 nurses and 201 midwives) participants, corresponding to 90.9% of the total population took part in the study.

Key Findings

1. This study found that nurses and midwives in the Sekondi-Takoradi metropolis have moderate knowledge (Average% = 49.5) on pharmacovigilance.
2. In general, the attitude of nurses and midwives in this study towards ADR reporting was negative as the data showed a composite score of 52.3%.
3. This study found out that ADR reporting among nurses and midwives in the Sekondi-Takoradi Metropolis was low, only 43 (8.1%) of them reported through the appropriate means by using an ADR reporting form.
4. The findings of this study revealed that age of respondents and types ADR were predictors of reporting of ADR.

5. The three top perceived barriers by the nurses and midwives to ADR reporting were unawareness of the ADR reporting system (56.5%), not knowing how to fill an ADR form (56%) and not receiving feedback after reporting an ADR (52.2%).

Conclusion

Based on the findings of this study, it could be concluded that nurses and midwives in the Sekondi-Takoradi Metropolis have moderate knowledge on pharmacovigilance. The nurses in this study have a negative attitude towards pharmacovigilance, and ADR reporting among them is low. A clear reason for the low ADR reporting could be the lack of training on the ADR reporting process as majority of respondents had not received training on the ADR reporting system.

Recommendations

Nurses and midwives in the clinical setting are the cadre of health care professionals who have long contact hours with patients and hence should be better placed to report the occurrence of ADRs. From the results of this study measures should be put in place to improve ADR reporting and pharmacovigilance. Here are some recommendations in this regard;

1. The Western Regional branch of the Food and Drug Authority should organize regular training to enhance the knowledge of Sekondi-Takoradi nurses and midwives on pharmacovigilance and the ADR reporting system.
2. The institutional contact person for pharmacovigilance at the hospitals should ensure that ADR reporting forms are readily available on the ward.

Additionally, The Management of the hospitals in the Sekondi-Takoradi enclave should consider uploading a soft copy of the ADR reporting form on the online health information management system so that nurses and midwives can easily fill the form online. The filled ADR forms could be printed out by the institutional contact person of pharmacovigilance then forwarded to the Western Regional Food and Drugs Authority branch.

3. The Western Regional Food and Drug board should provide prompt feedback to nurses and midwives on action taken on ADR reports from the Sekondi–Takoradi Metropolis.
4. The three top perceived barriers by the nurses and midwives to ADR reporting were unawareness of the ADR reporting system, not knowing how to fill an ADR form and not receiving feedback after as such these three key areas should be the concentration of policy makers in order to improve on the situation of reporting ADRs.
5. The findings of this study revealed that age of respondents and types ADR were predictors of reporting of ADRs for this reason there should be much focus on specific ages which show predominance of the ADRs in order to bring the situation to the level that can be controlled

Suggestions for Further Research

This study was conducted exclusively with registered nurses and midwives working at the four government hospitals in the Sekondi–Takoradi Metropolis. To be able to generalize findings, further studies involving all categories of health care professionals should be done. Furthermore, studies

should be carried out on patients' knowledge on ADR reporting and pharmacovigilance.

REFERENCES

Abideen, P. S. (2013). Practical implications of spontaneous Adverse Reaction reporting system in hospitals – An overview. *Asian Journal of Pharmaceutical and Clinical Research*, *6*(4), 10-15.

Adisa, R., & Omitogun, T. I. (2019). Awareness, knowledge, attitude, and practice of adverse drug reaction reporting among health workers and patients in selected primary healthcare centres in Ibadan, Southwestern Nigeria. *BMC Health Services Research*, *19*, 926 https://doi.org/10.1186/s12913-019-4775-9

Ahsan, M., & Mallick, A. K. (2017). Factors influencing the knowledge and attitude of nurses towards adverse drug reaction reporting in a teaching hospital. *International Journal of Basic & Clinical Pharmacology*, *6*(5), 1215-2020. Retrieved from https://doi.org/10.18203/2319-2003.ijbcp 20171679

Agbeko, R. D. (2016). Reporting of adverse drug reactions: Evaluation of knowledge, attitude, and practice among hospital pharmacists in Ashanti Region. Master's thesis, Kwame Nkrumah University of Science and Technology, Kumasi. Retrieved from https://ir.knust.edu.gh/xmuli/handle /123456789/10169

Alsaleh, F. M., Alzaid, S. W., Abahussain, E. A., Bayoud, T., & Lemay, J. (2017). Knowledge, attitude and practices of pharmacovigilance and adverse drug reaction reporting among pharmacists working in secondary and tertiary governmental hospitals in Kuwait. *Saudi Pharmaceutical Journal*, *25*(6), 830–837. https://doi.org/10.1016/j.jsps.2016.12.004.

Alshammari, T. M., & Almoslem, M. J. (2018). Knowledge, attitude & practices of healthcare professionals in hospitals towards the reporting of adverse drug reactions in Saudi Arabia: A multi-centre cross sectional study. *Saudi* Pharmaceutical Journal, 26(7) 925-931. https://doi.org/10.1016/j.jsps.2018.04.012.

Alwhaibi, M., & Al Aloola, N. A. (2020). Healthcare students' knowledge, attitude and perception of pharmacovigilance: A systematic review. *PlOS one*, *15*(5), e0233393.

Amedome, S. N., & Dadson, B.A. (2017). Pharmacovigilance practices: Knowledge and attitudes among the healthcare professionals at the Volta Regional Hospital of Ghana. *Journal of Pharmacovigilance, 5(3*), 1-9. https://doi.org/10.4172/2329-6887.1000229.

Amin, M. N., Khan, T. M., Masudur, S., Dewan, R., Islam, M. S., Moghal, M. R., & Ming, L. C. (2016). Cross-sectional study exploring barriers to adverse drug reactions reporting in community pharmacy settings in Dhaka, Bangladesh. 1–6. https://doi.org/10.1136/bmjopen-2015-010912

Ampadu, H. H., Hoekman, J., de Bruin, M. L., Pal, S. N., Olsson, S., Sartori, D., Leufkens, H. G., & Dodoo, A. N. (2016). Adverse drug reaction reporting in africa and a comparison of individual case safety report characteristics between Africa and the Rest of the World: Analyses of spontaneous reports in VigiBase®. *Drug Safety*, *39*(4), 335–345. https://doi.org/10.1007/s40264-015-0387-4

Aronson, J. K., & Ferner, R. E. (2003). Joining the DoTS: new approach to classifying adverse drug reactions. *BMJ Clinical Research*, *327*(7425), 1222–1225. https://doi.org/10.1136/bmj.327.7425.1222

Bahekar, S. E., & Patil, S. M. (2018). Evaluation of knowledge, attitude, and practice of adverse drug reactions reporting among doctors and nursing staff of a rural tertiary care teaching hospital of Maharashtra. https://doi.org/10.4103/JMISR.JMISR.

Beninger P. (2018). Pharmacovigilance: An Overview. *Clinical Therapeutics*, *40*(12): 1991–2004. https://doi.org/10.1016/j.clinthera.2018.07.012

Bennett, C (1975) Up the hierarchy. *Journal of Extension*, *13*(2).

Cantwell, P. (2008). Census. In P. J. Lavrakas (Ed.), *Encyclopedia of survey research methods* (pp. 91-93). Sage Publications, Inc., https://dx.doi.org/10.4135/9781412963947.n61

Chopra, D., Wardhan, N., & Rehan, H. S. (2011). Knowledge, attitude, and practices associated with adverse drug reaction reporting amongst doctors in a teaching hospital. *The International Journal of Risk & Safety in Medicine*, *23*(4), 227–232. https://doi.org/10.3233/JRS-2011-0543.

Coleman, J. J., & Pontefract, S. K. (2016). Adverse drug reactions. *Clinical medicine (London, England)*, *16*(5), 481-485.

Costa, M. J., Herdeiro, M. T., Polónia, J. J., Ribeiro-Vaz, I., Botelho, C., Castro, E., & Cernadas, J. (2018). Type B adverse drug reactions reported by an immunoallergology department. *Pharmacy Practice*, *16*(1), 1070. https://doi.org/10.18549/PharmPract.2018.01

De Angelis, A., Giusti, A., Colaceci, S., Vellone, E., & Alvaro, R. (2015). Nurses' reporting of suspect adverse drug reactions: a mixed-methods study. *Annali Dell'Istituto Superiore di Sanita*, *51*(4), 277-283. https://doi.org/10.4415/ANN_15_04_06

Edwards, I. R., & Aronson, J. K. (2000). Adverse drug reactions: definitions, diagnosis, and management. *Lancet*, *356*(9237), 1255–1259. https://doi.org/10.1016/S0140-6736(00)02799-9

Effia Nkwanta Regional Hospital. (2019). Hospital profile of Effia Nwanta Regiona hospital. Sekondi: Effia Nkwanta Regional Hospital.

Elnour, A. A., Ahmed, A. D., Yousif, M. A., & Shehab, A. (2009). Awareness and reporting of adverse drug reactions among health care professionals in Sudan. *Joint Commission journal on quality and patient safety*, *35*(6): 324–329. https://doi.org/10.1016/s1553-7250(09)35046-1

Essikado Government Hospital. (2019). Hospital Profile of Essikado Government Hospital. Essikado: Essiakado Government Hospital.

European Commission (2008). Proposal for a regulation amending, as regards pharmacovigilance of medicinal products for human use. *Regulation (EC) No 726/2004. Impact assessment.* http://ec.europa.eu/health/files/pharmacos/pharmpack_12_2008/pharmacovigilance-ia-vol1_en.pdf

Food and Drug Authority (2019). Druglens Issue 7. Accra, Ghana

Food and Drug Authority (2015). Druglens Issue 3. Accra, Ghana.

Food and Drug Authority (2013). Druglens Issue 1. Accra, Ghana.

Food and Drug Authority (2012). *Annual Report 2012*. Accra, Ghana.

Fox, W., & Bayat, M. S. (2007). *A Guide to Managing Research*. Cape Town City: Juta Publications. https://research-methodology.net/descriptive-research/#_ftn2

Fornasier, G., Francescon, S., Leone, R., & Baldo, P. (2018). An historical overview over Pharmacovigilance. *International Journal of Clinical Pharmacy*, *40*(4), 744–747. https://doi.org/10.1007/s11096-018-0657-1

Ghana Statistical Service. (2012). *2010 population and housing census final results*. Accra: Ghana Statistical Service.

Gidey, K., Seifu, M., Hailu, B. Y., Asgedom, S. W., & Niriayo, Y. L. (2020). Healthcare professionals knowledge, attitude and practice of adverse drug reactions reporting in Ethiopia: A cross-sectional study. *BMJ Open*, 10(2), e034553. https://doi.org/10.1136/bmjopen-2019-034553

Güner, M. D., & Ekmekci, P. E. (2019). Healthcare professionals' pharmacovigilance knowledge and adverse drug reaction reporting behavior and factors determining the reporting rates. *Journal of drug assessment, 8*(1): 13–20. https://doi.org/10.1080/21556660.2019.1566137

Gurmesa, L. T., & Dedefo, M. G. (2016). Factors Affecting Adverse Drug Reaction Reporting of Healthcare Professionals and Their Knowledge, Attitude, and Practice towards ADR Reporting in Nekemte Town , West Ethiopia. *BioMed Research International*, 5-8. https://doi.org/10.1155/2016/5728462

Haines, H. M., Meyer, J.C., Summers, R.S., & Godman, B. B. (2020). Knowledge, attitudes, and practices of health care professionals towards adverse drug reaction reporting in public sector primary health care facilities in a South African district. *European Journal of Clinical Pharmacology*, *76*, 991–1001 https://doi.org/10.1007/s00228-020-02862-8

Hanafi, S., Torkamandi, H., Hayatshahi, A., Gholami, K., & Javadi, M. (2012). Knowledge, attitudes, and practice of nurse regarding adverse drug reaction reporting. *Iranian Journal of Mursing and Midwifery Research*, *17*(1), 21.

Hazell L, Shakir S. A. W. (2006) Under-Reporting of adverse drug reactions. *Drug Safety*, *29*, 385-96.

Hussain, R., Hassali, M. A., Hashmi, & Akram, T. (2021). Exploring healthcare professionals' knowledge, attitude, and practices towards pharmacovigilance: A cross-sectional survey. *Journal of Pharmacology Policy and Practice*, *14*, 5. https://doi.org/10.1186/s40545-020-00287-3

Iasella, C. J., Johnson, H. J., & Dunn, M. A. (2017). Adverse Drug Reactions: Type A (Intrinsic) or Type B (Idiosyncratic). *Clinics in liver disease*, *21*(1), 73–87. https://doi.org/10.1016/j.cld.2016.08.005

Kaufman G. (2016). Adverse drug reactions: Classification, susceptibility, and reporting. *Nursing standard*, *30*(50), 53–63. https://doi.org/10.7748/ns.2016.e10214

Katusiime, B., Semakula, D., & Lubinga, S. J. (2015) Adverse drug reaction reporting among healthcare workers at Mulago National Referral and Teaching hospital in Uganda. *Afri Health Sci*, *15*(4), 1308-1317

Kunnoor, N. S., Sharanabasappa, Lohit K. (2017). Perception of doctors towards Adverse Drug Reaction (ADR) reporting: a cross sectional survey using a validated questionnaire. *International Journal of Basic & Clinical Pharmacology*, *6*(11), 2671-2675.

Kwesimintism Government Hospital. (2019) Hospital profile of Kwesimintism hospital. Kwesimintism: Kwesimintism Government Hospital.

Lemay, J., Alsaleh, F. M., Al-Buresli, L., Al-Mutairi, M., Abahussain, E. A., & Bayoud, T. (2018). Reporting of adverse drug reactions in primary care settings in Kuwait: A Comparative Study of Physicians and Pharmacists. *International Journal of the Kuwait University, Health Science Centre*, *27*(1), 30-38. https://doi.org/10.1159/000487236.

Lohit, K., Vidya K. R., & Manjunath, G. N. (2016). Development and validation of questionnaire to assess the knowledge, attitude and practice towards adverse drug reactions reporting among healthcare professionals. *Journal of International Medicine and Dentistry*, *3*(2), 63-72.

National Medicines Information Centre. (2019). Adverse Reactions to Medicines, 25(4), 2-3.

Nisa, Z. U., Zafar, A., & Sher, F. (2018). Assessment of knowledge, attitude, and practice of adverse drug reaction reporting among healthcare professionals in secondary and tertiary hospitals in the capital of Pakistan. *Saudi Pharmaceutical Journal*, *26*(4), 453–461. https://doi.org/10.1016/j.jsps .2018.02.014

Onkka, A. (2018). What is Bennett's Hierarchy Logic Model? Aurora Consulting. https://www.auroraconsult.com/what-is-bennetts-hierarchy-logic-model/

Osei, J. Y. (2016). Adverse drug reaction reporting among community pharmacists in the Greater Accra region of Ghana. Master's thesis, University of Ghana, Legon. Retrieved from http://ugspace.ug.edu.gh

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). http:/ /doi: 10.1186/1472-6904-9-14.

Parida, S. (2013). Clinical causality assessment for adverse drug reactions. *Indian Journal of Anaesthesia, 57*(3). doi: 10.4103/0019-5049.115608.

Patel, T. K., & Patel, P. B. (2018). Mortality among patients due to adverse drug reactions that lead to hospitalization: A meta-analysis. *Europe Journal of Clinical Pharmacology, 74*(6), 818-832.

Permanand, G., Mossialos, E., & McKee, M. (2006). Regulating medicines in Europe: The European Medicines Agency, marketing authorisation, transparency and pharmacovigilance. *Clinical medicine (London, England), 6*(1), 87-90. https://doi.org/10.7861/clinmedicine.6-1-87

Prashar, L, Jere, E, Kalungia, C.A. (2019). Inadequate knowledge and practice of pharmacovigilance affecting adverse drug reaction reporting by health professionals in private healthcare facilities in Lusaka, Zambia. *Medical Journal of Zambia, 46*(4), 314-320.

Radhakrishna, R., & Bowen, C. F. (2010). Viewing bennett's hierarchy from a different lens: Implications for extension program evaluation. *Journal of Extension, 48*(6), 1-5.

Rajalakshmi, R., Devi, B. V., Prasad, T. S. D., Swetha, S., & Dharini, B. (2017) (2018). Knowledge , attitude and practice towards pharmacovigilance and adverse drug reaction reporting among nurses in a tertiary care hospital, Tirupati. *International Journal of Pharmaceutical and Clinical Research*, *9*(11), 683-689.

Rohilla, A., & Yadav, S. (2013). Adverse drug reactions: An Overview. *International Journal of Pharmacological Research, 3*(1), 10-12. https://doi.org/10.7439/ijpr.v3i1.41

Sabblah, G.T., Akweongo, P., Darko, D., Dodoo, A.N.O., & Sulley, A.M. (2014). Adverse Drug reporting by doctors in a developing county: a case study from Ghana. *Ghana Medical Journal, 48*(4): 189-193.

Santosh, K. C., & Tragulpiankit, P. (2011). Pharmacovigilance: An overview. *Mahidol University Journal of Pharmaceutical Science, 38*, 1-7.

Santosh, K. C., Tragulpiankit, P., Edwards, I. R., & Gorsanan, S. (2013). Knowledge about adverse drug reactions reporting among healthcare professionals in Nepal. *The International journal of risk & safety in medicine*, *25*(1), 1–16.

Schatz, S. N., & Weber, R. J. (2018). Adverse drug reactions. *British Medical Journal, 363*, 1-2.

Shalviri, G., Yazdizadeh, B., Mirbaha, F., Gholami, K., & Majdzadeh, R. (2018). Choosing appropriate theories for understanding hospital reporting of adverse drug events, a theoretical domains framework approach. *Iranian Journal of Pharmaceutical Research*, *17*(2), 811-821.

Shibbiru T, & Tadesse F. (2016). Adverse Drug Reactions: An overview. *Journal of Medicine, Physiology and Biophysics*, *9*(23), 7-14.

Sultana, J., Cutroneo, P., & Trifiro, G. (2013). Clinical and economic burden of adverse drug reactions. *Journal of Pharmacology & Pharmacotherapeutics. 4*(1), 73-77.

Suyagh, M., Farah, D., & Farha, R. A. (2015). Pharmacist's knowledge, practice and attitudes toward pharmacovigilance and adverse drug reactions reporting process. *Saudi Pharmaceutical Journal, 23*(2), 147-153.

Takoradi Government Hospital. (2019) Hospital profile of Takoradi Government Hospital. Takoradi: Takoradi Government Hospital.

Toklu H. Z., Soyalan M., Gültekin O., Özpolat M., & Aydın, M. D. (2016). The knowledge and attitude of the healthcare professionals towards pharmacovigilance and adverse drug reaction reporting in Northern Cyprus. *Journal of Pharmacovigilance*, *4*(1), 1-7.

Torwane, N. A., Hongal, S., Gouraha, A., Saxena, E., & Chavan, K. (2015). Awareness related to reporting of adverse drug reactions among health caregivers: A cross-sectional questionnaire survey. *Journal of National Accrediation Board Hospitals Healthcare Providers*, *2*(1), 23-9.

Un, Z., Zafar, A., & Sher, F. (2018). Assessment of knowledge, attitude and practice of adverse drug reaction reporting among healthcare professionals in secondary and tertiary hospitals in the capital of Pakistan. *Saudi Pharmaceutical Journal, 26*(4), 453-461.

Uppsala Monitoring Centre. (2018). Making Medicines Safer – Uppsala Monitoring Center 40 years of pioneering pharmacovigilance. https://view.publitas.com/upsala-monitoring-center/making-medicines-safer/page/1

Uppsala Monitoring Centre (2020). WHO programme members. Retrieved from https://www.who-umc.org/

Vural, F., Ciftci, S., & Vural, B. (2014). *The knowledge, attitude and behaviours of nurses about pharmacovigilance, adverse drug reaction and adverse event reporting in a state hospital*. *North Clin Istanbul, 1*(3), 147-152. https://doi.org/10.14744/nci.2014.41636

World Bank. (2019). World Bank in Ghana. https://www.worldbank.org/en/ghana

World Health Organization. (2000). Safety monitoring of medicinal products. Guidelines for setting up and running a Pharmacovigilance Centre. London: *WHO Collaborating Centre for International Drug Monitoring*

World Health Organization (2002). *The importance of pharmacovigilance: Safety Monitoring of medicinal products.* http//apps.who.int/medicinedoc/pd//doi.orgorg/10.1002/0470853093

World Health Organization. (2003). *Drugs and Therapeutics Committees* – A Practical Guide. https:apps.who.int/medicinedocs/en/d/Js4882s/7.7.html

APPENDICES

APPENDIX A: ADR REPORTING FORM

15200

FDB/ADR
FOOD AND DRUGS BOARD
in Strict Confidence

ADVERSE REACTION REPORTING FORM

(A) PATIENT DETAILS:

Age/Date of Birth (dd/mm/yyyy): / / Gender: M ( ) F ( ) Wt: ..... kg
Name/Folder Number ..... Telephone No.: .....
Hospital/Treatment Centre .....

(B) DETAILS OF ADVERSE REACTION AND ANY TREATMENT GIVEN (Attach a separate sheet when necessary)

Date reaction started (dd/mm/yyyy): / / Date reaction stopped (dd/mm/yyyy): / /

(C) OUTCOME OF ADVERSE REACTION:

Recovered ( ) Not yet recovered ( ) Unknown ( )
Did the adverse reaction result in any untoward medical conditon? Yes ( ) No ( ) If yes, specify .....
SERIOUSNESS: Death ( ) Life threatening ( ) Disability ( ) (Specify) .....
Hospitalization ( ) Others (specify) .....

(D) SUSPECTED PRODUCT(S) (Attach sample or product label if available)

Brand name	Generic name	Batch no.	Expiry date	Manufacturer
Reason(s) for use (Indication)		**Daily dose:**	**Route of Administration:**	
Date started: (dd/mm/yyyy)		**Date stopped: (dd/mm/yyyy)**		
Did the adverse reaction subside when the drug was stopped (de-challenge)? Yes ( ) No ( )				
Was the product prescribed? ☐ **Yes** ☐ **No)**		**Source of Drug:**		

Was product re-used after detection of adverse reaction (re-challenge)? Yes ( ) No ( )
Did adverse reaction re-appear upon re-use? Yes ( ) No ( )

(E) CONCOMITANT DRUGS INCLUDING HERBAL MEDICINES TAKEN PRIOR TO THE ADVERSE REACTION

(Attach a separete sheet when necessary)

Name of Drug	Daily dose	Date started	Date stopped	Reason(s) for use

Attach all relevant laboratory tests/data

(F) REPORTER DETAILS

Name of Reporter: ..... Profession .....
Address: .....
Signature: ..... Tel: ..... E-mail: .....
Date (dd/mm/yyyy): / /

For all questions relating to Suspected Adverse Reactions, please call the Food and Drugs Board on

* Landline: + 233 (0302) 233 200/235 100,
* Mobile: + 233 (024) 4310 297.
* Fax +233 (0302) 229 794.
* E-mail: drugsafety@fdbghana.gov.gh

Please return the completed form to:
Food and Drugs Board, P. O. Box CT 2783, Cantonments-Accra, Ghana.

This form can also be downloaded from the Food and Drugs Board's website: www.fdbghana.gov.gh

Please, note that this report does not constitute an admission that the reporting medical professional or the suspected product caused or contributed to the event.

fold along this line

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:
*Medications (drugs and biologicals)
*Traditional and herbal remedies
*Medical Devices

Report Product Quality Problems such as:
*Suspected Contamination
*Questionable components
*Poor packaging or labeling
*Therapeutic failures

Report Even if:
*You're not certain the product caused the event
*You don't have all the details

Confidentiality: Identities of the reporter and patient will remain strictly confidential. Your support of the safety Monitoring programme is much appreciated. Information supplied by you will contribute to the improvement of drug safety and therapy in Ghana.

PLEASE USE ADDRESS BELOW-JUST FOLD IN THIRDS AND MAIL

fold along this line

WHEN COMPLETED PLEASE CALL **0244 310 297** FOR PICK UP
OR CONTACT NEAREST FDB ZONAL OFFICE
OR SEND BY POST TO:

FOOD AND DRUGS BOARD
P. O. CT 2783
CANTONMENTS
ACCRA, GHANA

APPENDIX B: QUESTIONNAIRE

QUESTIONNAIRE ON ADVERSE DRUG REACTION (ADR) REPORTING AMONG NURSES AND MIDWIVES IN THE SEKONDI – TAKORADI METROPOLIS

I am Sarah Bilson, a student in the Department of Health, Physical Education and Recreation of the University of Cape Coast. I am conducting a study on the topic "Adverse Drug Reaction reporting among Nurses and Midwives in the Sekondi- Takoradi Metropolis." Information given will be entirely used for the study. You will not be required to state your name to ensure anonymity and confidentiality. Thank you.

INSTRUCTION: KINDLY READ THROUGH THE QUESTIONS AND ANSWER APPROPRIATELY BY TICKING [√]

SECTION A: DEMOGRAPHIC DATA

1. Gender
    a) Male [ ]
    b) Female [ ]
2. Age in years……
3. Specialty
    a) Nurse [ ]
    b) Midwife [ ]
4. Years of practice ……
5. Marital Status
    a) Single [ ]
    b) Married [ ]
    c) Divorced [ ]
    d) Separated [ ]
    e) Widowed [ ]

SECTION B: KNOWLEDGE ON PHARMACOVIGILANCE AND ADR REPORTING

INSTRUCTION: KINDLY READ THROUGH THE QUESTIONS AND ANSWER APPROPRIATELY BY TICKING [√]

6. What is pharmacovigilance?

a) The science of monitoring ADR's happening in a hospital [ ]

b) The process of improving the safety of drugs [ ]

c) The detection, assessment, understanding and prevention of adverse effects [ ]

d) The science detecting the type and incidence of ADR after the drug is marketed

e) Do not know [ ]

7. Which of the following defines an Adverse Drug Reaction (ADR) correctly?

a) Noxious and unintended response to drug and occurs at doses normally used in man or animal for prophylaxis, diagnosis or therapy of disease [ ]

b) Any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a causal relationship with this treatment [ ]

c) Harm resulting from the use of substandard/counterfeit drugs [ ]

d) Adverse health outcomes associated with inappropriate drug use [ ]

e) All can define ADR [ ]

8. What is the main purpose of pharmacovigilance?

a) Improve patient care and safety in relation to medicine use [ ]

b) Contribute to assessment of risk/benefit of medicines [ ]

c) Promote understanding, education and clinical training in pharmacovigilance

d) Ensure effective communication of ADR reporting to public [ ]

e) Do not know [ ]

9. Which institution in Ghana receives ADR reports and takes regulatory action where necessary?

   a) Ministry of Health [ ]

   b) Ghana Health Service [ ]

   c) Food and Drugs board [ ]

   d) Pharmaceutical society of Ghana [ ]

10. Which type of ADR should be reported?

   a) Serious ADRs [ ]

   b) ADRs to herbal and non-allopathic drugs [ ]

   c) ADRs to new drugs [ ]

   d) Unknown ADRs to old drugs [ ]

   e) All ADRs [ ]

11. Who can report an ADR?

   a) Doctor [ ]

   b) Nurses /Midwives [ ]

   c) Pharmacist [ ]

   d) Patients [ ]

   e) All the above [ ]

12. What are the modes of reporting an ADR in Ghana?

   a) ADR Reporting form [ ]

   b) Online reporting form [ ]

   c) Med Safety APP [ ]

   d) All the above [ ]

   e) Do not know [ ]

13. Identify the types of ADR's

a) Type 1, 2, 3, 4, 5, 6 and 7 [ ]

b) Type A, B, C, D, E, and F [ ]

c) Known, unknown and common, uncommon [ ]

d) Reversible and irreversible [ ]

e) Do not know [ ]

14. Which of the following is a major risk factor for the occurrence of maximum adverse drug reactions?

a) Arthritis [ ]

b) Renal failure [ ]

c) Visual impairment [ ]

d) All of these [ ]

e) Do not know [ ]

15. Which of the following constitutes a serious adverse reaction?

a) Birth defect [ ]

b) Death [ ]

c) Disability [ ]

d) Prolonged hospitalization [ ]

e) All of the above [ ]

16. All ADRs are known before a medicine is marketed.

a) Yes [ ]

b) No [ ]

c) Do not know [ ]

17. Does your hospital have an institutional contact person for pharmacovigilance?

a) Yes [ ]

b) No [ ]

c) Do not know [ ]

SECTION C: ATTITUDE TOWARDS ADR REPORTING

INSTRUCTION: KINDLY READ THROUGH THE QUESTIONS AND ANSWER APPROPRIATELY BY TICKING [√]

QUESTION	Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree
18. ADR reporting is a professional obligation					
19. ADR reporting in the hospital by healthcare professionals should be voluntary					
20. ADR reporting should be mandatory for all healthcare professionals					
21. ADR reporting by one person can make a significant difference to the community					
22. ADR reporting creates additional workload					
23. ADR reporting is time consuming					
24. ADR reporting in the hospital should be financially rewarded					
25. I am willing to implement ADR reporting in my practice					

SECTION D: ADR REPORTING PRACTICE

INSTRUCTION: KINDLY READ THROUGH THE QUESTIONS AND ANSWER APPROPRIATELY BY TICKING [√]

26. Have you ever encountered patient with ADR in your clinical practice in the last 12 months?
    a) Yes [ ]
    b) No [ ]
27. How many patients with ADR have you encountered during the last 12 months?
    a) None [ ]
    b) 1 – 4 [ ]
    c) 5 -10 [ ]
    d) More than 10 [ ]
28. Have you ever reported an ADR?
    a) Yes [ ]
    b) No [ ]
29. How do you respond when you come across an ADR?
    a) Document ADR in nurses note [ ]
    b) Report to Nurse In charge [ ]
    c) Report to physician [ ]
    d) Complete an ADR reporting form [ ]
30. How often do you monitor your patients for possible ADRs after drug administration?
    a) Usually [ ]
    b) Never [ ]
    c) Sometimes [ ]
    d) Always [ ]

31. Have you ever received training on ADR reporting?

a) Yes [ ]

b) No [ ]

SECTION E: BARRIERS TO ADR REPORTING BY NURSES AND MIDWIVES

INSTRUCTION: KINDLY READ THROUGH THE QUESTIONS AND ANSWER APPROPRIATELY BY TICKING [√]

Which of the following factors discourage you from reporting ADRs	AGREE	DISAGREE
32. I did not know it was my duty to report ADRs		
33. I am unaware of the ADR reporting procedure		
34. I do not report due to lack of ADR reporting form		
35. I do not know how to fill an ADR reporting form		
36. I do not know how to recognize an ADR		
37. Heavy workload prevents me from reporting ADRs		
38. lack of time hinders me from reporting ADRs		
39. My facility does not encourage reporting of ADRs		
40. I do not receive feedback after reporting ADRs		

APPENDIX C: ETHICAL CLEARANCE

UNIVERSITY OF CAPE COAST
INSTITUTIONAL REVIEW BOARD SECRETARIAT
TEL: 0558093143 / 0508878309
E-MAIL: irb@ucc.edu.gh
OUR REF: UCC/IRB/A/2016/911
YOUR REF:
OMB NO: 0990-0279
IORG #: IORG0009096

2ND MARCH, 2021

Ms. Sarah Esi Bilson
Department of Health, Physical Education & Recreation
University of Cape Coast

Dear Ms. Bilson,

ETHICAL CLEARANCE – ID (UCCIRB/CES/2021/01)

The University of Cape Coast Institutional Review Board (UCCIRB) has granted **Provisional Approval** for the implementation of your research titled **Adverse Drug Reaction Reporting among Nurses and Midwives in the Sekondi –Takoradi Metropolis.** This approval is valid from 2nd March, 2021 to 1st March, 2022. You may apply for a renewal subject to submission of all the required documents that will be prescribed by the UCCIRB.

Please note that any modification to the project must be submitted to the UCCIRB for review and approval before its implementation. You are required to submit periodic review of the protocol to the Board and a final full review to the UCCIRB on completion of the research. The UCCIRB may observe or cause to be observed procedures and records of the research during and after implementation.

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

Always quote the protocol identification number in all future correspondence with us in relation to this protocol.

Yours faithfully,

Samuel Asiedu Owusu, PhD
UCCIRB Administrator

ADMINISTRATOR
INSTITUTIONAL REVIEW BOARD
UNIVERSITY OF CAPE COAST

APPENDIX D: INTRODUCTORY LETTER TO ESSIKADO HOSPITAL

UNIVERSITY OF CAPE COAST
COLLEGE OF EDUCATION STUDIES
FACULTY OF SCIENCE AND TECHNOLOGY EDUCATION
DEPARTMENT OF HEALTH, PHYSICAL EDUCATION & RECREATION

TELEPHONE: +233 - (0)206610931 / (0)543021384 / (0)268392819
EMAIL: hper@ucc.edu.gh
TELEX: 2552, UCC, GH
Cables & Telegrams: UNIVERSITY, CAPE COAST

Our Ref: **ET/MHE/18/0004/9**

5th February, 2021.

The Medical Superintendent
Essikado Hospital
P. O. Box 187
Sekondi, W/R

INTRODUCTORY LETTER: SARAH ESI BILSON (ET/MHE/18/0004)

The bearer of this letter is an MPhil student of the above department. In partial fulfilment of the requirements for the programme, she is collecting data on the topic" **Adverse Drug Reaction Reporting Among Nurses and Midwives in the Sekondi-Takoradi Metropolis."** and would need assistance from your outfit. The information collected will be used for academic purposes only and its confidentiality is assured.

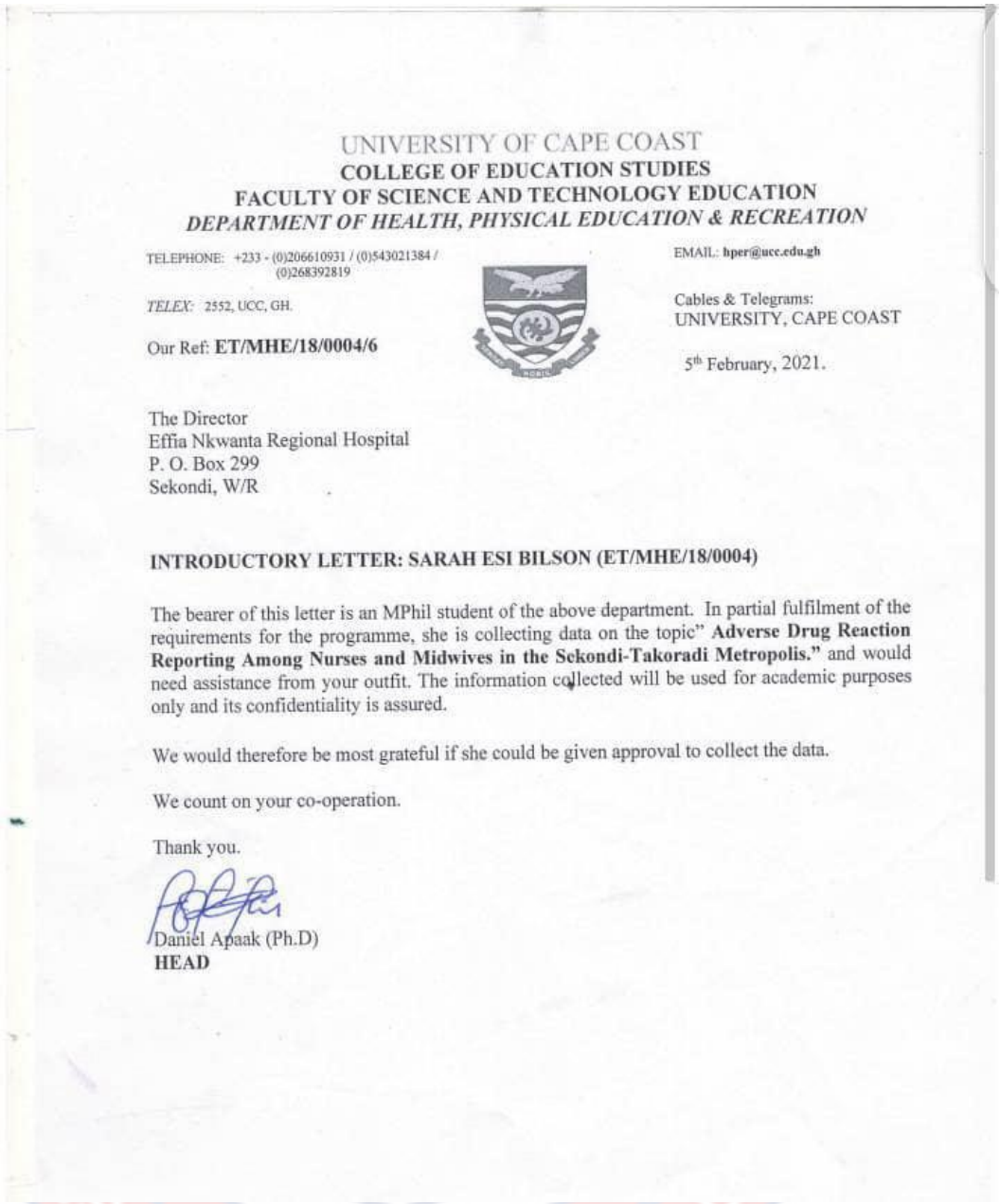
We would therefore be most grateful if she could be given approval to collect the data.

We count on your co-operation.

Thank you.

Daniel Apaak (Ph.D)
HEAD

APPENDIX E: INTRODUCTORY LETTER TO EFFIA NKWANTA REGIONAL HOSPITAL



UNIVERSITY OF CAPE COAST
COLLEGE OF EDUCATION STUDIES
FACULTY OF SCIENCE AND TECHNOLOGY EDUCATION
DEPARTMENT OF HEALTH, PHYSICAL EDUCATION & RECREATION

TELEPHONE: +233 - (0)206610931 / (0)543021384 / (0)268392819
TELEX: 2552, UCC, GH.
Our Ref: **ET/MHE/18/0004/6**

EMAIL: hper@ucc.edu.gh
Cables & Telegrams:
UNIVERSITY, CAPE COAST

5th February, 2021.

The Director
Effia Nkwanta Regional Hospital
P. O. Box 299
Sekondi, W/R

INTRODUCTORY LETTER: SARAH ESI BILSON (ET/MHE/18/0004)

The bearer of this letter is an MPhil student of the above department. In partial fulfilment of the requirements for the programme, she is collecting data on the topic" **Adverse Drug Reaction Reporting Among Nurses and Midwives in the Sekondi-Takoradi Metropolis."** and would need assistance from your outfit. The information collected will be used for academic purposes only and its confidentiality is assured.

We would therefore be most grateful if she could be given approval to collect the data.

We count on your co-operation.

Thank you.

Daniel Apaak (Ph.D)
HEAD

APPENDIX F: INTRODUCTORY LETTER TO KWESIMINTISM HOSPITAL

UNIVERSITY OF CAPE COAST
COLLEGE OF EDUCATION STUDIES
FACULTY OF SCIENCE AND TECHNOLOGY EDUCATION
DEPARTMENT OF HEALTH, PHYSICAL EDUCATION & RECREATION

TELEPHONE: +233 - (0)206610931 / (0)543021384 / (0)268392819

TELEX: 2552, UCC, GH.

EMAIL: hper@ucc.edu.gh

Cables & Telegrams:
UNIVERSITY, CAPE COAST

Our Ref: **ET/MHE/18/0004/7**

5th February, 2021.

The Medical Superintendent
Kwesimintism Hospital
Sekondi, W/R

INTRODUCTORY LETTER: SARAH ESI BILSON (ET/MHE/18/0004)

The bearer of this letter is an MPhil student of the above department. In partial fulfilment of the requirements for the programme, she is collecting data on the topic" **Adverse Drug Reaction Reporting Among Nurses and Midwives in the Sekondi-Takoradi Metropolis."** and would need assistance from your outfit. The information collected will be used for academic purposes only and its confidentiality is assured.

We would therefore be most grateful if she could be given approval to collect the data.

We count on your co-operation.

Thank you.

Daniel Apaak (Ph.D)
HEAD

APPENDIX G: INTRODUCTORY LETTER TO TAKORADI HOSPITAL

UNIVERSITY OF CAPE COAST
COLLEGE OF EDUCATION STUDIES
FACULTY OF SCIENCE AND TECHNOLOGY EDUCATION
DEPARTMENT OF HEALTH, PHYSICAL EDUCATION & RECREATION

TELEPHONE: +233 - (0)206610931 / (0)543021384 / (0)268392819
TELEX: 2552, UCC, GH.
Our Ref: **ET/MHE/18/0004/8**

EMAIL: hper@ucc.edu.gh
Cables & Telegrams:
UNIVERSITY, CAPE COAST

5th February, 2021.

The Medical Superintendent
Takoradi Hospital
Takoradi, W/R

INTRODUCTORY LETTER: SARAH ESI BILSON (ET/MHE/18/0004)

The bearer of this letter is an MPhil student of the above department. In partial fulfilment of the requirements for the programme, she is collecting data on the topic" **Adverse Drug Reaction Reporting Among Nurses and Midwives in the Sekondi-Takoradi Metropolis."** and would need assistance from your outfit. The information collected will be used for academic purposes only and its confidentiality is assured.

We would therefore be most grateful if she could be given approval to collect the data.

We count on your co-operation.

Thank you.

Daniel Apaak (Ph.D)
HEAD