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SCHOOL OF PUBLIC HEALTH

COLLEGE OF HEALTH SCIENCES

UNIVERSITY OF GHANA

ADVERSE DRUG REACTION REPORTING AMONG HEALTH PROFESSIONALS IN THE LAWRA MUNICIPAL HOSPITAL OF THE UPPER WEST REGION

BY

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

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DECLARATION

I Alexis Sang-ber Kuuridong hereby state that this research is the product of my autonomous work apart from references to the works of others that I have duly recognized. I also declare that this piece of work has not been presented for graduation at this institution or at other universities elsewhere.

Student's Name: Alexis Sang-ber Kuuridong

Signature ……

Date: ……

Supervisor's Name: Dr. Paulina Tindana

Signature ……

Date: ……

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DEDICATION

I dedicate this piece of work to my dear wife Madam Veronica Dooh Sonasal and children; Brian Mwinmaalu Kuuridong and Belvin Zunuo Kuuridong. This thesis is further dedicated to Mr. Kuuridong Sylverio Sang-ber and Madam Immaculate Kuuridong my parents; and to my uncle, Mr. Tingan Adolf.

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ABSTRACT

Background; Medicines have the potential to cause Adverse Drug Reactions (ADR) and therefore the need for health professionals to detect and spontaneously report to the Food and Drugs Authority (FDA) for further actions to ensure patients and public safety.

Aims: This study was conducted to ascertain the proportion of ADRs reported by health professionals in the Lawra Municipal Hospital of the Upper West Region of Ghana. The study also sought to assess the level of knowledge of health professionals on ADR reporting procedures.

Methods: This was a cross-sectional survey of 187 health professionals randomly selected from the Lawra municipal hospital. Data were collected through self-administered structured questionnaire from June 19 to July 4 2019 with 98.3% and 1.6% response rate . Data were analyzed using STATA software Version 15.0. Descriptive statistics were used to describe the background characteristics of respondents and the outcome such as proportion of ADR reported summarized in percentages, frequencies and charts.

Results:There was 64.4% ADR reporting rate and 68.75% health professionals who ever saw an ADR case reported it by completing the ADR form. Level of knowledge on ADR reporting procedures was 58.15% among respondents. The main systemic challenge with ADR reporting was lack of access to the online reporting portal for ADR.

Conclusion: The Lawra Municipal Hospital has high ADR reporting rate and high level of knowledge about ADR reporting procedures. However, there is the need to improve access to the online reporting system to staff. The limitation of the study was the possible recall bias by respondents and the inability of the researcher to verify the number of ADR cases reported.

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LIST OF ACRONYMS

ADR	Adverse Drug Reaction
CHPS	Community-based Health Planning and Services
CPD	Continuous Professional Development
FDA	Food and Drugs Authority
GHS	Ghana Health Service
ICPs	Institutional Contact Persons
ICSRs	Individual Case Safety Reports
MDC	Medical and Dental Council
NMC	Nursing and Midwifery Council
PIDM	Program for International Drug Monitoring
PSC	Patient Safety Centers
PV	Pharmacovigilance
RADR	Recognizing Adverse Drug Reaction
SWS	SafetyWatch System
UMC	Uppsala Monitoring Centre
WHO	World Health Organization

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OPERATIONAL DEFINITION OF TERMS

Health professionals; this refers to prescribers, nurses, midwives and pharmacy staff

Prescribers; these include physicians, medical assistants and physician assistants who are permanently employed by the Ghana health service

Pharmacy staff refers to pharmacists, pharmacy technicians and dispensing assistants

Nurses; these are enrolled and registered general nurses certified by the nurses and midwifery council of Ghana and are permanently employed by the Ghana health service

Casuals refers to staff that are locally and temporary engaged by the hospital

ADR reporting rate: this refers to the proportion of total ADRs reported.

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CHAPTER ONE

1.0 INTORDUCTION

1.1 Background

Medicines have the potential to cause Adverse Reactions and therefore the need for early detection and reporting to the Food and Drugs Authority (FDA) by health professional who directly take care of patients. Adverse drug reactions are responsible for considerable morbidity and mortality globally (Smith-Marsh, 2016). Adverse drug reaction (ADR) is an untoward response to a medicinal product that is noxious and unintended, including absence of efficacy, and that happens at any dose and may result from the use of the product under the terms of the marketing authorization, the use of the product outside the terms of the marketing authorization, including overdose, off-label use, misuse, abuse and mistakes in medication (Nwokike & Eghan, 2010).

Spontaneous system of reporting negative drug reactions is widely used and is the cheapest system for monitoring the safety of medicine in real life (Dodoo & Olsson, 2011). Despite the introduction of this cost-effect system of reporting ADRs, underreporting especially in developing countries is still observed. Pharmacovigilance and ADR reporting is relevant in part to the achievement of the sustainable development goal three which aims at ensuring access to safe and effective medicine (*UNDP_GH_IGC_SDGs_ Indicator_ Baseline_Report_2018.pdf*, n.d.).

The achievement of safe medicine and patient safety is not within the jurisdiction of one discipline. For instance, adverse drug reaction has economic burden on the health system and the patients (Güner, 2017). The attitude of health professionals and patients towards ADR

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reporting falls within ontology and the mechanism of reaction is science. It also cuts across five of the six health system building blocks of the World Health Organization (WHO) including medicine and technology, financing, health workforce, information and leadership (Manyazewal, 2017). Adverse drug reaction reporting is only an aspect of the pharmacovigilance system. To assess the pharmacovigilance system involves the assessment of all disciplines and the different systems that play a role in medicine safety. The conduct of this study assesses only the adverse drug reaction aspect of the pharmacovigilance system. The findings in part will contribute to the provision of relevant information on ADR reporting and how responsive the system is. It will also identify some possible challenges with the system in order to inform policy makers about suggestive ways to strengthen or improve on the current guidelines or policy direction.

Ghana joined the WHO (PIDM) as the first country in West Africa and the 65th member state in 2001. Each member country has an annual target of 200-500 Adverse Drug Reaction (ADR) report per 1,000,000 population per year (Haggar H. Ampadu et al., 2016).

The rate of ADR reporting in low middle-income countries is mostly lower than the WHO target of 200-500 ADR report per 1,000,000 per year. A study by Bello reported that adverse drug reactions are underreported in Sokoto, due to lack of physicians' awareness of channels for reporting. Out of 70.5% physicians that encountered potential ADRs in the past 12 months preceding that study only 7.0% of these were reported. About 95.1% of the respondents were unaware that the ADR system existed (ShaibuOricha Bello & Umar, 2011a).

Even though some health professionals in some health facilities may have high knowledge on ADR systems and reporting, the ADR reporting rate remains low. For instance, a study in

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Kuwait government hospital showed high knowledge (61.5%) of pharmacists on ADR reporting. However, the reporting rate in that same facility was only 26.8%. Adverse drug reactions may be seen but not reported. It is important that studies be conducted to answer the question why ADRs are under reported or not reported at all. Some studies revealed that the main reason for under reporting ADRs was not knowing how to report (68.9%) (Alsaleh, Alzaid, Abahussain, Bayoud, & Lemay, 2017). It therefore means that the existence of the ADR reporting system alone is not enough to improving the reporting rate. Creating awareness about the system and training those who are expected to use it are necessary for the system to achieve its purpose of prompt detection and reporting.

The situation of adverse drug reaction reporting in developing countries was assessed using Ghana as a case study. The study was conducted among Ghanaian doctors in the Greater Accra region. Findings from that study indicated that 59.5% of the doctors had seen suspected cases of ADR in the preceding twelve months. Only 20% however reported it by completing the ADR reporting form. It further found training and knowledge of the ADR reporting system to be associated with the likelihood of reporting ADR (Sabblah, Akweongo, Darko, Dodoo, & Sulley, 2014).

The Food and Drugs Authority of Ghana (FDA) is the National Pharmacovigilance Centre that coordinates Pharmacovigilance activities in country. The safety monitoring unit of the FDA is mandated to ensuring continual monitoring of the safety of products regulated under the Public Health Act, Act 851 by analyzing the adverse events reports and taking appropriate regulatory actions when necessary. It is also responsible for creating awareness and educating health professionals and the general public on the need to monitor and report adverse events

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to medicines and other products regulated by the Food and Drugs Authority (H. Hilda Ampadu et al., 2018).

1.2 Statement of the problem

Spontaneous reporting of adverse drug reactions by healthcare professionals help identify rare and unknown effects of drugs which may have been missed during pre-registration clinical trials. It is a very important and affordable means of pharmacovigilance in the general population which helps to identify ADRs in particular populations (Kumar & Khan, 2015).

In Africa, reporting of Individual Case Safety Reports (ICSRs) is extremely low compared with the rest of the world. The cumulative number of ICSRs from Africa to VigiBase was 103,499 representing 0.88% of the global total number of ICSRs in VigiBase in 2015 (Haggar H. Ampadu et al., 2016).

Ghana recorded 14 ADR per 1,000 000 population by healthcare professionals in 2012 which is lower than the WHO annual target of 200 to 500 per 1,000,000 population. Pharmacists reported about 56% of the total ADRs. (Darko, Mimi Delese, 2013).

Adverse drug reaction reporting that was originally limited to physicians has been widened to include other health professionals who are involved in the care of patients. This was to allow for the detection of full spectrum of adverse reactions related to pharmaceutical treatments (World Health Organization, 2002).

The FDA initiated innovation such as institutional contact persons, introduction of online reporting system known as the SafetyWatch System and training of health staff on ADR reporting to improve pharmacovigilance activities (Pharmacovigilance & Management,

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2018). This study was therefore conducted to assess health professionals' ADR reporting in the Lawra Municipal Hospital.

1.3. Objectives of the study

1.3.1 General objective

To assess adverse drug reaction reporting among health professionals in the Lawra Municipal Hospital.

1.3.2 Specific objectives

To determine the adverse drug reaction reporting rate of the hospital

To ascertain the proportion of adverse drug reactions reported by health professionals

To assess the level of knowledge of health professionals on adverse drug reaction procedures

To determine the systemic challenges with adverse drug reaction reporting

1.4 Research questions

The study sought to find answers to the following sub-questions;

1. What proportion of health professionals ever reported adverse drug reaction?
2. What do health professionals know about the reporting system?
3. What are the systemic challenges with ADR reporting?

1.5 Justification

The WHO target for ADR reporting is 200 per 1,000,000 population per year. Studies showed that Ghana never met this target since the introduction of the ADR spontaneous reporting

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system. Though Ghana has made strides in ADR reporting the past years, no health facility's contribution in the Upper west region has been showcased in research. It is important to continue to assess ADR reporting after the introduction of strategies by the FDA to improve ADR reporting in Ghana to improve the ADR reporting rate (Ghana Food and Drugs Authority, 2018).

Moreover, no study has been conducted regarding ADR reporting in the Lawra municipal hospital and the Upper west region at large before and after the FDA interventions in improving ADR repoting. This study is therefore necessary to ascertain the ADR reporting rate and knowledge of health professionals on ADR reporting procedures in the Lawra municipal hospital.

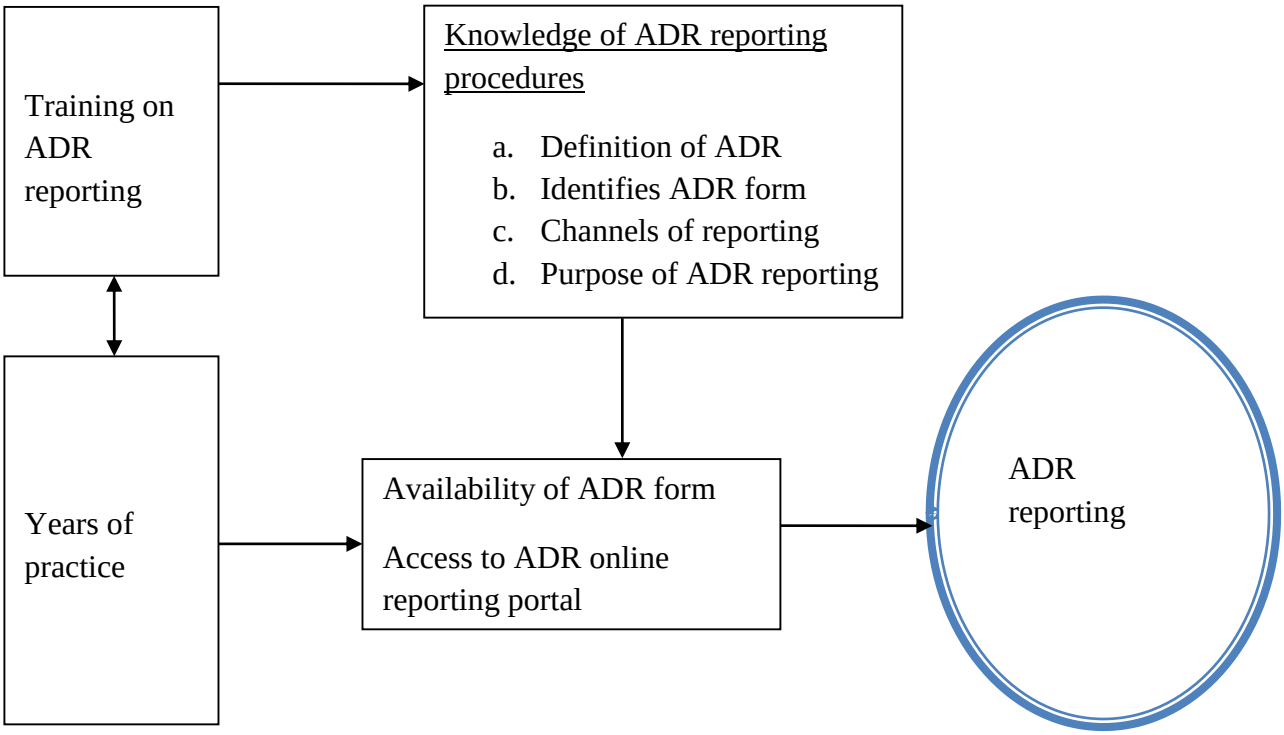

Figure 1: Conceptual framework

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The rate of reporting untoward drug reactions is dependent on the understanding of health professionals about the existence of the ADR reporting system and procedures in the Lawra municipal hospital. Training of health professionals will increase their knowledge of ADR reporting. The number of years of practice will offer the opportunity to be exposed to training on ADR reporting or otherwise. Those who serve longer could have higher chance of ever benefiting from ADR training that will further increase their knowledge and contribute to increased ADR reporting rate. Long service could also influence exposure to client with ADR and will directly increase reporting rate. Training, level of knowledge and exposure to clients with ADR will not directly affect ADR reporting. Availability of the ADR reporting forms and access to the online reporting portal are necessary to aid the reporting of ADR.

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CHAPTER TWO

2.0 LITERATURE REVIEW

2.1. Introduction

This chapter reviewed studies that have already been carried out regarding pharmacovigilance and adverse drug reaction across the globe.

2.2. Burden of ADR

A cross sectional survey conducted in four hospital in South Africa on mortality from adverse drug reactions in adult medical inpatients found that ADRs contributed 2.9% of total death of patients admitted to the adult medical wards. The overall mortality rate in the study wards was 18 per 100 (Mouton et al., 2015).

Another study on the incidence of ADR reporting and its associated factors in the Tuolouse University hospital revealed that 8.37% of adult admissions were due to ADR (Olivier et al., 2009). A nationwide study in Spain on the burden of ADR showed that 1.6% of all acute admissions was due to adverse drug reaction with more than 5% mortality (Carrasco-Garrido, De Andrés, Barrera, De Miguel, & Jiménez-García, 2010).

Further studies also found that out of 624 adult patients admitted in Lagos State University Teaching Hospital, 10.7% experienced adverse drug reactions (Aderemi-Williams, Awodele, & Boyle, 2015). Another study in UK revealed that the incidence of Medicine-Related Harm (MRH) hospital readmission was 78 per 1000 discharge. The study estimated an annual cost of £396 million to the National Health Service for treating medicine related harm (Parekh et

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al., 2018). In some literature, it is estimated that management of ADRs may cost 30.1 billion dollars annually in the USA (Sultana, Cutroneo, & Trifirò, 2013).

A recent World Health Organization Upsala Monitoring Center report indicated that, globally up to 11% of unplanned hospital admissions are associated with medicine harm. The elderly are the most susceptible and contributed 70% of the of the patients admitted with ADR (Pidm, 2019).

The WHO has classified ADRs into six main categories including certain, probable, possible, unlikely, conditional and un-assessable based on the mechanism of the reaction. These classifications are necessary for the treatment or management of the ADRs (Nourbakhsh & Vaez, 2015).

2.3 History of Spontaneous ADR Reporting

In 1963, the Sixteenth World Health Assembly adopted a resolution reaffirming the need for early action on the fast dissemination of data on adverse drug reaction and leading to the creation of the International Drug Monitoring Programme (PIDM) by the World Health Organization. The program created processes in member states for collecting Individual Case Safety Reports (ICSRs) and evaluating them with the reports kept in a central database, managed and maintained by the Uppsala Monitoring Center (UMC) in Sweden. The UMC works with WHO's policy guidelines to serve the significant purpose of contributing to the work of national drug regulatory authorities and other appropriate stakeholders by enhancing understanding of medicines' safety profiles. (Venulet & Helling-Borda, 2010).

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Ghana joined the WHO (PIDM) as the 65th member in 2001 and the first country in West Africa with FDA as the pharmacovigilance center in Ghana. In 2015 however, the membership of African countries in the PIDM increased to 35. The global membership with the PIDM continues to expand as they were 159 countries in total (*DevelopmentsofPVatUMC20152017.pdf*, n.d.).

Besides the collection and analysis of case report of ADRs, the Uppsala Monitoring Centre (UMC) is also involved in making regulatory choices based on reinforced signals and alerting healthcare practitioners, suppliers and the general public to current adverse reaction threats. The Center relies on health professionals who observe ADRs to report by filling the blue ADR reporting form that is made available at the various health facilities and downloadable from the FDA website. The FDA routinely sends reports to healthcare professionals on pharmacovigilance. These include analysis of submitted ADR reports, issues concerning safety of medicines available on the Ghanaian markets when necessary (FDA, 2016).

2.4 Communication channel for ADR

Information dissemination among the various stakeholders and the general public regarding pharmacovigilance and ADR reporting remains vital in awareness creation and early detection of suspected harm from medicines. Various communication channels have been identified and used as part of the communication system for pharmacovigilance to share relevant information on ADR. In Ghana, safety newsletters or bulletin, web alert, radio/TV interviews, phone calls, among others are currently mostly used to disseminate medicine safety information (Gwira & Board, 2014).

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In terms of reporting, it is allowed for health professionals to report directly to the FDA. For better coordination however, health professionals report to an Institutional Contact Person (ICP) for pharmacovigilance for onward submission to the FDA. ICP are nominated to report directly to the FDA (FDA, 2016).

The WHO through the Uppsala Monitoring Centre recommends the involvement of all health professionals (specialists, pharmacists, dentists, midwives, nurses and other health professional who may prescribe or administer drugs) in reporting of adverse drugs events encountered during their practice (UMC 2000).

2.5 Reporting rate of adverse drug reaction

A study conducted to document the knowledge, attitude and practices of pharmacists toward pharmacovigilance and ADR reporting and to explore the barriers to implementing a fully functional PV programme in Kuwait revealed that only 26.8% of participants had previously reported an ADR (Alsaleh et al., 2017). The ADR reporting by health professional was found to be 0.65% in Yaoundé, Cameroon (Phillips et al., 2014).

In Nigeria out of 61 physicians that were interviewed in a study, 43 (70.5%) had encountered potential ADRs in the 12 months before the study but only 3 (7.0%) of these were reported (ShaibuOricha Bello & Umar, 2011b). Another study on ADR reporting among health workers in tertiary hospital in Nigeria also showed a 35.9% ADR reporting rate (Fadare, Enwere, Afolabi, Chedi, & Musa, 2011).

Nurses knowledge, attitude and practices towards pharmacovigilance was assessed in Western Indies. The study concluded that though attitude was good (93.7%), ADR reporting (55.3%)

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and awareness (13.5%) among respondents was limited relative to the attitude (Obi, Campbell, & Gossell-williams, 2018).

According to the 2017 DrugLens issue 5, the Ghana National Pharmacovigilance Centre received highest number (1,607) of spontaneous reports in the history of ADR reports (Yu et al., 2016).

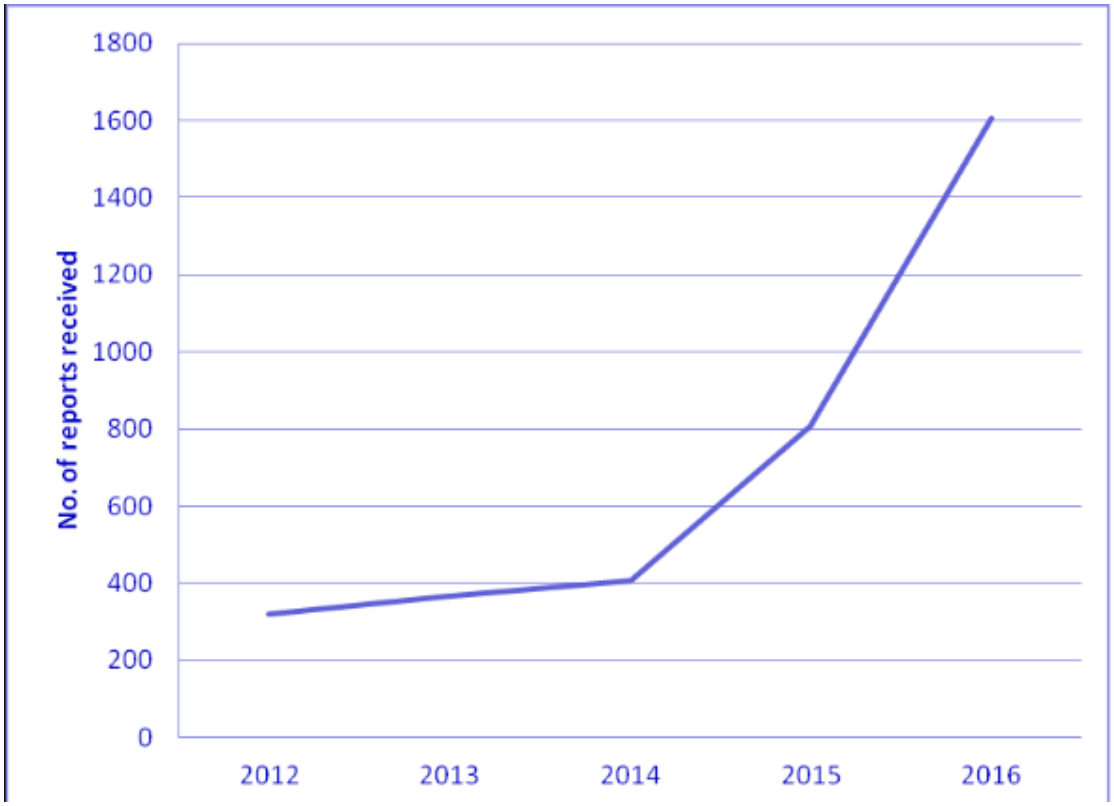

Figure 2: Number of adverse event reports received from 2012 to 2016
Source; DrugLens issue 5 pg3, 2017

The areas of Upper West and Upper East regions submitted the highest number of suspected ADR reports per 1,000,000 inhabitants in 2016. This was largely due to a public health program known as the Seasonal Malaria Chemoprevention (SMC) in these two regions (Yu et al., 2016). Figure 3 has the summary.

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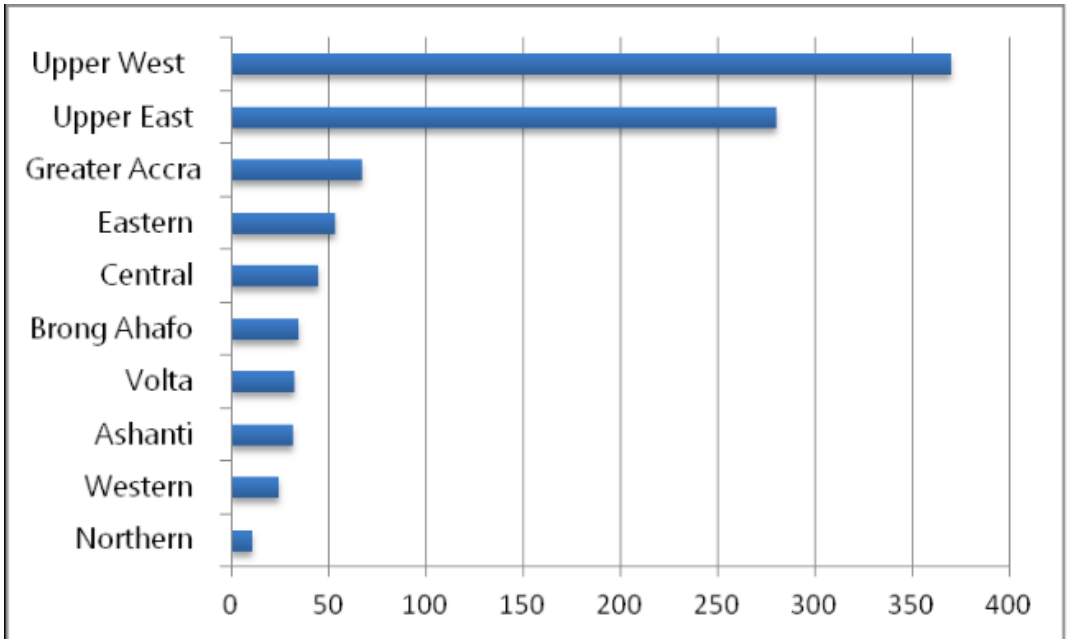

Figure 3: Reports received from Regions per 1,000,000 inhabitants in 2016
Source; DrugLens issue 5 pg3, 2017

Though ADR reporting rates in developing countries is generally low, the situation is different in some other countries like Italy. In 2010, 300 ADRs per 1000000 population was recorded. This was in excess of the WHO annually target for reporting ADR per country (Leone, 2017).

Patients reporting to the health professionals cannot be over overlooked in meeting the annual target of ADR reporting over the world. A five-year study in Italy on the trend of ADR reporting by patients to general practitioners found 11.02 ADRs per 100 consultations. It also found that more women (58%) report ADRs than the men (38.9%) (Leone, 2017)

2.6 Reasons for low reporting

It is established by earlier studies (Charles, 2017) that there is underreporting of ADR. Several reasons or factors could be responsible for that. For instance, it was found in a study

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that70.4% of respondents did not report ADR due to the absence of the ADR forms. The same study further revealed that 24.8% of the study participants were ignorant about the type of ADR to be reported and hence did not report. One other reason given for not reporting was mildness of the observed effect and the uncertainty of the diagnosis (Charles, 2017)

In other studies, the major reason found for underreporting suspected ADRs was not knowing how to report (68.9%). Other impediments that were documented included lack of awareness, poor collaboration and communication among healthcare workers (Alsaleh et al., 2017).

In the United State of America, a survey of health professionals on Adverse Drug Event (ADE) reporting revealed that majority (66%) of the participants lacked time to report ADE. About 53% indicated poor integration of the ADE reporting system and 52% said uncertainty of the reporting procedures accounted for the underreporting of ADEs (Stergiopoulos, Brown, Felix, Grampp, & Getz, 2016).

A related study conducted in Jordan at a comprehensive cancer center found that, lack of training (37.58%) was the major reason for low reporting of adverse drug reaction among physicians and nurses. Other reasons that the study documented were insufficient time and not knowing the rules for reporting ADRs. Among pharmacists the lack of feedback on previous ADR reported was the major barrier to ADR reporting (Kadam, 2017). The research was undertaken to evaluate health professionals ' understanding, attitude and practices of pharmacovigilance.

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2.7 Knowledge of ADR reporting procedures

A study conducted to assess the knowledge, attitude and practices among pharmacists working in secondary and tertiary governmental hospitals towards Pharmacovigilance (PV) and ADR reporting and to explore the barriers to the implementation of a fully functional PV program in Kuwait found that the presence of an ADR reporting system was known to only 7% of pharmacists (Alsaleh et al., 2017).

A study conducted in Sokoto found that about 95.1% of the physicians were not aware that an ADR reporting system was available in Sokoto. It also revealed a staggering lack of awareness of ADR reporting channel in by majority of the physicians interviewed (ShaibuOricha Bello & Umar, 2011b) .

In Ghana a study conducted in the Volta Regional Hospital on Pharmacovigilance Practices among health professionals revealed that majority of doctors, pharmacists, and nurses (83.3%, 100%, 76%) knew about the ADR reporting and monitoring systems in the country. The same study found that most doctors, pharmacists and nurses (93.3%, 93.3% and 78%) also knew the tools for reporting ADR and where to report it (Amedome SN, 2017).

2.8. How to improve adverse drug reaction reporting

Reviewing the efficiency of ADR reporting schemes and good creative methods of improving them is very crucial. Efforts of the Ghana FDA in improving ADRs reporting rate and ensuring patient safety cannot be overemphasized. Ghana was the first country in Africa to collaborate with the WHO Collaborating Center for advocacy and training in pharmacovigilance to train the first batch of Qualified Persons for Pharmacovigilance. The FDA has further introduced the Patient Engagement Medicine Safety program in 2016 with

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the aim to encourage patients report issues with their medical products at various Patient Safety Centers (PSC) through community pharmacists. Also the pharmacy council in 2018 as part of measures to mandate pharmacists take part in the patient engagement in medicine program, began the award of Continuous Professional Development (CPD) points to Pharmacists who submit Safety report (Pharmacovigilance & Management, 2018).

Training program for Medical Doctors on Pharmacovigilance in Promoting Patient Safety has also been introduced by the Food and Drug Authority. The Ghana Medical and Dental Council has accredited the training program and to award 3 CPD points. The objective is to enhance signal generation and improve the ADR reporting rate in Ghana (Pharmacovigilance & Management, 2018).

The technological advancement in the health sector could have been introduced as a measure to improving ADR reporting across the globe. A systematic literature review on improving ADR reporting concluded that the use of electronic health information in conjunction with other ADR reporting techniques could enhance effectiveness and precision (Molokhia, Tanna, & Bell, 2009).

An ecological study in Portugal to promote the use of hyperlink and online form in ADR reporting found that hospitals with hyperlink access median ADR reports per month significantly increased from two to five reports. It further revealed that the median of ADR reports per month using the online form also increased significantly from one before the intervention to four after the intervention. The study concluded that the inclusion of hyperlinks to online ADR reporting forms is an easy and cost-effective way to change health

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professional behavior regarding spontaneous ADR reporting (Ribeiro-Vaz, Santos, Da Costa-Pereira, & Cruz-Correia, 2012).

A systematic review of the use of information systems to promote ADR reporting showed that the use of a web-based software doubled the number of ADRs reported. It concluded that it would be an efficient method to develop electronic based systems to assist healthcare professionals increase ADR reporting rate (Ribeiro-Vaz, Silva, Costa Santos, & Cruz-Correia, 2016).

In Europe, two digital tools for reporting ADRs and broadcasting safety tips about medical products were explored, a mobile phone and the social media. Three mobile apps were developed and launched as part of the WEB-RADR (Recognizing Adverse Drug Reaction) to improve pharmacovigilance (Pierce et al., 2019).

Motivation health staff may be a factor in ADR reporting and pharmacovigilance as a whole. A study on incentives to improve ADR reporting practices and pharmacovigilance portrayed that, education and training of undergraduates and continuous education of healthcare professionals will motivate them report ADRs during real life practice in their various disciplines (Güner, 2017).

Patient education on the need to report ADRs to health practitioners is a significant factor in ADR reporting. A United Ara research disclosed that majority (82.1%) of participants endorsed the opinion that entreating patients to report ADRs to pharmacists was relevant to the pharmacovigilance system (Pharmacists & Qassim, 2014).

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CHAPTER THREE

3.0 METHODS OF THE STUDY

3.1. Introduction

This chapter describes systematically how the study was conducted to answer the research questions. It is organized under ten thematic areas; the study design, study area and setting, the study population, sampling, data collection tool, variables, data analysis, inclusion and exclusion criteria, quality control and ethical clearance.

3.2 Study design

A cross-sectional descriptive approach was employed to undertake the study among health professionals in the Lawra municipal hospital using structured questionnaire to collect quantitative data. The type of data collected was tightly pre-specified on the questionnaires before the data collection. It focused on pre-defined variables to be measured.

3.3 The study area/setting

The study was conducted in the Lawra municipal hospital of the Upper West region of Ghana. Lawra was one of the districts that was elevated to the status of a municipality in March 2018. The hospital was established in 1928 with a current total bed capacity of one hundred and ten (110) and three hundred and five (305) staff population. It is the only referral hospital in the municipality that receives referrals from 21 other health facilities. It also serves as the primary contact for clients within the Lawra Township. It serves a projected population of sixty-four thousand five hundred and forty-three (64,543). The municipality also has one polyclinic, five health centers and eighteen functional CHPS zones that provide clinical and preventive health

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care services. There is a nursing training college where students are taught pharmacovigilance and medicine safety. Fourteen over-the-counter medicine shops also sell medicines to the populace. The hospital provides varied health services including, major and minor surgeries, outpatient services, inpatient services, obstetric and gynaecological services, reproductive and family planning services, immunization services, counseling and testing for HIV, laboratory services among others. These services are provided in the various units such as surgical, maternity, children, male and female wards, emergency, outpatient department among others. The hospital shares borders with Jirapa to the South and East, Burkina Faso to the West and Nandom to the North. The Lawra municipal hospital was chosen as the study site because it has the highest staff capacity in the municipality that could volunteer information about ADR reporting. It also always records and has recorded the highest outpatient and inpatient attendance of 32,774 and 6,844 respectively in 2018 among whom ADR cases could be seen by health professionals. As a referral facility, it is expected to have an ADR reporting system that forms an aspect of my study (Lawra Municipal Hospital, Annual report, 2018. unpublished).

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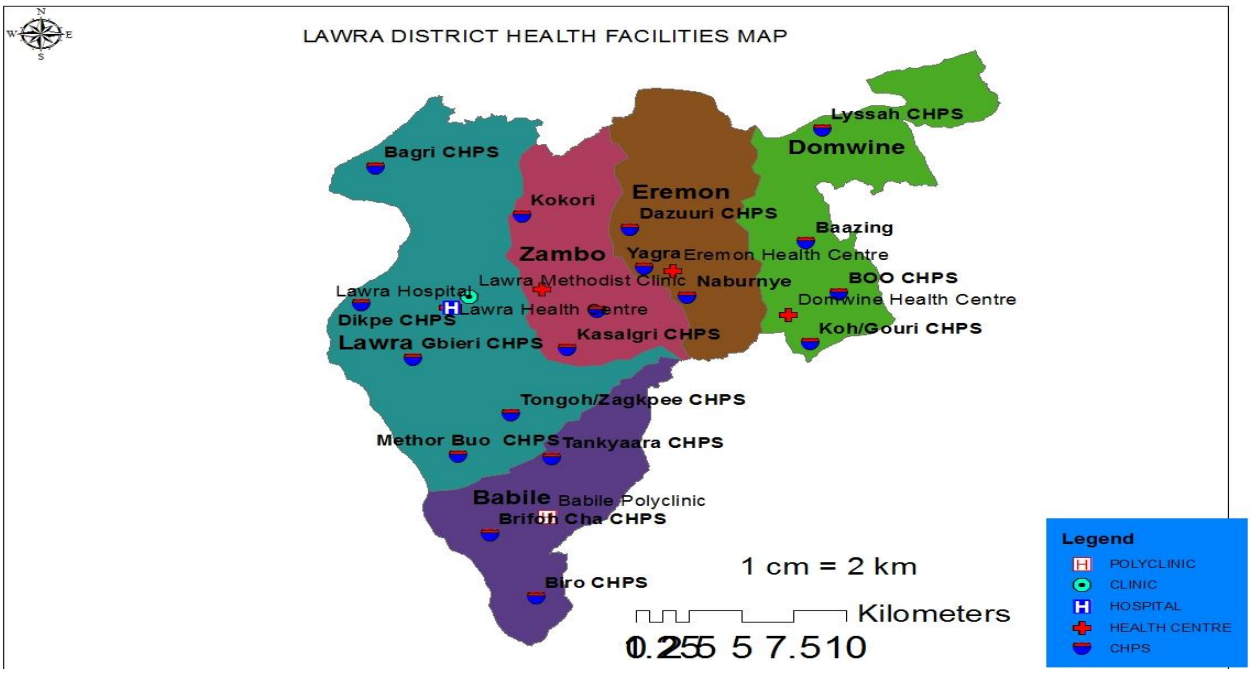

Figure 4: Health facility map of Lawra Municipality

3.4 The study population

The study population was health professionals in the Lawra municipal hospital. These include nurses, prescribers, midwives and pharmacy staff who practiced in the hospital for the past twelve months at the time of the conduct of this study. At the time of conduct of this study, the hospital had a staff strength of 305 as categorized in Table 1

Table 1: Human resource population of the Lawra municipal hospital, 2018

Cadre	Frequency	Present at time of studies
Prescribers (doctors and physician assistants)	9	9
Pharmacy staff (pharmacist, pharmacy technicians and dispensary assistants)	13	13
Nurses	170	163
Midwives	40	35
Paramedics	18	18
Casuals	55	55
Total	305	293

Source; Lawra Municipal Administrative Records, 2019

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3.5 Inclusion and exclusion criteria

Prescribers (doctors and physician assistants), pharmacy staff (pharmacist, pharmacy technicians and dispensing assistants), nurses and midwives who have been involved in clinical care at least twelve months at the time of this study were included. Other cadres and those who were less than a year in clinical practice were excluded. Students and personnel on internship under the categories stated above were also excluded.

3.6 Sampling

3.6.1 Sample size calculation

One hundred and eighty-seven (187) health professionals were estimated to take part in the study. The minimum sample size for the research was calculated using the Cochran, 1963 formula as follows:

$$N = \frac{z^2 p (1-p)}{d^2}$$

Using a 12.7% ADR reporting rate among health professional in in Ghana (Keluarga, 2016), p=0.127

Allowable margin of error (d) is 5% = 0.05

The z value corresponding to a 95% confidence interval= 1.96

The above parameters were substituted into the formula to get the minimum sample size required for the study as follows;

$$N = \frac{1.96^2 (0.127) (1-0.127)}{(0.05)^2} = 170$$

Adjusting for none response rate of 10%, a minimum sample size of 187 was finally obtained.

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3.6.2 Sampling procedure

Simple random sampling was done to select the nurses' cadre of respondents. The investigator visited all the units where the nurses work and folded papers with "YES" and "NO" inscriptions on them. The folded papers were put in a container and presented to prospective respondents to select. Those that selected "YES" during each visit were included in the study. Those that picked "NO" had the chance to be selected in the subsequent sampling procedure. This procedure was done two times in each ward for the period of the data collection. Due to the small numbers of the prescribers, pharmacy staff and midwives, all those that were at post during the period of data collection were all included in the study.

3.7 Data collection method and tools

Structured questionnaires were used as the tools to collect the data. Each questionnaire consisted of five sections. Part "A" covered the socio-demographic data of the respondents, section "B" comprised of nine knowledge questions with two options of "YES" for having knowledge and "NO" for not having knowledge on ADR reporting, section "C" covered the proportion of ADR reported by health professionals, section "D" sought data on challenges of ADR reporting and the last section solicited data on how to improve ADR reporting. Since all respondents were literates, the questionnaires were distributed to participants and clarifications made on questions that respondents did not understand and later retrieved by the principal investigator. Respondents that had time and answered the questionnaires outright were retrieved the same day. Those that could not were given at most 72 hours to answer and return them. Out of 187 questionnaires distributed, 184 were retrieved giving a respond rate of 98.3%. Data was collected from 19th to 30th June, 2019.

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3.8 Variables

The outcome variable of the study was the ADR reporting in the hospital. The independent variables were training, knowledge, availability of ADR forms, access to the online reporting portal for ADR, years of practice, feedback and incentives for ADR reporting.

Level of knowledge was measured using the total score of nine responses. Seven to nine "YES" responses was graded high knowledge, 5-6 "Yes" was graded moderate knowledge and 1-3 "YES" was considered low level of knowledge about ADR reporting.

3.9. Quality control

The questionnaires were pretested at the Babile Polyclinic though no changes were made apart from few typographical errors that were corrected. Validity of the design of the questionnaire was guided by literature and the research objectives. No data collection assistant was recruited. Participants that were busy and could not immediately answer the questionnaire were given maximum of three days to return the answered questionnaire.

3.10 Data analysis

The unit of analysis was the cadre of health professionals. Questionnaires were sorted and screened for errors. Data were first entered into Microsoft Excel, cleaned and coded before being exported to STATA software version 15.0 for analysis. The characteristics of respondents such as age was described in mean and standard deviation. All background characteristics were also summarized and presented in frequencies and percentages. The outcome variable was described in frequencies and proportions.

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3.11 Ethical issues

The Ghana Health Service Ethics Committee granted approval [GHS-ERC039/05/19] for the conduct of the study. Written permission was obtained from the Lawra municipal hospital management to use the hospital as the study site and their health professionals as the study participants. Participants read and signed a consent form that had the investigator's name, the tittle of the study and the purpose as an indication of their free will to participate in the study. Data collection tools were anonymous of respondents' names. Explanations were given in areas participants did not understand. Participants reserved the right not to respond to any of the questions and to withdraw from the research at any point even after consenting to participate in the study. There were minimal risks associated with the study and no compensations were paid to participants. The study was purely an academic research devoid of conflict of interest. Therefore, the findings are the real reflection of ADR reporting practices by health staff at the Lawra municipal hospital.

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CHAPTER FOUR

4.0 RESULTS

This study was conducted to assess adverse drug reaction reporting among health professionals. The result is presented in six sections, background characteristics of health professional, knowledge on ADR reporting, proportion of ADR reported by health professionals, systemic challenges with ADR reporting and ways to improve upon it.

4.1 Background characteristics of respondents

A total of 184 health professionals took part in the study. Table 2 shows that most health professionals were within 30-39 age category representing 47.28% (n=87) of the total respondents. The 20-29 age category formed 43.48% (n=80). The least age group (9.24% n=17) was those that were 40 years and above. A little over half (51.09% n=94) were females with the males forming less than half (48.91 n=90). Over half of them were married (54.89% n=101) while the rest were not married. Out of the one hundred and eighty-four participants, more than half (69.02%, n=127) were nurses, 19.02% (n=35) midwives, 7.0% (n=13) pharmacy staff and the least being prescribers (4.89%, n=9). More than half of the health professional were very young in practice with 1-3 years work experience and constituted 56.83% (n=104) of the total respondents. A good number (n=41, 22.40%) had also worked for 4-6 years while very few of them representing 2.73% (n=2) had worked for sixteen or more years at the time of this study.

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Table 2: Background characteristics of respondents

Variable name	Frequency (n=184)	Percentage (%)
Age (years)		
20-29	80	43.48
30-39	87	47.28
>=40	17	9.24
Sex		
Male	90	48.91
Female	94	51.09
Marital status		
Not married	83	45.11
Married	101	54.89
Cadre of staff		
Prescribers	9	4.89
Pharmacy staff	13	7.07
Nurses	127	69.02
Midwives	35	19.02
Years of practice		
1-3	104	56.83
4-6	41	22.40
7-9	21	11.48
10-15	12	6.56
>=16	5	2.73

4.2 ADR reporting

The summary in Table 3 shows that 96 (52.17%) of health professionals ever encountered a patient with suspected ADR in the past twelve months. Out of 96 participants who saw ADR cases, more than half (68.75%, n=66) reported it by completing the ADR form while a little above quarter (31.25%, n=30) however did not report.

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Table 3: Proportion of adverse drug reaction reported by health professional

Variable Name	Frequency (n=184)	Percentage (%)
Ever seen a patient with ADR for the past one year		
No	88	47.83
Yes	96	52.17
Ever reported ADR	**(n=96)**	
No	30	31.25
Yes	66	68.75

In figure 5, over 50% (n=96) of all cadres of health professionals except midwives ever saw a patient with adverse drug response in the past twelve months. More prescribers (88.89%, n=8) than pharmacy staff (69.23%, n=9), nurses (51.18%, n=65) and midwives (40%, n=14) ever saw adverse drug reaction cases at the time of this study. More than 60% (n=66) of all cadres reported the ADR they saw. The proportion among the pharmacy staff was highest (88.89%, n=8) and that of the nurse was lowest (63.08% n=41) relative to the other cadres.

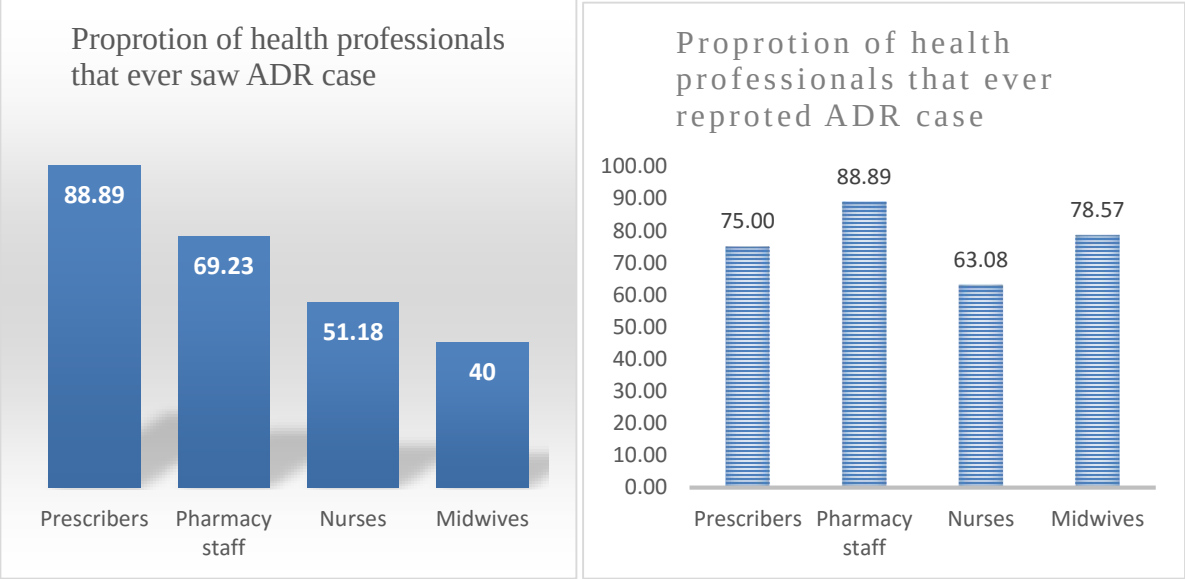

Figure 5: Proportion of ADR seen and proportion reported by cadre

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In figure 6, 106 (64.4%) out of 162 adverse drug reaction cases seen for the past one year were reported by participants using the ADR forms. The remaining 58 (31.6%) were not reported.

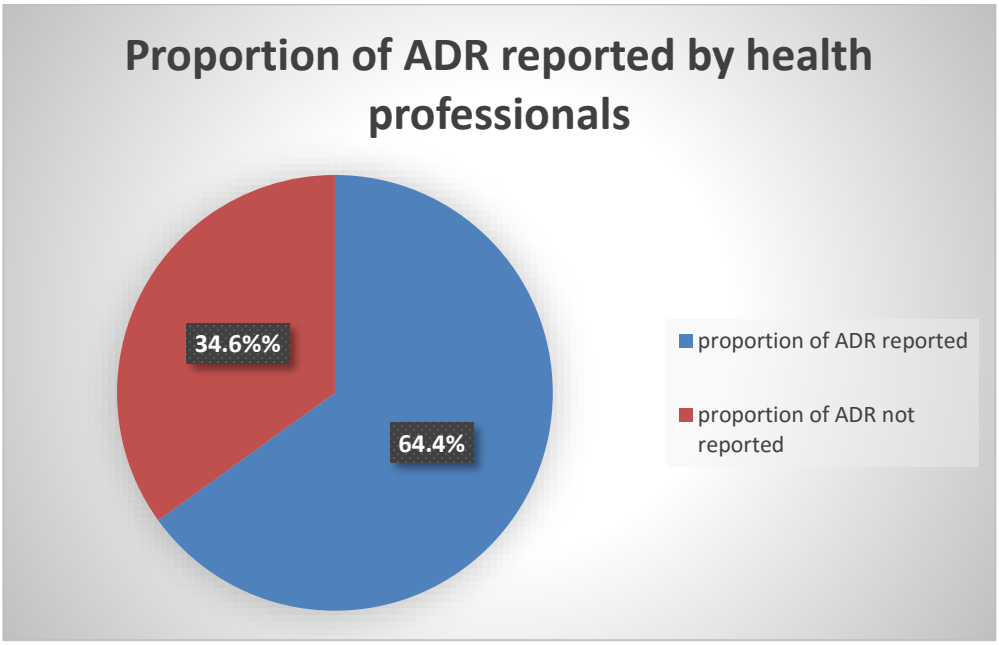

Figure 6: Proportion of total ADRs reported

Respondents ascribed different reasons when they were asked the question why some ADR cases were not reported. The most (33.33%, n=16) cited reason for not reporting ADR was non-availability of the ADR forms followed by not knowing the reporting procedure (31.25%, n=15). About 19% (n=9) indicated that they did not report because they considered the reaction to be normal and commonly associated with that medicine. Almost 15% (n=7) said they did not know they were supposed to report it. Not thinking that the ADR reporting was important or serious was not a reason for non-reporting. The least (2.08%, n=1) reason for non-reporting was lack of time.

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Table 4: Reasons for not reporting adverse drug reaction

Reasons for not reporting ADR	Frequency	Percent
I did not know I was supposed to report	7	14.58
The reporting form was not available	16	33.33
I do not know the reporting procedure	15	31.25
I did not have time to report	1	2.08
I did not think it was important/serious	0	0.00
I considered it "normal because it is a common reaction with that medicine	9	18.75

4.3 Knowledge on adverse drug reaction reporting

The summary in Table 5 and 6 regarding the knowledge on ADR reporting procedures portrayed that majority (96.20%, n=177) of respondents ever heard of adverse drug reaction reporting in Ghana. More prescribers (100%, n=9) and pharmacy staff (100%, n=13) than the other cadres heard about ADR reporting in Ghana and also knew that all health professionals are obliged to reporting ADRs. Midwives were the least (97.14%, n=34, 82.86, n=29) that heard of the ADR reporting in Ghana and also knew that ADR reporting is a professional obligation to all health professionals. Cumulatively, 63.04% (n=9) of total respondents knew the tools for reporting ADR in Ghana. By cadre, all pharmacy staff (13) knew the ADR reporting tools while 88.89%, 57.48% and 74.29% of prescribers, nurses and midwives respectively also knew the ADR reporting tools. Moreover 66.30% knew the types of ADR to be reported. In terms of reporting procedure, 59.24% knew where to obtain the ADR forms. More prescribers (88.89%) knew where to obtain the ADR forms compared to the pharmacy

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staff (69.23%), nurses (64.57%) and midwives (58.57%). About 55.9% knew the information to put on the ADR form. Also, 59.24% knew where to submit the filed forms. Almost 90% of prescribers knew where to return the filed ADR form to but fewer nurses (52.76) relative to the other cadres knew where to submit the filed ADR form. Generally, as much as 98.37% thought it was necessary to report ADRs and 89.69% knew the reasons for reporting them. By cadre, all prescribers and pharmacy staff thought it necessary to report ADRs and knew the reasons for reporting.

Overall, more than half (58.15%, n= 107) of respondents had high level of knowledge about adverse drug reaction reporting with those that had low level of knowledge constituting for less than 10% of the total respondents. Moderately, 32.07% of health professionals had knowledge of adverse drug reaction reporting.

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Table 5: Knowledge of health professionals on ADR reporting

Level of knowledge criteria	Positive response Frequency n=184	Percentage (%)
Have you heard about adverse drug reaction reporting in Ghana?	177	96.20
Do you know that all health professionals who directly take care of patients are responsible for reporting ADRs?	152	82.61
Do you know the tools for reporting ADR in Ghana?	116	63.04
Do you know the type of ADRs that are supposed to be reported?	122	66.30
Do you know where to obtain the reporting tools for reporting ADRs in your hospital?	109	59.24
Do you know the information that is required on the ADR form?	103	55.98
Do you know where to send the filed ADR form to?	109	59.24
Do you think it is necessary to report ADR?	181	98.37
Do you know the reason for reporting ADR?	165	89.67
Level of knowledge on ADR reporting		
Low knowledge	18	9.78
Average knowledge	59	32.07
High knowledge	107	58.15

The level of knowledge was measured using the total score of nine responses. Seven to nine "YES" responses was graded high knowledge, 5-6 "Yes" was graded moderate knowledge and 1-3 "YES" was considered low level of knowledge about ADR reporting.

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Table 6: Awareness of respondents on ADR reporting procedures

knowledge questions	Prescribers n=9 frequency (%)	Pharmacy Staff n=13 frequency (%)	Nurses n=127 frequency (%)	Midwives n=35 frequency (%)
Have you heard about adverse drug reaction reporting in Ghana?	9 (100)	13 (100)	121(95.28)	34 (97.14)
Do you know that all health professionals who directly take care of patients are responsible for reporting ADRs?	9 (100)	13 (100)	101(79.53)	29 (82.86)
Do you know the tools for reporting ADR in Ghana?	8 (88.89	13 (100)	75 (57.48)	26 (74.29)
Do you know the type of ADRs that are supposed to be reported?	8 (88.89	10(96.92)	82 (64.57)	22(62.86)
Do you know where to obtain the reporting tools for reporting ADRs in your hospital?	8 (88.89	9 (69.23)	68 (53.54)	24 (68.57)
Do you know the information that is required on the ADR form?	9 (100)	10(96.92)	61 (48.03)	23 (65.71)
Do you know where to send the filed ADR form to?	8 (88.89	9 (69.23)	67 (52.76)	25 (71.43)
Do you think it is necessary to report ADR?	9 (100)	13 (100)	124(97.64)	35 (100)
Do you know the reason for reporting ADR?	9 (100)	13 (100)	114(89.76)	29 (82.86)

Though the level of knowledge was generally high among respondents, further analysis showed that prescribers particularly had the highest (100%) level of knowledge. Nurses had moderate (39.37%) knowledge while midwives had the least of knowledge on ADR reporting procedures with 14.29% compared to the other cadres as shown in figure 7 below.

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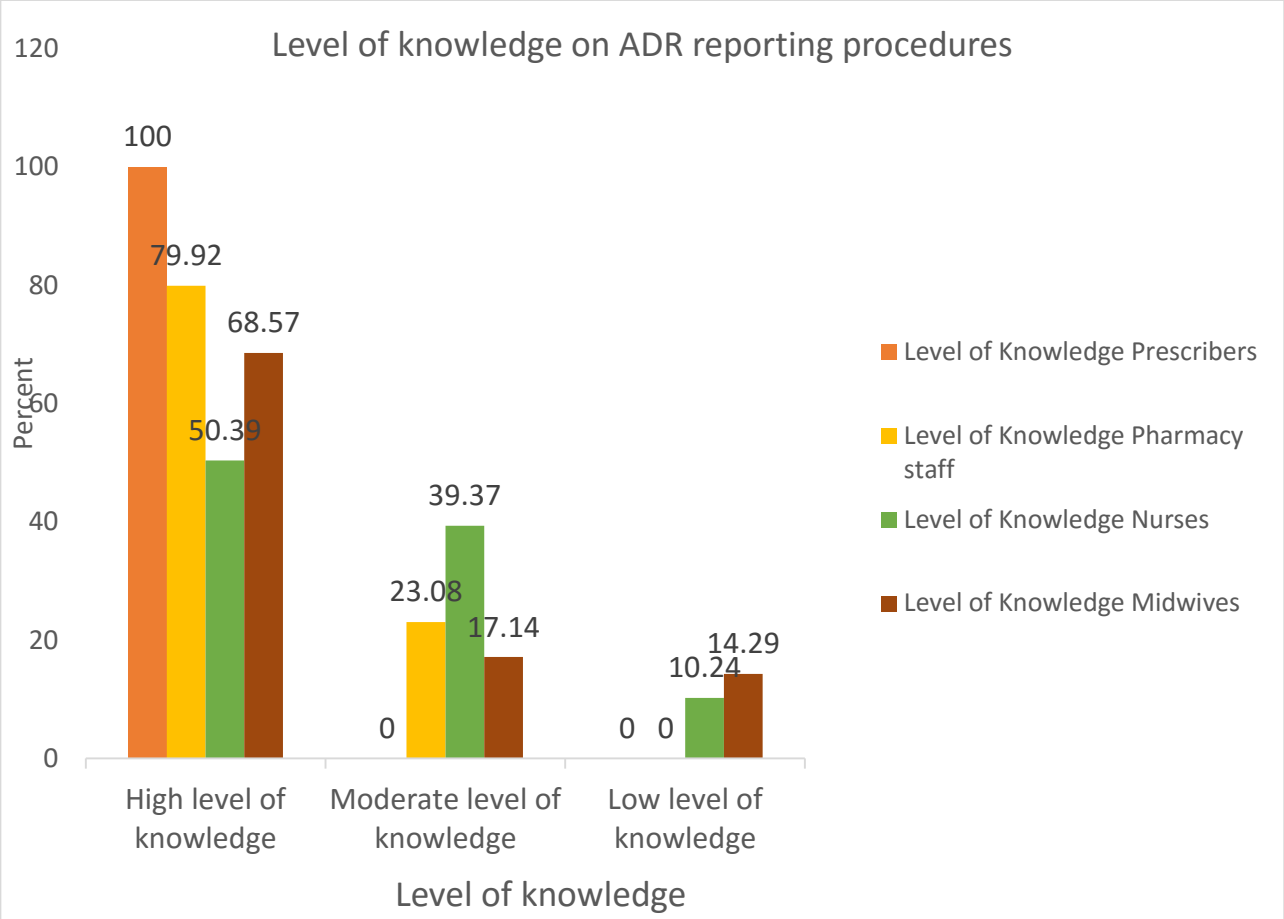

Figure 7: Level of knowledge of health professionals on ADR reporting procedures

4.4 Challenges with ADR reporting

Regarding the question on the challenges with ADR reporting, it was found that lack of access to the internet ADR reporting portal (94.02%), non-availability of the ADR forms (64.69%), lack of training (67.93%), and no extrinsic motivation (35.87) were the major challenges in the Lawra municipal hospital.

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Table 7: Systemic challenges with ADR reporting

Systemic Challenges	Frequency	Percent
Non-availability of the ADR forms	119	64.67
Lack of access to the online reporting portal	173	94.02
Internet connectivity	92	50
No extrinsic motivation	67	35.87
Lack of in-service trainings/orientation on ADR reporting	125	67.93

4.5 How to improve ADR reporting

As shown in table 8, closed to 70% of respondents thought WhatsApp platform should be added to existing ADR channels for ADR. Almost 18% chose E-mail as an additional mode of reporting ADR while very few (15.22%) felt that nothing should be added to the current reporting channels. Majority (83.15%) of respondents indicated that giving phone recharge cards for online reporting will help improve ADR reporting rate. Less than 10% (13) did not know whether giving the recharge cards will improve the reporting rate or not. Closed to 100% indicated that patient education on ADR will further improve ADR reporting. All (100%) respondents said training of health staff will improve ADR reporting rate. As many as 183 (99.46%) respondents further thought that availability of ADR forms is a way of improving ADR reporting whilst only 0.05% didn't think so. The results also showed that a greater proportion (91%) of respondents were of the view that integrating ADR reporting into the monthly cases and deaths (CD1) reporting system for diseases under surveillance will also improve the reporting system of ADR.

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Table 8: Suggested ways to improve ADR reporting

Ways to improve ADR reporting	Frequency (n=184)	Percent
Reporting through WhatsApp platform	123	66.85
Reporting through E-mail	33	17.93
Giving phone recharge cards as motivation report ADR online	153	83.15
Patient education on need to visit the health facility in times ADR	183	99.46
Training of health professionals on ADR reporting	100	100
Availability of ADR forms in all wards	183	99.46
Will integration of ADR into the weekly cases and death (CD1) reporting system improves ADR reporting	169	91.85

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CHAPTER FIVE

5.0 DISCUSSION

5.1. Introduction

The study was conducted to generally assess adverse drug reaction reporting among healthcare workers in the Lawra municipal hospital of the Upper West Region. The results of this study are discussed below.

5.2 Proportion of respondents that ever saw ADR and the proportion that reported

This study revealed that 52.17% (n=96) respondents ever saw cases of adverse drug reaction and out of which 68.77% (n=66) reported them by filling the ADR forms. Among the different cadres, more proportion of prescribers than the other cadres ever saw and reported ADR cases. In contrast, a study conducted in the Volta regional hospital on knowledge and attitude among health professionals on pharmacovigilance found that only 16.7% and 24% of doctors and the nurses had ever reported ADRs by using the Blue form (Amedome , 2017). Further studies by Ekmeci on healthcare professionals' knowledge on pharmacovigilance and ADR reporting behavior and factors determining the reporting rates also found contrasting proportion of ADR reported by healthcare professionals compared to the current studies. About 41% of ADR seen were reported in their study compared to 52 % in the present study (Ekmekci, 2019). The 88.89% (n=8) prescribers that ever saw ADR is in consonance with finding by Dodoo et al., (2014) that showed that more than 50% of doctors ever saw ADR case. The proportion (75.00) of prescribers that reported ADRs from the current study however differs from the 20% that Dodoo et al., (2014) observed in their study. In the Indian

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Maharashtra rural tertiary hospital, more doctors (59%) than nurses (18%) ever reported ADR (Bahekar & Patil, 2018). This is similar to the findings from the present study where more prescribers than nurses reported ADRs in the past 12 months. Only 3% of respondents who ever encountered ADRs in Saudi Arabia actually reported it (Kopciuch, Paczkowska, & Ratajczak, 2019). This is dissociated with the rather high proportion of health professionals reporting ADRs as documented in this study. The high proportion of health staff that saw ADRs and the proportion that reported it in the current study could be due to the high level of knowledge and awareness of the ADR reporting system in the study facility. It could also be due to the presence of an Institutional Contact Person (ICD) in the hospital.

5.3 Proportion of adverse drug reactions reported

This study found that the proportion of the total number of ADRs reported by respondents was high (64.4%). This observation contrasted with earlier findings from Sokoto that showed as low as 7.0% ADR reporting rate by clinicians (Bello & Tukur, 2011). Patients reporting with ADRs to the hospital could account for the high proportion of ADR reported by health professionals in the past 12 months preceding this study. Public health reporting of ADRs from public health programs such as seasonal malaria chemoprevention and mass drug administration in the Lawra municipality might also contribute to the high ADR reporting rate. This is because the hospital staff usually benefited from sensitizations on the importance and how to report ADRs. The seasonal malaria chemoprevention is implemented only in the Upper West Upper East and the Northern regions. The FDA conducted active monitoring during these programs to ensure that all ADRs are reported.

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5.4 Level of knowledge on ADR reporting procedures

Generally, there was high knowledge (58.15%) on ADR reporting across all cadres of respondents. This supports earlier studies by Adosome in the Volta Regional Hospital of Ghana which found that Doctors, Pharmacists and Nurses Prescribers are knowledgeable in pharmacovigilance in Ghana (Amedome, 2017). The 82.61% awareness of the ADR reporting system described in the current study however do not support a 39.6% awareness of healthcare professionals about the domestic pharmacovigilance system documented by Al-Madinah Al-Munawwarah, Kingdom of Saudi Arabia (Ekmekci, 2019). Approximately 70% of pharmacists in Nigeria did not know where to get the ADR reporting forms (Kopciuch et al., 2019). This is not in correlation with findings from the current study where 53.54% of pharmacy staff knew where to get the ADR reporting forms. Studies elsewhere recorded generally poor knowledge in ADR reporting among healthcare professionals contrary to what this current study found (Almandil, 2016). The high level of knowledge on ADR reporting from the present study might be due to the interventions that were instituted by the FDA in 2015 to improve the ADR reporting in Ghana. It could also be due to sensitization of health professionals during public health programs like the mass drug administration and the Seasonal Malaria Chemoprevention (SMC) which staff of the Lawra municipal hospital were part.

5.5 Reasons for not reporting ADR

This study documented varied reasons for not reporting negative drug reactions. Relative to those that saw ADRs but did not report, the major reasons were non-availability of the reporting forms and not knowing the reporting procedure (33.33% and 31.25%). Related

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outcomes were observed in other studies among pharmacists (Pharmacists & Qassim, 2014). Poor stock management of the ADR forms by the institutional contact person for pharmacovigilance might have contributed to the non-availability of the ADR forms. Poor coordination between the hospital institutional contact person and the FDA or the various wards of the hospital could be another factor to the non-availability of the reporting tools. This calls for the FDA to ensure provision of ADR forms to health facilities and the need to continuously orient health staffs on ADR reporting.

5.6 Systemic challenges with ADR reporting

The online reporting portal was not accessible to most (94.02%) respondents and most of them were not trained or oriented on pharmacovigilance though most of them ever reported ADRs. The present study found similarity with a study in Uganda that found 56% of health professionals to have lacked training on ADR reporting (Katusiime, Semakula, Lubinga, & Katusiime, 2015). Qassim also documented related findings among pharmacists (Pharmacists & Qassim, 2014). These observations may be attributed to the fact that the ADR system is still developing and the hospital has not assumed full responsibility for pharmacovigilance activities. It could also be due to inadequate policy direction or dissemination on making ADR reporting an integral part of the health system.

5.7 Ways to improve ADR reporting

Respondents' perspective of how to improve ADR reporting was through training (100%), patient education (99.46%) and ensuring the availability of ADR forms (99.46%). Patients that were aware and knew about ADR reporting system actually reported the ADRs they

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experienced to health professional (Jacobs, Hilda Ampadu, Hoekman, Dodoo, & Mantel-Teeuwisse, 2018).

5.8. Implications of findings for policy and practice

The implication of the findings on policy and practice is that the Pharmacovigilance policy and other policies will achieve their purpose if they are disseminated and implemented. As observed in this study, the high level of knowledge of participants about the ADR reporting systems led to high ADR reporting in the hospital.

5.9 Limitations of the study

The study did not cover all health professional due to financial and time constrains hence sample was drawn from the target population for the study. There could be recall and personal bias by respondents that could have effect on the data and the outcome of this study. Data provided about the number of ADR ever seen and reported could not be independently verified and authenticated. Findings from the study are limited to only the Lawra Hospital and should therefore be interpreted with the above limitations in mind.

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CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The Lawra municipal hospital has high ADR reporting rate. Prescribers and pharmacy staff reported more ADR cases than the nurses and midwives. Most health professionals that saw ADR in the past one year reported it by completing the ADR reporting form. Knowledge on ADR reporting was generally high. The main systemic challenge with ADR reporting was lack of access to online portal on ADR reporting though it was one of the strategies to improve ADR reporting in Ghana. Training and access to the ADR reporting tools are relevant to increasing the current ADR reporting rate of the Lawra Municipal Hospital.

6.2 Recommendations

1. All health professionals in close contact with patient should be given access to the online reporting portal for ADR
2. The FDA should ensure regular training of all clinical cadres of health staff to improve the rate of ADR reporting in hospitals
3. FDA should consider linking the online reporting system to WhatsApp to facilitate reporting of ADR
4. Hospital management should include ADR reporting in the appraisal of its staff to compile them look out for and report ADRs.
5. Future research could be done to evaluate the whole pharmacovigilance system in the Lawra municipality focusing on the minimum requirement and what is currently practiced.

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APPENDICES

Appendix 1: Informed Consent

TITLE OF STUDY: ADVERSE DRUG REACTION (ADR) REPORTING AMONG HEALTH PROFESSIONALS IN THE LAWRA MUNICIPAL HOSPITAL

Introduction: Dear Respondent, I am Kuuridong Alexis Sang-ber, a student of the School of Public Health, University of Ghana. You can contact me on 0203990879/0247559005 or via kuuridong@gmail.com

Background and Purpose of research

Adverse Drug Reaction is a response to a medicinal product which is noxious and unintended including lack of efficacy and which occurs at any dosage and can arise from the use of product within the terms of the marketing authorization. Adverse drug reactions are responsible for considerable morbidity and mortality globally. Spontaneous reporting of adverse drug reactions by healthcare professionals help identify rare and unknown effects of drugs which may have been missed during pre-registration clinical trials.

I am conducting a study on Adverse Drug Reaction (ADR) reporting among health professionals in the Lawra municipal hospital. This study seeks to assess ADR reporting and knowledge of ADR reporting procedures among health professionals in the Lawra municipal hospital of the Upper West Region of Ghana.

Nature of research

The study involves answering a questionnaire on the ADR reporting. I want to ascertain the proportion of adverse drug reactions reported by the various categories of health the professionals in the hospital. This is purely an academic research and forms part of my work for the award of a Master's Degree in public health.

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Participants involvement

Duration /what is involved

The study is a one-month duration. Participants will sign a consent form indicating his/her willingness to take part in the study and will therefore answer a self-administered questionnaire that will last about fifteen minutes.

Potential Risks

There are no potential risks or harm in participating in the study.

Benefits

The results of this study will help identify gaps in ADR reporting and suggest ways to improving it. It will also inform policy makers on the need to maintain or revise the current policy on ADR reporting.

Costs

There will be no cost in participating in the study. No travelling is required. The questionnaires will be given to respondents in the wards or unit to answer**.**

Compensation

There is no compensation for time lost in participating in the study**.**

Confidentiality

Your name is not required on the questionnaire and all information you will provide will be treated highly confidential and used for research purposes. Your responses will not be shared with anybody who is not a member of the study team. Data analysis will be done at the aggregate level to ensure anonymity.

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Voluntary participation and withdrawal

Your participation in this study is voluntary. You have the right not to answer any individual question or all the questions and also to withdraw from the study anytime without any penalty.

Outcome and Feedback

Findings from the study will be disseminated to participants of the study and the hospital management**.**

Funding information

No organization or institution will offer financial support for the studies. I am obliged to all financial matters emanating from this study.

Sharing of participants Information/Data

The results of this study are for academic purposes only. The knowledge I will learn from this study will be shared with the respondents, management of health facilities and the municipal health directorate to enable them institute measures that can promote ADR reporting. I may publish the results for others to learn from.

Provision of Information and Consent for participants

A copy of the Information sheet will be given to you after it has been signed or thumb-printed to keep.

Who to Contact for Further Clarification/Questions

All queries concerning this study should be directed to Kuuridong Alexis Sang-ber

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School of Public Health, University of Ghana

(0203990879/0247559005)

For enquiries about ethical clearance on your right as a participant in the study please contact the Madam Hannah Frimpong, the administrator of the Ghana Health Service Ethic Committee on 0507041223.

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Appendix 2: Certificate of Consent

I acknowledge that I have read the purpose and contents of the Participants' Information Sheet and all questions have been satisfactorily explained to me in a language I understand. I fully understand the contents and any potential implications as well as my right to change my mind (that is withdraw from the research) even after I have signed this form.

I voluntarily agree to be part of this research

Name or Initials of Participant…… ID Code ……

Participants' Signature …… OR Mark (Please specify)…….

Date: …….

INVESTIGATOR'S STATEMENT AND SIGNATURE.

I certify that the participant has been given ample time to read and learn about the study. All questions and clarifications raised by the participant have been addressed.

Researcher's name Kuuridong Alexis Sang-ber

Signature …….

Date…….

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Appendix 3: Questionnaire

SECTION A: DEMOGRAPHIC CHARACTERISTICS OF RESPONDENTS

A1. Sex

a. Male [ ] Female [ ]

A2. What is your age as at your last birth day (completed years**)** ☐☐

A3. What is your marital status?

a. Not married [ ] b. Married [ ]

A4. Which Cadre of staff are you?

a. Prescriber [ ] b. Pharmacy staff [ ]

c. Nurse [ ] d. Midwife [ ]

A5. Number of years of practice ☐☐

SECTION B: LEVEL OF KNOWLEDGE ABOUT ADVERSE DRUG REACTION (ADR) REPORTING

For the set of questions in the table please tick **YES** or **NO** in the appropriate box

No.	ITEMS	CODE	
		YES (1)	NO (0)
B1	Have you heard about adverse drug reaction reporting in Ghana		
B2	Do you know that all health professionals who directly take care of patients are responsible for reporting ADRs?		
B3	Do you know the tools used for reporting ADR in Ghana?		
B4	Do you know the type of ADRs that are supposed to be reported?		
B5	Do you know where to obtain the reporting tools for reporting ADRs in your hospital?		
B6	Do you know the information that is required on the ADR form?		
B7	Do you know where to send the filled ADR form to?		
B8	Do you think it is necessary to report ADR?		
B9	Do you know the reason for reporting ADR?		
	Total score		

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Classification of level of knowledge of ADR reporting

High level of knowledge; 7-9 yes responses

Moderate level of knowledge; 4-6 yes responses

Low level of knowledge; 1-3 yes responses

SECTION C: Proportion of ADR reported by various health professionals

C1. Have you seen a patient with an ADR in the past one year?

a. Yes [ ] b. No [ ]

If "**No",** to question C1 skip to **section D**

C2. If **"YES",** how many cases did you see? .....

C3. Did you report the ADR by completing the form or through online?

a. Yes [ ] b. No [ ]

C4. If **"YES",** how many did you report?

C5. If **"NO"**, why didn't you report**?** (Circle all that apply)

a. I did not know I was supposed to report [ ]
b. The reporting form was not available [ ]
c. I do not know the reporting procedure [ ]
d. I did not have time to report [ ]
e. I did not think it was important/serious [ ]
f. I considered it "normal because it is a common reaction with that medicine [ ]

SECTION D: SYSTEMIC CHALLENGES OF ADR REPORTING

Please indicate by ticking whether each of the statement is a challenge in ADR reporting or not

D1. Availability of ADR forms readily available to you?

a. Yes [ ] b. No [ ]

D2. Do you have the mobile up for online reporting of ADR

a. Yes [ ] b. No [ ]

D3. Internet connectivity

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a. Yes [ ] b. No [ ]

D4. Extrinsic incentive for reporting ADR?

a. Yes [ ] b. No [ ]

D5. In-service trainings or orientation on ADR reporting?

a. Yes [ ] b. No [ ]

D6. Institutional contact person for ADR in this?

a Present [ ] **b. Not present** [ ]

D7. Feedback system for ADR

a. Present [ ] **b. Not present** [ ]

SECTION E: HOW TO IMPROVE ADR REPORTING

Please choose the following by ticking those you think will help improve ADR reporting among health professionals

Q No	Suggested ways to improve ADR reporting	Tick (√)
E1	Reporting through WhatsApp platform	
E2	Reporting through E-mail	
E3	Giving phone recharge cards as motivation report ADR online	
E4	Patient education on need to visit the health facility in times ADR	
E5	Training of health professionals on ADR reporting	
E6	Availability of ADR forms in all wards	
E7	Will integration of ADR into the weekly cases and death (CD1) reporting system improves ADR reporting	

Thank you for your time

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Appendix 4: Ethics Approval Letter