UNIVERSITY FOR DEVELOPMENT STUDIES

ADVERSE EVENTS FOLLOWING IMMUNIZATIONS REPORTING AMONG MOTHERS IN THE TAMALE METROPOLIS

AGNES ALO

UDS/MPH/0038/18

FEBRUARY 2021

UNIVERSITY FOR DEVELOPMENT STUDIES

ADVERSE EVENTS FOLLOWING IMMUNIZATIONS REPORTING AMONG MOTHERS IN THE TAMALE METROPOLIS

A THESIS SUBMITTED TO THE DEPARTMENT OF COMMUNITY HEALTH AND FAMILY MEDICINE, IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF MASTER OF PUBLIC HEALTH DEGREE IN THE UNIVERSITY FOR DEVELOPMENT STUDIES

AGNES ALO

UDS/MPH/0038/1

FEBRUARY, 2021

DECLARATION

Student

I hereby declare that this thesis is my own work towards the award of a Master of Public Health degree and that, to the best of my knowledge it does not contain any material previously published by another person nor material which has been presented for the award of any degree in this university or elsewhere, except for references to other people's which have been appropriately acknowledged.

Name of Student Signature Date

AGNES ALO ……. ……..

Supervisor

I hereby declare that the preparation and presentation of this dissertation was supervised in accordance with the guidelines on submission of dissertation/ thesis laid down by the University for Development Studies.

Name of Supervisor Signature Date

Dr. SAMUEL ZANYA BUGRI …… ……

DEDICATION

This work is dedicated to my lovely husband, Dr. Amadu Issah, and my beloved children.

ACKNOWLEDGEMENTS

Thanks be to the almighty God for making it possible for me to undertake and complete this MPH course successfully. It would be impossible to acknowledge name-by-name of all those who contributed in various ways to the success of this study. However, it is again impossible not to notice the contributions of the following people. I would like to begin by acknowledging the guidance and supervision of Dr. Samuel Zanya Bugri, my hardworking supervisor. He gave me not only the academic skills to survive MPH research but also considerable insight on how to approach life after completion of this course.

I am thankful to the Northern Regional and Metropolitan Health Directorates for the permission to carry out my study in the health facilities in the Tamale Metropolis. To many other friends who became companions in this journey of this work, I express my sense of gratitude. I am grateful to all the respondents within the communities who spent time with me to share their views and thoughts and relevant information, for being indispensable in this work. Finally, to my colleagues at the Department of Community Health and Family Medicine, 2018/2019 academic year group, who shared in my responsibilities, I say thank you all for the friendship and support.

ABSTRACT

Background: Immunization activities are regarded as core components of public health interventions that are geared towards the provision of immunity against vaccine preventable diseases in both developed and developing countries. However, adverse events following immunization (AEFI) has the potential to reduce immunization coverage and confidence in vaccinations. This study was therefore aimed at assessing the adverse events following immunization among mothers and healthcare workers in the Tamale Metropolitan.

Method: A health facility-based cross-sectional study (involving a mixed method approach) was conducted from October 2019 to July 2020 among Bilpeila, Nynohini, Vittin and Tamale Central Health Facilities. A total of 248 mothers and 4 healthcare informants were recruited onto the study. A chi-square test analysis was performed to identify the factors that are associated with the knowledge, and reporting of AEFIs. A 95% confidence level and statistical significance of $p<0.05$ was used. The qualitative data was analysed using thematic content analysis.

Results: The mean age of the study participants was 28.29 years (SD: 15.65). The prevalence of self-reported AEFIs was 85.9% (213). Knowledge of AEFIs was 89.9% (223). About 80.2% (199) indicated that they have ever reported incidence of AEFIs to a health facility. The major factors associated with non-reporting of AEFIs among mothers with under-five year's children at health facilities in the Tamale Metropolis were found to include, condition not serious to report (65.3%), health workers do not give me the needed attention (63.3%), I manage at home (53.2%), I do not know how to report (44.4%) and I do not think it was necessary to report (41.5%). The factors that affect AEFIs reporting among healthcare workers included non-recording of AEFIs, teaching mothers' on how to manage AEFIs at home, cumbersome in the

filling of the form and fear of being implicated for negligence. Educational status was significantly associated with reporting of AEFIs among the mothers at a p-value of 0.017**.**

Conclusion: The study identified high reporting rate and knowledge of AEFIs among mothers and low reporting rate of AEFIs among healthcare workers in the Tamale Metropolis. Addressing the barriers to the low documentation of AEFIs among healthcare workers might improve reporting of AEFIs in the various health facilities.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

AEFIs	Adverse Events Following Immunization
EPI	Expanded Programme on Immunization
GSS	Ghana Statistical Service
HCW	Healthcare Workers
LMICs	Low- and Middle-Income Countries
SPSS	Statistical Package for Social Sciences
UDS	University for Development Studies
VPD	Vaccine Preventable Disease
WHO	World Health Organization

CHAPTER ONE

STUDY BACKGROUND

This chapter gives a background on Adverse Events Following Immunizations (AEFIs) from the global and to the local perspectives including the research problem, research questions, objectives conceptual framework, justification, and organization of the study.

1.0 Study Background

Immunization activities are regarded as core components of public health interventions that are geared towards the provision of immunity for vaccine preventable diseases (VPDs) in both developed and developing countries. Research has it that between 1974-2017 immunization coverage has tremendously risen from 5% to about 86% amongst children worldwide (WHO, 2017). Though immunizations are intended to offer protective benefits, nonetheless, vaccines employed are noted to be allied with several inadvertent events (Ankrah, et al., 2018) which is often called Adverse Events Following Immunization (AEFI) which may pose health challenges to children especially and discourage prospective users of these vaccines. An AEFI is recognized as occurrence of any medical condition which commences after immunization and may not essentially have a causal association with the usage of the vaccine (WHO, 2019). The timely reporting and documentation of safety information as well post-vaccination events are necessary for the accomplishment of set goals and targets of immunization activities (Bonhoeffer et al., 2008). As have been maintained by studies including Masuka et al. (2019) and Bonhoeffer et al. (2008) the reporting and documentation of vaccine-related adverse effects allows the profiling of the benefit-risk of vaccines and also motivate other potential consumers to make themselves available for the for the vaccine uptake.

Equally, Rennels (2000) explained that in immunization exercises, there is a larger population involvement as paralleled with a lesser sample size employed in the pre-licensor periods. This makes it difficult to realize all potential adverse events on users, as Ellenberg et al. (1997), Rennels (2000) and Yamoah et al. (2019) explained that several of the adverse events allied with vaccines used in immunization exercises are often rare and characterized with late-onset, unanticipated, as well as being population specific. It is therefore essential to continuously monitor the post-licensor events (Ankrah, et al., 2018) including the adverse events of vaccines currently in use amongst children. As mentioned by Doherty et al. (2016) presently, several vaccines are employed for immunization exercises amongst the adult general population and specific populations including children, adolescent, and pregnant women with varying applications. For instance in Ghana, the Expanded Programme on Immunization (EPI) has it that, immunization programmes for children under-five years are targeted at thirteen (13) vaccine-preventable diseases (VPD's). These VPD's are noted to include tuberculosis, poliomyelitis, diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenza type b (Hib), measles, rubella, pneumonia, rotavirus, and yellow fever and are administered at various stages of the development of children under five years (EPI-Ghana, 2014).

To effectively monitor Adverse Events Following Immunizations (AEFI's) in Ghana, and other parts of the world, surveillance systems, including active and passive approaches to surveillance are concurrently in use. The active surveillance approach to AEFI is acknowledged to include a regular and systematic exploration for well-defined AEFIs in specific populations, with the aim of profiling, determining the range and exact frequencies of the events and generally carried out for freshly introduced vaccines (Ankrah et al., 2018; Razuri et al., 2012). The passive AEFI surveillance approach has also been noted to involve vaccine-related condition on both existing

and newly introduced vaccines reports made by the general populace who are mostly users of vaccines and reports made by healthcare professionals including community health nurses (Ankrah et al., 2018; Razuri et al., 2012). The employment of both systems offers an opportunity to collect the needed information to guide existing and future immunization programs. Nonetheless, the important question to ask is, how effective are these systems in low-income settings and rural settings where monitoring and evaluation activities are often taken for granted?

The role of healthcare workers (HCW) in AEFI surveillance cannot be overlooked as maintained by Kuçuku (2012). According to Parrella, et al. (2013), regular documentation and reporting of alleged cases of AEFI's by HCW's are considered significant and essential for the monitoring and evaluation of post-licensure vaccine safety. Contemporary studies have suggested in lower income settings, including Ghana, the absence of a functional pharmacovigilance structures, the HCW's are often relied on and duty bound to carefully observe any medication related harms including AEFI's and document them appropriately (Yamoah et al., 2019; Olsson et al., 2015). According to the WHO (2015) African countries have weak vaccine pharmacovigilance systems. Thus, African countries practice of monitoring the effects of vaccines after they have been licensed for use, especially to identify and evaluate previously unreported adverse reactions is poor (WHO, Vaccine Safety Database, 2015). Again, the WHO further mentioned that about 1% of AEFI reports globally originated from Africa with approximately 97% of the African AEFI reports coming from countries like "Egypt, Democratic Republic of Congo, Morocco, South Africa, Sierra Leone, Zimbabwe, Tunisia, Ghana, Nigeria, and Senegal" (WHO, Vaccine Safety Database, 2015). This portrays a disturbing phenomenon considering the emergence of new and more vaccine regimens on the African continent as results of the occurrence and re-occurrence

life-threatening infectious diseases and an increasing population (Nyaaba et al., 2017; Kazungu et al., 2017; WHO, Global vaccine safety blueprint, 2015).

As a result, AEFIs are anticipated to increase appreciably as observed in African countries (Yamoah et al., 2019a). This highlights the need to educate, train and encourage HCW's and to a larger extent, users of vaccines in Ghana and the sub-region to better appreciate AEFIs. This will help to foster effective and prompt diagnosis, report, documentation and improve vaccine safety in the absence of an effective pharmacovigilance structures. As maintained by Parrella et al. (2013), adequate awareness and understanding of AEFI's improves the management and treatment of life-threatening disorders allied with some AEFI's.

To achieve the goals of immunization programmes especially amongst children under the age of five, fairly depends on HCW's and mothers or parents children who are usually users of most of the vaccines and should been recognized as important stakeholders in immunization programmes (Institute of Medicine (US) Committee on Review of Priorities in the National Vaccine Plan, 2010). An adequate collaboration between the two will facilitate a functional feedback loop where mothers could easily report any suspicion of AEFI's to HCW's for onward documentation. Correspondingly, an adequate information and understanding of vaccines, combined with the accompanying adverse events among HCW's could increase immunization coverage as this will greatly influence the quality of information and education given to consumers at the health facilities, communities and also enhancing the safety of vaccines (Masika et al., 2016). Likewise, Gahunia et al. (2013) and Netterlid et al. (2009) acknowledged that factors such as low awareness and inaccurate opinions amongst HCWs, concerning the storage and administration of vaccines together with poor appreciation of AEFI's are connected with the failures of several immunization programmes.

Despite the efforts demonstrated by most HCW's and consumers of vaccines on AEFI's, other studies have acknowledged several challenges including incomplete recording and documentations, under-reporting, biased reporting, the failure to differentiate between accidental adverse events from causal adverse events in addition to late reports (Wharton, 2010; Griffin et al., 2009; Varricchio et al., 2004; Ellenberg et al., 2002; Ellenberg et al., 1997). The assigned reasons to the observed challenges according to Parrella et al. (2014) are legion and may result from inadequate appreciation and understanding of safety surveillance by HCW's, restrictions on provider time, in addition to imprecise explanations to what may constitutes a reportable AEFI. For instance, Yamoah et al. (2019) observed in a study in Ghana among HCW's on the knowledge of AEFI's to be relatively low with proportions of 49 (10.8%) as high, 213 (47.0%) as moderate and 191 (42.2%) as low among the HCW's. It was again observed that the main "negative perception was the lack of desire to learn more about how to diagnose, report, investigate, and manage AEFI. In addition, it was also recognized amongst the participants that surveillance did not increase the public confidence in immunization programmes. The negative perceptions and the lack of vastly well-informed HCWs concerning AEFIs may exist as possible hindrances to AEFI diagnosis, management, prevention, and reporting Yamoah et al. (2019).

Given the above on AEFI's combined with the paucity of data and contemporary research in the Northern Region of Ghana on AEFI's, this current study focuses on adverse events in the Tamale Metropolis and that are measured to be within the domain of community health nursing services.

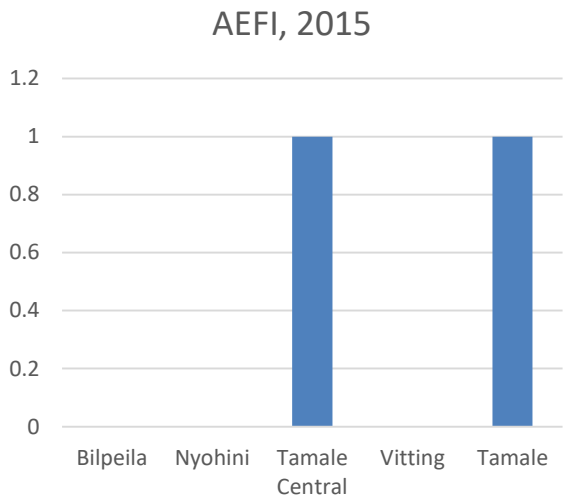
1.2 Problem Statement

Ghana rolled out the Expanded Programme on Immunizations (EPI) in 1978 and currently has thirteen (13) Vaccine Preventable Diseases (VPDs) with remarkable gains over the years since its inception (Expanded Programme on Immunization Field Guide, Ghana 2014). Despite the

remarkable gains in the fight against VPD's, it is still reported that there is stagnation in the coverage of immunization among children under the age of five years with more than one in every ten children not vaccinated. The observed stagnation of the EPI programme may partly result from AEFI's which may discourage consumers or mothers of children under-five years from patronizing immunization programmes. Equally, as vaccine consumers also live within the population, the recognition of AEFI's may serve as hindrance to immunization programs by prospective vaccine consumers and subsequently affect the introduction of new vaccines. The current approach, which is mainly passive surveillance of AEFI's in the Tamale Metropolis seems not to be effective resulted in poor reporting and poor documentation of AEFI's amongst HCW's and vaccine consumers, especially mothers with children under-five years. Passive surveillance of AEFI's is noted to recognize about 1% to 10% of all AEFI cases (Bharat, 2014: Choe et al., 2011). Current statistics on AEFI's from 2015 to 2019 amongst the four sub-metros (including Bipeila, Nyohini, Tamale Central, Vittin and Tamale) in the Tamale Metropolis demonstrates either non-reporting or under-reporting of the AEFI's in the metropolis. In 2015 and 2019 Tamale Central and Bipeila reported one case of AEFIs, respectively. In 2016, 2017, and 2018 none of the health facilities in the metropolis reported AEFIs as presented in **figures 1-5.**

The question to ask is; is it the case that mothers are not reporting any observed AEFI's to the health centres or is it the case that healthcare workers in these facilities are not documenting reported cases of AEFI's. This may challenge the progress made against VPD's in the Region and Ghana at large and affect the introduction of vaccines acceptability among mothers, especially at a time the Ghana Health Service is considering the initiation of malaria vaccination

among children under-five years. The current study therefore aims to assess the adverse events associated with the current immunization programmes in the Tamale Metropolis.



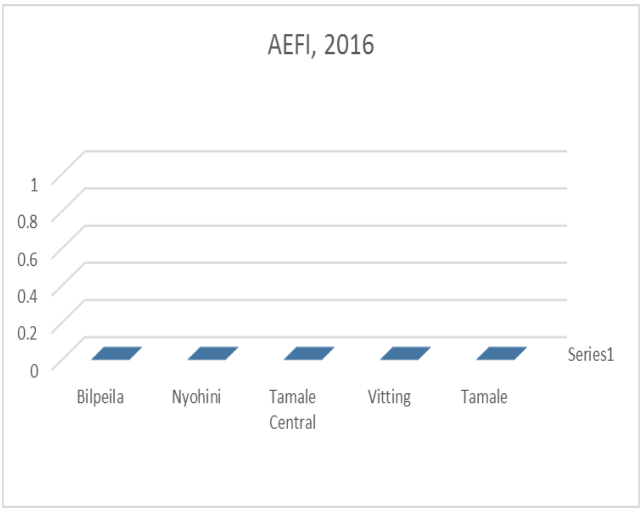
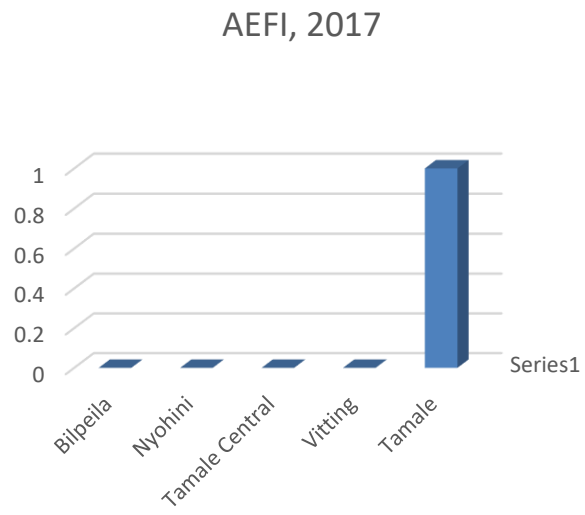


Figure 1.1 ***Figure 1.2***

Figure 1.1 to 1.2 Reports on AEFIs among health facilities in the Tamale Metropolis. Source: Tamale Metropolitan Health Directorate, 2019.



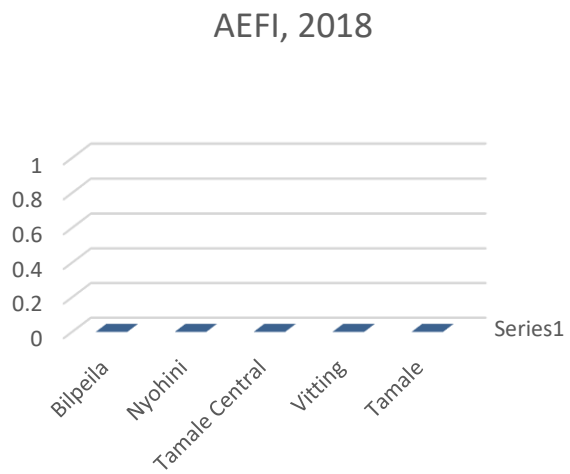


Figure 1.3 ***Figure 1.4***

Figure 1.3 to 1.4 Reports on AEFIs among health facilities in the Tamale Metropolis. Source: Tamale Metropolitan Health Directorate, 2019.

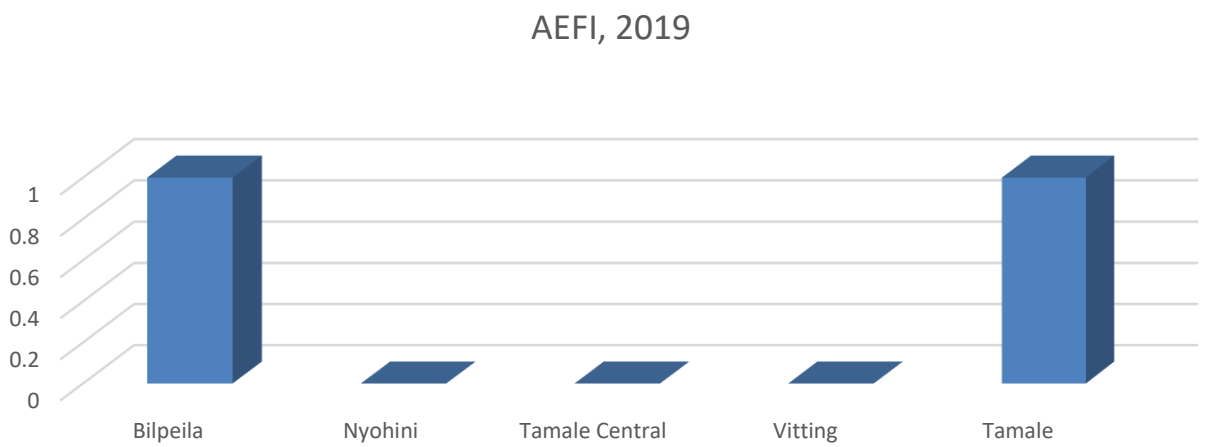


Figure 1.5 Reports on AEFIs among health facilities in the Tamale Metropolis. Source: Tamale Metropolitan Health Directorate, 2019.

1.3 Research Questions

1. What is the self-reported prevalence of AEFI among mothers with under-five years children at health facilities in the Tamale Metropolis?
2. What is the level of AEFIs knowledge of mothers with under-five years children at health facilities in the Tamale Metropolis?
3. What are the AEFIs reporting behaviours of mothers with under-five years children at health facilities in the Tamale Metropolis?
4. What are the factors associated with AEFIs reporting amongst mothers with under-five years children at health facilities in the Tamale Metropolis?

1.4 Objectives

1.4.1 General Objective

The study is aimed at assessing reporting of adverse events associated with the current immunization programmes among health facilities in the Tamale Metropolis.

1.4.2 Specific Objectives

1. To determine the prevalence of self-reported AEFIs among mothers with under-five years children at health facilities in the Tamale Metropolis.
2. To assess AEFIs knowledge amongst mothers with under-five years children at health facilities in the Tamale Metropolis.
3. To determine the AEFIs reporting behaviours of mothers with under-five years children at health facilities in the Tamale Metropolis.
4. To examine factors associated reporting of AEFIs among mothers with under-five year's children at health facilities in the Tamale Metropolis.

1.5 Study Justification

This study will provide baseline data on the adverse events associated with the EPI in the Tamale Metropolis and would be useful to the EPI to accurately inform and build public trust in the vaccine and sustain immunization programmes in the Metropolis and the Northern Region at large.

1.6 Conceptual Framework

The conceptual framework was developed by the author in an attempt to understand key issues on adverse events associated with the current immunization programmes in the Tamale Metropolis including participants' knowledge, AEFIs behaviours and associated factors of reporting of observed AEFIs among the participants. The main constructs in the framework are Population Characteristics, Self-Reported AEFI Prevalence, Knowledge of AEFI and AEFIs Reporting Behaviours

The researcher theorized that the Population Characteristics, Knowledge of AEFIs and AEFIs Reporting Behaviours work in concert to either increase or decrease the Self-Reported AEFI Prevalence among the study participants.

To explain further, the age of the participants' such as being a teenager or adult could be associated with the level of awareness of AEFIs and the reporting behaviours. A teenage mother may feel reluctant to report observed AEFIs due to fear of stigmatization or discrimination from health care workers. This will eventually result in non-reporting of AEFIs. Equally, the educational status as a population characteristic could have a direct bearing on participants' knowledge of AEFIs and consequently the reporting behaviour and self-reported prevalence of AEFIs. A participant with low education on AEFIs is likely to be unnoticed AEFIs and vice versa. This will in-turn affect the reporting behaviours and self-reporting of AEFIs among the participants.

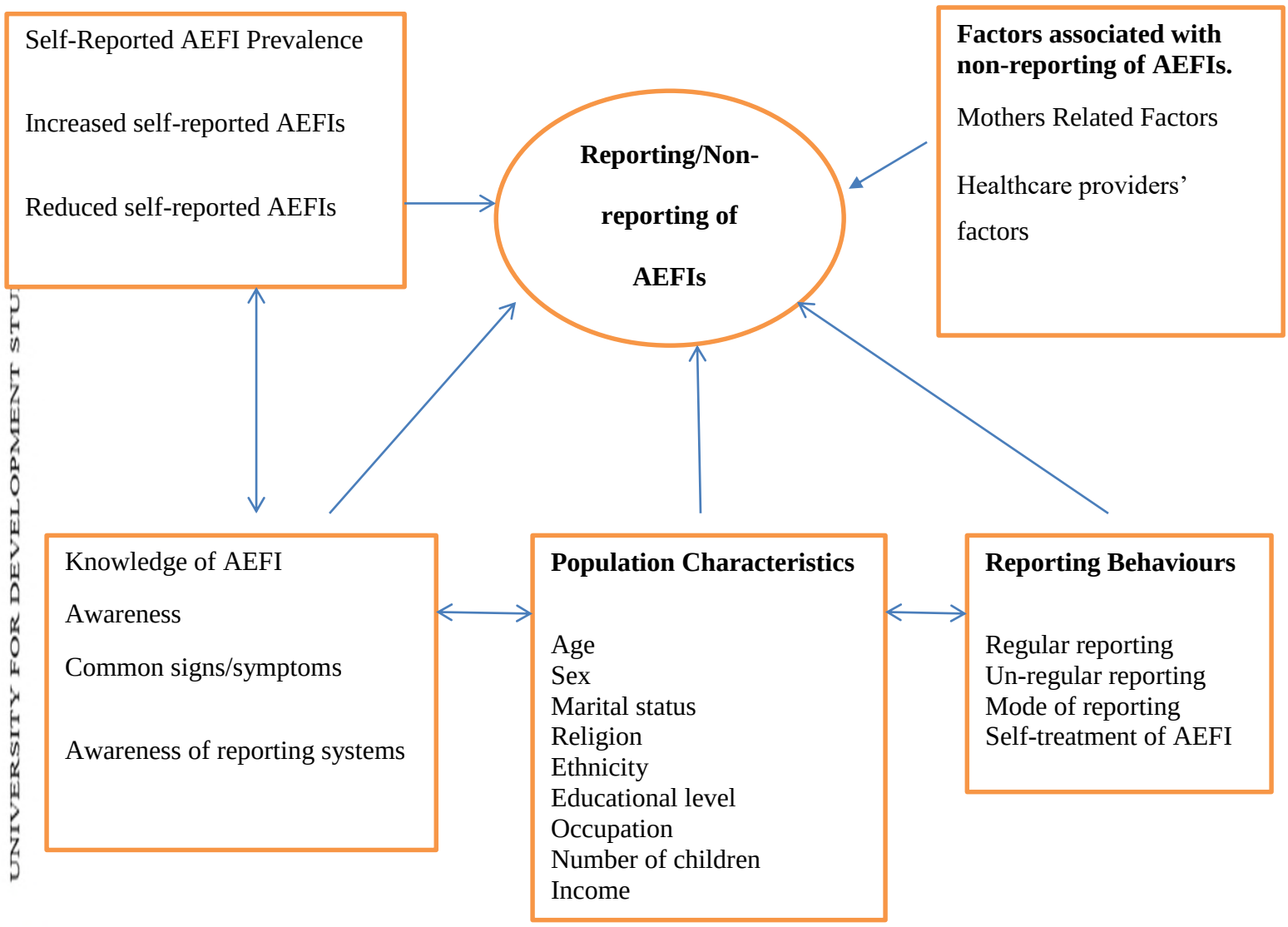


Figure 1.6. Conceptual Framework on AEFIs Reporting Pathway for Mothers Presenting their Children at Health Facilities in Tamale Metropolis. Source: Author (2019).

1.7 Study Organization

The study is organized into six (6) main chapters with references and appendices.

Chapter One

The chapter one gives the study background, the problem statement, research questions, research objectives, the study's conceptual model, justification and the study organization.

Chapter Two

The chapter two of the study also reviewed literature on AEFI's. The review was carefully done in line with the research questions and or objectives.

Chapter Three

The chapter three described the methods that was be used to conduct this research. The chapter looked at key topics like; Study Area, Study Setting, Study Design, Study Population, Sample Size, Sampling Method, Study Variables, Data Collection Tools, Data Analysis and Presentation Methods, Data Quality Control Measures, and Ethical Considerations.

Chapter Four

The chapter four was used to present the data analysis and results of the study.

Chapter Five

The chapter five discussed the results of the study. The discussions of the results were done in line with other studies on the topic to confirm or to reject the assertions of such studies.

Chapter Six

The chapter six also gives a summary of the study outcome, conclusion, key recommendations and study limitations, dissemination of study outcome, and further research opportunities.

CHAPTER TWO

LITERATURE REVIEW

2.0 Chapter Overview

This chapter is dedicated to the review of relevant literature related to the study. The review is organized under the following sub-themes:

2.1 Immunity, Immunization, Vaccine, and Vaccination

2.3 The thirteen Vaccine Preventable Diseases

2.4 The concept of Adverse Events Following Immunizations

2.5 Recognition of Adverse Events Following Immunizations

2.6 Prevalence of Adverse Events Following Immunizations

2.1 Immunity, Immunization, Vaccine, and Vaccination

The term immunity according to the Centre for Disease Control and Prevention (CDC), refers to the protection an individual has from an infectious disease or it its toxic agents. That is, if an individual has an immunity against a certain disease, he/she do not become infected when exposed to such a disease or its toxic agent(s) (https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm)

To define vaccine, it is a suspension of killed, weakened or inactivated microorganisms or its toxic products or of antibodies or lymphocytes that is administered purposely to illicit immune response and prevent diseases. (https://www.britannica.com/science/vaccine). Again, it is

acknowledged that vaccines offer active immunity to individuals on specific toxins or agents by invigorating the immune system to attack the toxin or agent introduced into the body. The mechanism of action of remains that once the immune system is successfully activated by the attenuated agent (vaccine), there is a sensitization of the antibody-producing cells (B lymphocytes) in readiness for attack or defend the body when the agent gain entry into the body once again. Additionally, a vaccine can also offer individuals passive immunity. The passive immunity is coffered on individuals by giving antibodies or lymphocytes that has been established by humans or an animal donor. The route of administration for vaccines has predominately been parenteral administration however, emphasis must also be made that it can also be administered orally and nasally which is associated with the flu vaccine. Previous studies have suggested that vaccines administered onto mucosal surfaces, including the lining the of gut as well as the nasal passages, trigger much immune responses and would be the most effective route of administration.

The term vaccination and immunization has often been used interchangeably. However, vaccination refers to the the act or process of introducing a a vaccine into the body of an individual to offer immunity to an infectious disease or its toxic product. Immunization also refers to the process when an individual gets inoculated or made resistant to an infectious disease or its harmful products through the administration of a vaccine (WHO, 2020). The WHO further admits that vaccination or immunization programs are acceptable prevent measure for preventing, controlling, and eliminating several infectious diseases in recent times and associated with the prevention of about 2 to 3 million mortalities annually. Additionally, the WHO explains that, vaccinations or immunizations has become a cost-effective health investment saving

millions of lives, especially in developing countries including Ghana (https://www.who.int/topics/immunization/en/).

Most countries including Ghana has adopted the Expanded Program on Immunization (EPI) to effectively vaccinate against childhood infectious diseases (Brenzel et al., 2015; EPI-Ghana, 2014). It is recognized that through the EPI, there would a be tremendous reduction in mortality and morbidity associated with childhood infectious diseases and significantly contribute to the attainment of the sustainable development goals of reducing childhood mortalities (Brenzel et al., 2015).

2.2 Vaccine Preventable Diseases

Epidemiologically, the rate and burden of VPDs are known to vary from region to region and country by country and is associated with the coverage and uptake of vaccines (Brenzel et al., 2015). It is also explained other important factors that accounts for the variations in the burden of VPDs consists of nutritional status, geography, seasonal patterns, crowding, and genetic variances in populations which affect disease severity (Kai, 2012).

According to President et al. (2020), an individual's age, lifestyle, overall-health, and previous vaccinations are all important factors to consider the type of vaccines individuals need. It is researched that vaccines are extremely important for children, especially in the early days of the child's life, from infancy to about 5 years of age. The CDC recommended fourteen (14) vaccinations to help prevent diseases among children, however in Ghana, the EPI recommends nine main vaccines among the thirteen VPDs (CDC, 2020, EPI-Ghana, 2014). As maintained by CDC (2019) and CDC (2020) adhering to the immunization schedules for infants is essential to provide maximum protection for the child in the early stages of his or her life. Additionally,

Metcalf et al. (2015) stated that anytime a child is immunized against any of the VPDs or specific pathogen, the risk of developing such a disease together associated asymptomatic carrier decreases. Equally, it is well established that for most of the VPDs to spread among the population successfully, a greater number of such population should be recognized as susceptible (Metcalf et al., 2015). Conversely, if large portion of the population have herd immunity against such diseases, the rest of the small proportion who are not immune to disease become somewhat protected (Ventola, 2016). CDC (2020) also added that if the population continue to receive immunizations for diseases which are, such diseases may become extinct.

2.3 The Thirteen Vaccine Preventable Diseases

The thirteen VPDs targeted in the EPI in Ghana are includes Tuberculosis, Poliomyelitis, Diphtheria, Tetanus, Pertussis (Whooping Cough), Viral Hepatitis, Haemophilus influenzae type B (Pneumonia-meningitis-septicaemia etc.), Streptococcus pneumoniae (Pneumonia, meningitis other IPD), Rotavirus diarrhoea, Measles, Rubella and Congenital Rubella Syndrome, Yellow fever and Meningococcal meningitis (EPI-Ghana, 2014).

2.3.1 Tuberculosis

It is well known that Tuberculosis (TB) bacterial infection and often described as a chronic lower respiratory tract infection. TB is known to be caused by *Mycobacterium tuberculosis*. Aside the lungs, TB also affects other organs in the human body resulting in several clinical disease manifestations (Golden et al., 2011). TB spreads through air droplets, especially when an infected person coughs or sneezes into the open air or space (EPI-Ghana, 2014). In 2013, the WHO estimated that about 9.0 million were infected with TB and 1.5 million died from the disease (WHO 2014). Even though there are some recommended for the treatment and

management of TB, it is recommended that the effective way to control and prevent the spread of TB is through preventive vaccination. The recommended TB vaccine currently is the bacillus Calmette-Guerin (BCG).

2.3.2 Diphtheria

It is known that Diphtheria is caused by a toxin-producing strain of the bacterium *Corynebacterium diphtheriae* (Brenzel et al., 2015). Diphtheria is also acknowledge to be an infection of the upper respiratory tract caused by Corynebacterium diphtheriae (Borba et al., 2015). The mode of transmission of Diphtheria is by means of respiratory droplets and physical contact with infected persons (EPI-Ghana, 2014). Some studies have shown that isolates of Diphtheria can be found in the throat and leishmaniotic ulcers (Mattos- Guaraldi et al. 2003, 2011, Mishra et al., 2005). Other sites that have been associated with Diphtheria includes the ear, conjunctiva, vagina, sperm, heart valves and in cancer patient lesions (Gomes et al., 2009; Ganeshalingham et al., 2012, Berger et al., 2013).

Research shows that the main virulence factor of C. diphtheriae is the diphtheria toxin, which has the potential of causing systemic effect as well as protein synthesis inhibition and cell death, particularly in high perfusion organs (Borba et al., 2015). It is acknowledged that the vaccine formulation of diphtheria contains toxoid which is engrossed on aluminum hydroxide and conserved with thimerosal (NNii 2014). Regardless of the widespread use of diphtheria vaccines, the WHO reports of some cases in some parts of the world (WHO, 2014). As a result of children being more susceptible to diphtheria, it is therefore recommended that children are vaccinated at early ages of their life globally (Fredlund et al., 2011). The WHO indicated that before the introduction of diphtheria immunization program more than 5% population of the

world suffered clinical diphtheria at some point during their lifetimes (Brenzel et al., 2015; Griffith 1979).

2.3.3 Poliomyelitis

The poliomyelitis disease is recognized as a highly infectious viral disease caused by the polio virus (Borba et al., 2015). The polio virus could rapidly replicate in the intestines and enter systemic circulation with effect on nerves resulting paralysis (EPI-Ghana, 2014). According to the WHO (2014) about 90 to 95% of individuals are asymptomatic to the polio virus whereas the 5% of individuals who are symptomatic presents manifestations such as fever, diarrhea. Again headache, vomiting, neck rigorousness and pains in the arms and legs are associated with poliomyelitis (WHO, 2014). Poliovirus is transmitted through contacts with contaminated feces and usually faeco-oral transmission. According to Butler (2013) poor surveillance and low vaccination coverage has the potential to cause an outbreak. Additionally, Butler (2013) stated that most case of poliomyelitis which are asymptomatic can equally increases the risk of others as they remain unnoticed and spread the virus. The effective way of controlling and preventing the spread of poliomyelitis is using the oral polio vaccine or inactivated polio vaccine especially among children who are most vulnerable to the contraction of poliomyelitis (EPI-Ghana, 2014).

2.3.4 Pertussis

Pertussis disease is a known bacterial infectious disease caused by *Bordetella pertussis*. It causes an acute respiratory tract infection (Brenzel et al., 2015; Borba et al., 2015). The clinical presentations of pertussis are known to consist of fever as well cough illness which can last for more than a week. The cough associated with pertussis has a characteristic of paroxysms of coughing, inspiratory whoop and posttussive vomiting (WHO 2014). Pertussis is spread through

direct contact with an infected person and air droplets via coughing and sneezing (EPI-Ghana, 2014). The WHO reports that pertussis remains an endemic disease globally and life-threatening to all walks of life including children who are more susceptible (WHO, 2014). Statistics given by the WHO in 2014 showed that about 136036 cases and 89000 deaths were reported among children who are unimmunized in developing countries. Currently, research shows that there exist two main vaccines against pertussis and consisted of a whole cell (Pw) and as pertussis acellular (Pa) (Witt et al., 2013; WHO 2014. The whole cell (Pw) preparation is composed of inactivated bacterial whole-cell, and the pertussis acellular (Pa), vaccine contains purified pertussis antigens called pertussis toxin and filamentous haemagglutinin (FHA) (Witt et al. 2013; WHO 2014). According to the Ghana's EPI (2014), a pentavalent vaccine is currently used in Ghana to protect children against pertussis.

2.3.5 Tetanus

Tetanus is caused by the bacterium *Clostridium tetani*. It is acknowledged that *Clostridium tetani* is ubiquitous in the environment globally. According to Cherry et al. (2004) spores of *Clostridium tetani* remain can maintain its viability for several years in the soil and dust as well as contaminated. The bacterial can spread through direct contacts with wounds or cuts on the surface of the skin. Other previous studies have stated that the bacterial can also can entry via the umbilical stump and associated transmission through circumcision and other surgical procedures (Brenzel et al., 2015; Birmingham et al., 2004). According to Brenzel et al. (2015) mothers without immunity to tetanus tend to give birth to children with high susceptible to neonatal tetanus. It is also acknowledged that countries with high unskilled delivery, poor hand hygiene practices and poor healthcare maternity facilities may have increased risk of tetanus

(Birmingham and others 2004; Griffiths and others 2004). In Ghana, the Pentavalent vaccine (DPT-Hib-HepB) has been recommended for children (EPI-Ghana, 2014).

2.3.6 Measles

Measles is a well-known highly infectious viral disease caused by the measles virus belonging to the genus *Morbillivirus* (Borba et al., 2015). Measles infection is usually described as fever rash disease among children (EPI-Ghana, 2014). Measles spread through airborne droplets with contaminated measles virus from an infected person (EPI-Ghana, 2014). The disease has been described by previous studies that the rate of transmission is extremely high among children who have not been immunized against the diseases. Measles spread easily from infected individual to the other rapidly through droplets with route of entry into the body consisting of the nose, mouth, or throat. Infected persons usually present clinical manifestations as high temperature (fever) rhinorrhea, and red eyes. Additional notable symptoms include tiny white spots in the mouth, rashes on the face. The WHO (2014) has it that some individuals do recover within 2-3 weeks of infection, nonetheless, poses serious complications especially among malnourished children. The serious complications associated with measles disease includes blindness, encephalitis, severe diarrhea, ear infection and pneumonia (WHO 2014). Measles is effectively prevented through the measles vaccine consisting of the mumps, and rubella (MMR) vaccine (EPI-Ghana, 2014).

2.3.7 Viral Hepatitis B Virus

Viral hepatitis B is known to be a serious liver infection which is known to be caused by the hepatitis B virus (HBV). Hepatis B infection can be acute or chronic. The acute HBV infection resolves within six months whereas the chronic infection last more than six months. It is known

that chronic infection increases the risk of liver failure, liver cancer and cirrhosis. The virus is acknowledged to spread from an infected person to another person via means such as body fluids, including infected blood. Some risks associated with HBV includes having unprotected sex with an infected person, having multiple sex partners as well as using infected sharp objects. Again, an infected pregnant woman can pass onto the child. Previous studies indicated that in most African countries, the spread of HBV starts predominantly in early childhood as result of mucosal contact with infectious body fluids as well as unsafe injection practices (Brenzel et al., 2015). Research also shows that when children especially among children less than five years contracts HBV, it increases the risk of developing a chronic disease. Additionally, some individuals who are chronic HBV are known to be asymptomatic and would go undiagnosed till the individual starts developing complications. The most effective preventive measure to HBV is by means of vaccination using the hepatitis B vaccine (EPI-Ghana, 2014).

2.3.8 Haemophilus influenzae type B (Pneumonia-meningitis-septicaemia etc.)

The *Haemophilus influenza* type b (Hib) infection is a childhood bacterial infection associated serious pneumonia, meningitis, and other invasive diseases. The mode of spread is usually via the respiratory tract from infected individuals to susceptible individuals. The infection is attributed to other serious inflammatory infections of the face, mouth, blood, bones, peritoneum, and epiglottis, joints, heart, and trachea. Hib is a disease with global burden; however, it is said that developing countries were the most affected before the introduction of the Hib vaccine.

The WHO (2020) has it that vaccines are the most effective public health intervention to the spread of Hib among the population there, it recommends the administration of Hib conjugate vaccines to be included in all routine infant immunization programmes.

2.3.9 Streptococcus pneumoniae (Pneumonia, meningitis etc.)

Streptococcus pneumoniae is a gram-positive and facultative anaerobic bacterium known to have more than 90 serotypes. It has equally been established that pneumococci are normal residents of the respiratory tract and can be isolated from the nasopharynx of healthy persons. Additionally, about 5 to 10% and 20-60% of the adult and children population are known to be carriers of pneumococci (https://www.cdc.gov/pneumococcal/clinicians/streptococcus-pneumoniae.html).

According to Weiser et al. (2018) invasive inflammatory diseases associated with pneumococci is because of local spread and seeding to the bloodstream. It is also acknowledged that *S. pneumoniae* is known for several diseases, including otitis media, community-acquired pneumonia, sepsis, and meningitis. The known symptoms of pneumococci include fever, cough, shortness of breath, and chest pain. Again, symptoms such as stiff neck, confusion, increased sensitivity to light and joint pain can be associated with pneumococci (https://wwwnc.cdc.gov/travel/diseases/pneumococcal-disease-streptococcus-pneumoniae). Some studies have also acknowledged symptoms like chills, ear pain, sleeplessness, and irritability. It is also reported by some previous studies that serious cases of pneumococci infections would lead to loss in hearing, brain damage, as well as death. It has been recommended that vaccination against the disease is the most effective way of prevention among the general population, especially children (EPI-Ghana, 2014).

2.3.10 Rotavirus

Rotaviruses, according to the WHO are the major cause of several childhood diarrhoeal diseases globally. The WHO estimates in the year 2013 also showed that approximately 215 000 children

aged under 5 years died annually from vaccine-preventable rotavirus infections. The burden of rotavirus is known to be higher in low-income countries. It is also acknowledged that the disease spreads more easily among infants and young children. Rotavirus is associated with complicated watery diarrhoea, vomiting, fever, and abdominal pain. Equally, it is acknowledged that children who get rotavirus disease can become dehydrated leading to hospitalization. It is recommended that a child is given rotavirus vaccine which is effective at preventing rotavirus disease (https://www.cdc.gov/rotavirus/index.html). WHO further recommended that, rotavirus vaccines should be incorporated into national immunization programmes and be regarded as national priority especially in sub-Saharan African countries. Additionally, WHO stated that the first dose of rotavirus vaccine be given to the children after 6 weeks of age together with other vaccine such as DTP vaccine (https://www.who.int/immunization/diseases/rotavirus/en/).

2.3.11 Rubella and Congenital Rubella Syndrome

Rubella is a viral infection. The congenital rubella syndrome (CRS) is also associated with severe birth defects among children. The virus is capable of being transmitted from pregnant woman to the unborn child, resulting in CRS as well as death and several birth defects. Some associated birth defects include deafness, and defects of the eyes, heart, as well as the brain. The spread of rubella is through airborne droplets, especially when an infected person sneeze or cough. The recommended vaccine for Rubella and Congenital Rubella Syndrome is live attenuated viral rubella vaccine

(https://www.who.int/immunization/monitoring_surveillance/burden/vpd/surveillance_type/passive/rubella/en/).

2.3.12 Yellow fever

As maintained by Suzuki et al. (2016) yellow fever is regarded as a viral haemorrhagic fever (VHF) with great public health concern. Statistics shows that yellow fever affects about 200,000 individuals globally and an estimated 30000 deaths yearly (WHO, 2016). It well known that the spread of yellow fever is through (WHO, 2016). It is also reported that Aedes aegypti is an important vector in the spread of yellow fever especially among West African countries (Suzuki et al., 2016; Hemingway et al., 2000). The Aedes aegypti is recognized to breed predominantly in crab holes, tree holes, and on fallen leaves. Equally, other previous studies listed breeding sites for Aedes aegypti to include rock pools, domestic containers, snail shells, leaf axils, rain pools, and latex cups in rubber plantations (Suzuki et al., 2016). Immurana et al. (2016) stated yellow fever cases has seen rise in the number of infection and can be attributed urbanisation, lack of herd immunity, increasing deforestation, climate change, combined with immigration. To effectively prevent the spread of yellow fever, the WHO (2014) recommends the use of the Yellow fever vaccine which is known to be cost-effective. Therefore, Ghana has incorporated yellow fever vaccine in the routine immunization programs for children (Immurana et al., 2016).

2.3.13 Meningococcal meningitis

Learning from the WHO (2020), Meningococcal meningitis is an infection of bacterial etiology that affects the brain and spinal cord. The infection is caused by the bacterial Neisseria meningitidis bacteria and has been implicated in cause of several large epidemics (WHO, 2020). The twelve types of N. meningitides, called serogroups, have been identified, six of which (A, B, C, W, X and Y) can cause epidemics. Similarly, the WHO (2020) admits that Meningococcal meningitis has a high case fatality rate, especially when left untreated with serve complications.

It is acknowledged that meningococcal meningitis has a global importance, however, the most affected countries are in the sub-Saharan Africa regions which are in the meningitis belt. Approximately 30,000 cases of meningococcal meningitis are reported on yearly basis from countries in the meningitis belt.

The mode of spread of the meningococcal meningitis bacterial is through direct contact with an infected person. The bacterial can transmit from an infected person to another individual via droplets of respiratory or throat secretions from the infected person. Some studies also reported risk factor for the contraction of meningococcal meningitis to include smoking, close contact with an infected person, droplets from sneezes and cough as well as overcrowding.

The WHO recommends the use of serogroup specific vaccines against meningococcal meningitis. It is acknowledged that as at the year 2010, there have been the administration of meningococcal A conjugate vaccine against meningitis, especially among countries in the meningitis belt including Ghana (https://www.who.int/news-room/fact-sheets/detail/meningococcal-meningitis).

2.4 The concept of Adverse Events Following Immunizations

According to the definition by the WHO (2014) Adverse Events Following Immunizations (AEFIs) refers to the presence of "any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine". Additionally, the AEFIs may also comprise of somewhat undesirable or accidental sign, anomalous laboratory result, symptom, or disease (WHO, 2020). Similarly some studies have implicated injection reaction and program errors as other factors associated with the

development of AEFIs which equally affects the uptake of immunization exercises (Yenyi, 2019: Masika et al., 2016).

2.4.1 Classification and types of Adverse Events Following Immunizations

There exist two main classification systems for AEFIs, namely, regulatory and cause specific AEFIs classification systems (Expanded Programme on Immunization, Ghana, (EPI) 2014).

2.4.1a Regulatory Classification System of AEFIs

The regulatory classification system of AEFIs identifies AEFIs into serious and non-serious AEFIs (EPI-Ghana, 2014; Tozzi et al., 2013).

As described by EPI-Ghana (2014), Tozzi et al., (2013) and Menezes et al. (2020) the serious otherwise known as severe AEFIs are characterized with events that are described as life-threatening, potential to cause death and necessitating in-patient hospitalization as well long hospital stay. Additionally, serious, or severe AEFIs has the potential to cause substantial disability or injury, as well as resulting in a congenital anomaly or birth defect (Institute of Medicine, 2012). Mehmeti et al. (2017) also listed some of the serious AEFIs to comprise of seizures, hypotonic hypo responsive episodes, prolonged crying, and thrombocytopenia.

The non-serious, otherwise known as the mild AEFIs also constitutes temporary mild to moderate reactions or events after immunizations (EPI-Ghana, 2014).

2.4.1b Cause Specific Classification System of AEFIs

According to the EPI-Ghana (2014), WHO (2014) and the Vaccine Quality, Efficacy and Safety on AEFIs (2020) the cause specific classification system of AEFIs categorizes AFEIS in to five (5) main types, namely: (1) Vaccine product-related reactions (2) Vaccine quality defect-related

reactions (3) Immunization error-related reactions (4) Immunization anxiety-related reactions and (5) Coincidental events.

Vaccine product-related reactions: these reactions or events occur because of the inherent properties of the vaccine such as anaphylaxis resulting from some vaccine component(s) (EPI-Ghana, 2014).

Vaccine quality defect-related reactions: these reactions also occur because of defects during the manufacturing of the vaccine. This can result from the inability of the manufacturer to attenuate a live vaccine adequately. Examples may include polio and yellow fever vaccines (EPI-Ghana, 2014).

Immunization error-related reactions: These are reactions resulting from poor handling, storage, and administration of the vaccine. These reactions are also recognized as program-related errors and could result in reactions such as abscess at the injection site (EPI-Ghana, 2014).

Immunization anxiety-related reactions: These reactions also occur from nervousness before or during vaccination. Such as reactions may include fainting attacks (EPI-Ghana, 2014).

Coincidental events: These are events often described as unrelated to the vaccine or the vaccination and may occur from a disease such as malaria after the vaccination (EPI-Ghana, 2014).

It is equally important to stress that some AEFIs are also described as unknown cause (EPI-Ghana, 2014). No matter the type of AEFI, it has the potential to threaten public health, especially among children who are also recognized as vulnerable and also lead to a reduction in

vaccination uptake among children and the general public (Demicheli et al., 2003; Schattner, 2005; Agorastos et al., 2009). As such it has become increasingly important to systematically assess and survey AEFIs to achieve the highest safety in immunization programs. This will also be critical to inform public health activities and preserve confidence in immunizations exercises among the general population (Tozzi et al., 2013).

2.5 Recognition of Adverse Events Following Immunizations (AEFIs)

Ensuring the safety of vaccines is an essential characteristic of the health system as safety of vaccines is key to promote and have effective immunization programs especially during the introduction of new vaccines (Gidudu et al., 2019). Even more importantly, with the increase in the introduction of new and old vaccines into developing countries, recognized with increasing infectious diseases highlights the importance of maintaining vaccine safety (Gidudu et al., 2019). It is worth emphasizing that several of these vaccines have been designed exclusively for these developing countries, further stressing the need for extra attention to be dedicated to the safety of vaccine ensure effective vaccination programs (Chen et al., 2015; Kochhar et al., 2013). As reported by Menezes et al. (2020) failing to act swiftly and effectually deal with AEFIs has the potential to decrease the assurance of public in vaccines, which eventually cause a decreased immunization coverage as well as a rise in the occurrence of vaccine preventable diseases. Previous studies have indicated poor reporting of AEFIs in most developing countries including Ghana and often lower than the ratio of 10 reported AEFI per 100,000 surviving infants (Lei et al., 2018). It is recommended that both serious and non-serious AEFIs observed in the population especially among children should be reported to the country surveillance system (Gidudu et al., 2019). Even though, AEFIs can transpire after immunizations, however, to achieve vaccine safety and promotion of vaccines both serious and mild unexplained AEFIs should be reported

immediately (WHO, 2020). AEFIs cases calls for special attention and has the tendency to be first reported by the media which could spark fear and panic within the public space. Negative reportage by the media on vaccine-related events would impact negatively on immunization coverage generally as the public confidence and acceptance of vaccines would be reduced (Joshi et al., 2018). Therefore, strict adherence to laid down reporting system in a health system and the needed attention to a suspected AEFI should be considered as essential. As asserted by Verma et al., (2011) the important features of effective surveillance system are known for its swift and robust notification, evaluation of information, responsiveness and triggering of appropriate action. Previous studies have reported some AEFI surveillance systems (Netterlid et al., 2009). In the year 1999, the WHO established the Global Advisory Committee on Vaccine Safety (GACVS) to work to ensure the safety of vaccines globally and ensure country specific guidelines on vaccinations (Folb et al., 2004). Previous studies have reported the use of national monitoring systems by countries to conduct surveillance on AEFIs. As reported by Awaidy et al., 2010 about 53% of member states of WHO have a national AEFI monitoring system.

2.5.1 Surveillance of Adverse Events Following Immunizations

Surveillance is recognized in research cycles as the systematic and continues collection of information or data and analysis to guide the decision-making process. Previous studies have indicated that there exist three main types of AEFIs surveillance systems, namely, passive surveillance, active surveillance, and spontaneous surveillance.

In Ghana, according to the EPI-Ghana (2014), the active and spontaneous systems of surveillance have been the commonly used in the detection and reporting of AEFIs.

2.5.1a Passive surveillance

As explained by Joshi et al. (2018) the passive surveillance system employed by most countries depend on the capacity of healthcare workers and healthcare facilities to identify and collect data on serious AEFIs. The reporting of the AEFIs are to be done in line with a standard format, investigated and community concern regarding the event addressed (Joshi et al., 2018). Additionally, depending on the nature of the event, the clustering of several events across time/place or vaccine (Joshi et al., 2018). When examined, the reported AEFIs are to be equally analyzed for causal relationship with the vaccine or vaccination process. It is important to stress that, to create a causal relationship of AEFI with vaccine entails important feature as clinical details, epidemiological context, and programmatic conditions as well as qualified experts to carry out (Yenyi, 2019). As has been indicated in some country specific operational guidelines on AEFIs such as that of India, reporting of common and non-serious AEFIs is done on monthly basis through Health Management Information System (HMIS) (Operational Guidelines for AEFI Surveillance in India, 2014). These common AEFIs included minor fevers, redness, local swelling, and others that normally resolve on their own (Operational Guidelines for AEFI Surveillance in India, 2015). Likewise, serious AEFIs including inconsolable screaming (> 3 h), hypotonic-hypo-responsive episodes, severe local reaction, injection site abscess, seizures, lymphadenitis which are less common are documented in a Block AEFI register as well as HMIS (Operational Guidelines for AEFI Surveillance in India, 2015). However, serious AEFIs are to be reported immediately for investigation and action within forty-eight (48) hours (Operational Guidelines for AEFI Surveillance in India, 2015). Such serious AEFIs comprise of deaths, hospitalization, long hospital stays, disability and injury (Operational Guidelines for AEFI Surveillance in India, 2015).

2.5.1b Active surveillance

As defined by the WHO (2020), active surveillance is a form of surveillance that is characterized by regular visitations to healthcare facilities, interviewing healthcare workers and review of medical records to identify selected AEFIs. In the active system of surveillance, a trained healthcare staff regularly make visitations to healthcare facilities to assess or collect information on suspected AEFIs among children who visited those healthcare facilities. Importantly, the active surveillance allows for the review of all reported cases of AEFIs in medical records and registers of healthcare facilities. Observed AEFIs are documentations are made to include the clinical and epidemiological data and a possible and a possible laboratory specimen is taking for immediate action, according to national policy on vaccinations (WHO, 2020). The WHO (2020) further explained that the active surveillance system is often used when AEFI is normally targeted for eradication or elimination.

2.5.1c Spontaneous AEFI Surveillance

According to the EPI-Ghana (2014) the spontaneous surveillance system is where a client or the parent of the child comes to a health facility to report on AEFIs after receiving a vaccine or a healthcare worker connects a client's condition to vaccine. Some studies have described the spontaneous system of surveillance as the widely used system of surveillance by most health systems to identify AEFIs (Yun et al., 2012). However, the use of spontaneous surveillance system is acknowledged to be unproductive as it characterized by under-reporting (Yun et al., 2012). According to Yun et al. (2012) spontaneous surveillance system can only recognize about only 5% of all AEFIs. Equally, the use of the spontaneous surveillance system lacks essential clinical information (Yun et al., 2012).

2.6. Reporting of Adverse Events Following Immunizations

Reporting of AEFIs according to the WHO (2020) is the responsibility of parents of immunized infants, healthcare workers and staff of accident and emergency department in hospitals. Explaining further, healthcare workers have the responsibility of identifying and treat any AEFIs as most are the first to recognize any untoward event after vaccination. The WHO equally recommends that all healthcare workers, especially, those who are involved in immunization programs must be able to detect and report adverse events. Importantly, the identification of AEFIs requires effective staff training and education among mothers to facilitate the accurate detection and reporting of AEFIs (WHO, 2020).

2.6.1 Role Healthcare workers in AEFIs Reporting

The role of healthcare workers in reporting AEFIs cannot be over-emphasized in recent times. Healthcare workers, especially those who are involved in immunization programs are likely to be the initial persons to observe any events after immunization. It is a common knowledge that equipment and tools does not work to give desired results. Therefore, providing all required materials necessary for the detection of AEFIs also requires qualified healthcare workers to detect and document any event after immunization. In as much as healthcare workers play an important role in the reporting and documentation of AEFIs, it has been acknowledged that low knowledge as well as management of AEFIs has been the major challenges to the reporting of AEFIs (Muchekeza et al., 2014). As held by Yenyi (2019), in an effort to address the observed challenges among the health profession towards reporting of AEFIs, it is important to orient and train healthcare workers on key issues of AEFIs including; the definition, identification, treatment and management, documentation processes and notification to appropriate authority.

These interventions, according to Yenyi (2019), would increase healthcare workers appreciation of AEFIs, documentation processes and vaccine safety in general.

2.6.2 The Role of Infant's parents

Public health interventional programs such as immunization programs should be regarded as a partnership between beneficiaries and the providers of such interventions. This underline the role of parents and the community's role in the reporting of any observed AEFIs. As asserted by Adedokun et al. (2017) and Muchekeza et al. (2014), parents or caregivers' knowledge on AEFIs greatly influences the reporting of observed AEFIs on their children. A poor knowledge of AEFIs among caregivers has been observed to be associated with the low reporting of AEFIs in most countries (Adedokun et al., 2017; Muchekeza et al., 2014). As has been acknowledged by some studies on the reliance on caregivers or parents in spontaneous surveillance of AEFIs (Yun et al., 2012), it therefore becomes a good call to continually address the low knowledge level of AEFIs among caregivers or parents. To address the poor knowledge level of AEFIs among caregivers or parents Yenyi (2019) suggested a health talk on AEFIs at child welfare centers prior to immunization schedules. Importantly, the quality of information provided during the health talk sessions on AEFIs would impact positively or negatively on caregivers or parents' attitudes towards AEFIs (Adedokun et al., al., 2017; Aina et al., 2013). Similarly, other salient factors that have been reported in previous studies to affect reporting of AEFIs included poor healthcare seeking behaviors, no felt need attitudes and inaccessibility to healthcare facilities (Muchekeza et al., 2014; Sanou et al., 2009). Other studies also reported factors such as fear of victimization from healthcare workers, predilection of home treatment, perceived non-severity of observed AEFI, ineffective communication, wrong religious notion, and low socioeconomic status (Tsafack et al., 2015). The point can be made that, for an AEFI to develop on a child

means the child was made available for an immunization, demonstrating a good healthcare seeking behavior among the caregiver or parent (Adedokun et al., 2017). Hence, caregivers or parents' refusal to report on observed AEFIs to healthcare facilities or community volunteers might stem from poor knowledge level or other demotivating factors the needs urgent attention (Adedokun et al., 2017). Not going back to report could result in dropouts in vaccination programs.

2.7 Adverse Events Following Immunizations and Immunization Dropout

Previous studies have emphasized that immunization coverage levels are essential in monitoring the performance of immunization programs in communities and at the global front. Again, the immunization coverage levels are critical to guide planning towards eradication, elimination, and control of VPDs (WHO, 2015; WHO, 2014; WHO, 2005). According to Mbabazi et al. (2013) most VPDs are in low levels in developed countries and with high immunization coverage programs for the population especially among children under age five. Wolfson et al. (2008) also added that globally, about three quarters of children have received the recommended vaccines. The statistics on immunization coverage levels in sub-Saharan African countries shows that just about half of the children population have access to the recommended vaccines against VPDs (Sally & Kenu, 2017). Previous studies continue to show that the least covered in immunization programs in most countries are the hard to reach communities, especially in LMICs. Statistics on immunization programs among hard-to-reach communities shows that just one in twenty children have been dully vaccinated (Wolfson et al., 2008). In the year 2014, it was reported that about 18.7 million children globally were not reached with the recommended vaccines (Sally & Kenu, 2017). Statistics on immunization programs in Ghana, shows that from 1993 to 2008, the immunization coverage among children increased from 54.8% to 79.0%. However, there was a

significant decline in 2014 with a reported immunization coverage of 77.3% (Ankrah, et al., 2018). The drop and yet to be reached children in immunization programs in Ghana could increase the susceptible population to VPDs. Efforts to address the drop in immunization coverage and reach out to the yet to be reached children population could further be compounded by AEFIs. As an illustration, a mother who have had to worry over an AEFI observed on the children is likely not be motivated to make the child available for the dose of vaccination. With experiences of WEFIs among the mothers' mothers are likely to become defaulters to immunization schedules and eventually leading to immunization dropout. There is less empirical evidence to the association between AEFIs and immunization dropout, nonetheless, some studies that have attempted to study the determinants of immunization dropouts has often reported on factors including poor knowledge about immunization, lack of suitable venues and furniture at outreach clinics in Ghana (Bosu et al., 1997). Equally, factors such as financial difficulties, long waiting times, transport difficulties, poorly motivated service providers and weak intersectoral collaboration has also been reported as factors that hinder immunization programs (Kiptoo, 2015).

2.8 Knowledge and Self-reported Adverse Events Following Immunizations among Mothers

AEFIs seems to be on the rise as previous studies have reported increasing prevalence of AEFIs (Twene et al., 2018). The increasing trend of AEFIs have the potential to reduce the public confidence in vaccines. As held by Selvakumari (2011), the adequacy of knowledge among mothers on matters related to immunizations is a key indicator to ascertain the health status of the child especially on VPDs among children under five years old. Selvakumari (2011), further explained that if mothers of children under five years are associated with factors including

ignorance, misapprehension and insufficient knowledge as well as poor healthcare seeking behaviors impacts directly on the well-being of the child in general and the decision to make to partake in immunizations. In India, Datta et al. (2017) reported in a study involving 330 mothers with children between the ages of 12 to 23 months on of mother's awareness and approaches towards AEFIs, it was noted that about 90.0% of the mothers were knowledgeable about AEFIs, with some of the commonly reported AEFI comprising of low grade fever (82.1%). Equally, the other AEFIs reported by Datta et al. (2017) included myalgia and gastro-intestinal upset, followed by local reaction- pain, swelling and redness constituting about 16.8% of the AEFIs. Overall, 20.9% of the mothers indicated having noted AEFIs among their children previously. Additionally, another study in India showed that out of the 1206 children between the ages 0-6 years, who received immunization, about 22.71% of reported AEFIs (Aherkar et al., 2016). Similarly, the commonly reported AEFIs included, fever (84.67%) and DPT vaccine commonly associated with AEFIs (37.8%) (Aherkar et al., 2016). In another related study conducted in Saudi Arabia by Yousif et al. (2013) among mothers with children of age 0-12 months showed that most of the mothers were knowledgeable (86.9%) about the schedule of vaccinations for their children. Yousif et al. (2013) concluded that the substantial knowledge of mothers on immunization schedules greatly influenced the immunization coverage. Yousif et al. (2013) therefore recommended that activities in the form of health education on immunizations, by emphasizing the need, the doses, schedules, and possible side effects are very essential in improving the coverage of immunizations. The findings of Sanaa et al. (2013) in Italy among mothers on their knowledge, attitude and behavior towards immunization demonstrated that about 54% of mothers were knowledgeable about VPDs. The common VPDs given by the mothers included tuberculosis, hepatitis, and measles. Sanaa et al. (2013) further indicated that

among the mothers that were knowledgeable on VPDs approximately 46.4% were educated and do make their children available for immunization timely. Importantly, Sanaa et al., (2013) indicated that about 50% of mothers who had no education were observed to also delay in presenting their children for immunization schedules.

Additionally, Mohammad et al. (2010) revealed that the prevalence of associated complications of immunizations among 5776 children in Iran reported that 29% of these children reported one or more of AEFIs. AEFIs mostly observed among the children included fever (24%), pain (3.8%), swelling (2.5%), erythema (2.5%), induration (2.1%) as well as ulceration (2.1%). Mohammad et al. (2010) indicated the serious AEFIs observed were encephalitis and febrile seizures among one and two participants, respectively. MMR vaccine was the most noted vaccine to cause serious AEFIs leading to hospitalization and out of every four children, one has had an AEFI, commonly fever (Mohammad et al., 2010). Similarly, in Napal, Davkota et al. (2013) reported in a study that looked at the knowledge level and childhood immunization practices among mothers' demonstrated that about 72.5% of the participants were knowledgeable about vaccines their children were supposed take and facilitated by health education on the media about immunizations.

According to Afolaranmi et al. (2020) in a cross-sectional study involving 400 mothers with children of age 0–23 months in Nigeria, about 55.5% of the mothers indicated adequate knowledge on AEFIs. The mothers reported AEFI prevalence of 46.5% and fever being the commonly observed AEFIs (90.3%). Other AEFIs reported included pain (75.8%), generalized rashes (18.3%) swelling (14.0%) and convulsions (3.2%). Afolaranmi et al. (2020) asserted that just about 14.5% of the mothers were able to adequately provide interventions to observed AEFIs. Again it was noted in the study that mothers employment status was significantly

associated with the appropriateness of intervention given to the child (COR= 3.84; 95% CI =1.366–10.575; P= 0.007) (Afolaranmi et al., 2020). Other important aspects of Afolaranmi et al. (2020) study showed that some of the mothers consisting of 44.5% and 32.3% indicated that AEFIs were as a consequence of infections that arise form improper handling of the vaccines as well as accidental events, respectively. The findings equally showed that some mothers had fair knowledge about some AEFIs, which can be said that it will help in the reporting of AEFIs once these mothers notice them on their children and also given that about 64.8% of the mothers 'indicated the need to report on AEFIs. The given AEFIs by the mothers' according to Afolaranmi et al. (2020) comprised of fever 79.5%,, convulsions (18.3%) and weakness of the limbs (41.5%). The vaccines implicated in Afolaranmi et al. (2020) study included pneumococcal conjugate vaccines (69.4%), pentavalent vaccine (68.3%), BCG vaccine (31.7%), yellow fever and measles vaccines (1.1%).

As was reported in a case control study by Olumuyiwa et al. (2008) in Nigeria involving mothers with children between the ages of 12-23 months that most of the unimmunized children belonged to mothers with no education and poor socioeconomic rankings. Olumuyiwa et al. (2008) further stated that mothers who had no education had poor understanding on VPDs paralleled with mothers who are educated. Another important observation made by Olumuyiwa et al. (2008) was that given mothers health talk on VPDs effectively arouse the interest of mothers to especially among those without education to want to learn more about VPDs and apply the knowledge gained to improve the health of their children. This observation therefore presupposes that increasing health education especially on AEFIs and vaccinations in general is likely to increase vaccination coverage and identification of AEFIs as well the confidence in immunization programs globally. As maintained in Olumuyiwa et al. (2008) study that the

completeness of vaccination schedules by mothers was significantly associated with the level of knowledge of mothers on immunization. A cross-sectional study conducted by Olumuyiwa et al. (2008) in Nigeria on the determinants of immunization coverage among mothers showed that most of the study participants (97%) showed substantial knowledge about vaccination in general. Olumuyiwa et al. (2008) further indicated that approximately 55% of the participants had knowledge about some signs and symptoms of VPDs. Olumuyiwa et al. (2008) admitted in the study that the vaccination coverage increased tremendously after a sensitization program was organized on the VPDs from 61.9% to 81% among children. Having education or increasing the knowledge of mothers would significantly impact immunization programs. This would include the identification of AEFIs. In an effort to increase vaccination coverage could also increase observed AEFIs among the populace, especially among children under five (5) years. It is therefore important to shift attention to factors such as AEFIs that could derail the progress made so far. In another cross-sectional study involving 331 mothers to assess their knowledge on AEFIs in Nigeria, Ekwueme (2009) reported that about 82.5% of the mothers indicated fever as an AEFIs. Other AEFIs reported by the mothers in Ekwueme (2009) study included Pain and swelling (23.3%), rash (10.3%), convulsion (3.9%) boils (3.0%) paralysis or weakness of limbs (2.7%) as well as ulcers 0.6%. In all 66.5% of the mothers' indicated haven ever seen AEFIs on their children. Ekwueme (2009) also observed that the common AEFIs reported by the mothers included fever (90.4%), pain or swelling (27.7%), rashes and convulsion (2.7%) each. Ekwueme (2009) similarly added that ulcer and paralysis or collapse was indicted by 0.9% and 0.5% of the mothers. The study equally reported about 93.2% of the AEFIs were noted within 24hours with DPT (80.0%) been the most noted vaccine with AEFIs. The other vaccines reported to be associated with AEFIs included HBV (16.8%), BCG (16.4%), OPV (9.5%), measles

(5.5%), yellow fever (4.5%) and CSM (3.2%). Similarly, Ekwueme (2009) observed that most of the mothers provided some form of intervention when thy observed the AEFI. Such interventions according to Ekwueme (2009) included the use of paracetamol (57.4%), avoided other immunization schedule (21.1%), and about 19.5% also indicated that the child was sent to a healthcare facility. took the child to hospital. Importantly, about 0.9% of mothers also indicated that they visited a traditional herbalist for intervention, creating a disturbing scenario and a poor healthcare seeking behavior. As was also maintained by Lawan et al. (2016) in a study involving 372 children to study the pattern of AEFIs in Nigeria, it was observed that the reported AEFI prevalence was 33.1%. The AEFIs reported also included fever (79.8%), pains, or swelling (76.9%). Additionally, Lawan et al. (2016) indicated that the AEFIs happened with the first three (3) immunization visits.

Previous studies have reported low immunization coverage in some parts of the world and have been associated with increasing false impression, AEFIs combined with poor level knowledge and of education among healthcare workers and mothers (Masika et al., 2016). As observed in a study conducted by Smaillbegovic (2003) disclosed that 34% of mothers declined to make available their children for immunization programs and attributed this observation to the increasing misconception. Equally, other studies have reported that most education and information offered by healthcare workers on immunization programs including AEFIs are inadequate. This negatively impact the reporting and management of AEFIs. Learning from a study conducted by Kabir et al. (2005) in Nigeria showed even though there was increasing health education on immunization, however, about 25% of the population indicated not being aware of immunization programs, this observation is compounded with the increasing AEFIs which has the tendency to reduce vaccine coverage. Again, learning from Kabir et al. (2005)

study, 75% of the mothers' indicated knowledge of immunization programs, however, quite a substantial proportion (68%) indicated poor knowledge of the vaccination schedule. More importantly, 54% of the mothers revealed that they were not willing to make their children available for vaccinations because of fear of developing an AEFIs and another 59% also indicated that vaccines do not have the potential of protecting their children from VPDs.

In Ghana, a previous study reported 2,282 AEFI cases with 21% of these cases been serious that resulted in complications such as hospitalization, disability, and death (Poster et al., 2019).

2.9 Knowledge and Self-reported Adverse Events Following Immunizations among Healthcare Workers

As has been expressed by other studies about the tremendous role of healthcare workers in immunization programs and AEFIs identification (Mehmeti et al., 2017) their knowledge on AEFIs is equally important. As was observed among 86 healthcare workers by Muchekeza (2010) in Zimbabwe, about 61 of the participants adequately explained what an AEFI is. However, the nurses indicated not documenting AEFIs and assigned reasons such as none-existence of training on how to document AEFIs (91.8%), lack of documentation forms (70.5%) as well as mothers not being aware of AEFIs (34.6%) (Muchekeza, 2010). The findings of Muchekeza (2010) further explained that the nurses were not able to correctly explain or define what constituted AEFI with only 6% of the nurses also indicating ever been trained on AEFIs investigation and surveillance. The poor training among these nurses could be the reason for the poor knowledge on AEFIs noted among the nurses. On the documentation of AEFIs among the nurses, the findings of Muchekeza (2010) showed that none of the AEFIs forms had been filled during the study period in 2010 however there were about 86 reported cases of AEFIs in 2009 on T5 surveillance system. It is interesting to note that some of the nurses (11.5%) indicated having

attended to cases AEFIs in 2010 of which the AEFIs were not documented appropriately. Assigned reasons for documenting AEFIs were "not knowing the reporting procedure, fear of causing unnecessary alarm and unavailability of stationary for reporting the cases" and the healthcare facilities involved in the study also did not have AEFI case definition and documentation procedure displayed (Muchekeza, 2010). The observations in Muchekeza, (2010) does not only show the knowledge gap on AEFIs among the nurses but also reflects the weak healthcare systems in Zimbabwe and most other African countries.

In Kenya, Masika et al. (2016), reported in a study among 274 healthcare workers that on the level of knowledge, practices and perceptions towards AEFIs were 29.2%, 32.1%, and 45.3% respectively. Similarly, the results showed that about 51.8% of the healthcare workers did not have any formal training on AEFIs with only 37.4% indicating no knowledge of the causes of AEFIs. Additionally, Masika et al. (2016) findings showed that just 10.3% of the healthcare workers are able to correctly report on AEFIs and another 25.5% of the healthcare workers indicating that AEFIs needed to be assessed within 24 hrs. About 40% of the healthcare workers demonstrated knowledge on the management of AEFIs as well as healthcare workers with diploma or degree educational level demonstrated higher levels of appreciation of AEFIs ($p = 0.022$) compared to healthcare workers with lower educational level. Likewise, Masika et al. (2016) study showed that healthcare workers with previous training on AEFIs were more knowledgeable on AEFI surveillance ($p< 0.0001$).

In Ghana, Yamoah et al. (2019) findings among nurses tend to demonstrate higher knowledge of AEFIs compared to what was described by Muchekeza (2010) in Zimbabwe. Yamoah et al. (2019) indicated that majority of the nurses (83.4%) were able to define AEFI and stated the main AEFI to include injection site abscesses. Yamoah et al. (2019) findings also showed that

the nurses noted that the main factors that accounts for AEFIs included reconstituted vaccine stored longer than normal or expired and vaccine reactions. Additional causes given by the nurses also comprised of wrong route of administration, contaminated vaccines, as well as treatment of a coincidental illness (Yamoah et al., 2019). Similarly, Yamoah et al. (2019) reported that most of the nurses were of the believe that reporting of AEFIs and surveillance systems would impact on increasing public confidence in immunization programs in Ghana. However, the question to ask is, does their belief really impact the documentation of AEFIs to improve surveillance? As was observed by Yamoah et al. (2019) it can be deduced that nurses do not actually reported AEFIs and assigned reasons such lack of time to document resulting from busy work schedule. Again, Yamoah et al. (2019) findings showed that most of the nurses indicated the lack of interest to know more AEF Is. The lack of interest to learn more about AEFIs indication by the healthcare workers could impact negatively on AEFIs surveillance, given the fact that knowledge on AEFIs could change overtime. The factors observed to be statistically significant with the healthcare workers knowledge included work location ($p<0.0001$), gender ($p = 0.006$), as well the number of AEFIs trainings attended within a year ($p=0.002$) (Yamoah et al., 2019).

In another previous study by Gidudu et al. (2019) involving 306 healthcare in Ghana across 169 facilities in Ghana showed that 57.5% of the healthcare workers indicated ever encountered AEFI in line of duty. Among healthcare workers who have encountered AEFIs about 55.0% specified that they reported the AEFI, however only 31.7% documented the AEFI by way of completing a reporting form. Likewise, the challenges to reporting of AEFIs observed in Gidudu et al. (2019) study included fear of queries (44.1%), poor knowledge and training on AEFIs reporting (25.2%) together with AEFIs regarded as not being serious to report (22.2%). Gidudu

et al. (2019) also indicated that supervision AEFIs was statistically associated with reporting of AEFIs (OR 7.39; $p < .001$). In a related study in Ghana among 47 healthcare workers, Twene et al. (2018) noted that about 89.4% have had training on AEFIs but surprisingly, about 63.8% of them could not define AEFI. Twene et al. (2018) further indicated that the healthcare workers were of the view that AEFIs were mostly caused by poor vaccine storage, preparation, and administration of the vaccines. The associated vaccine AEFIs mentioned by the healthcare workers included pain, swelling and redness (28.5%) or irritability, malaise, and systemic symptoms (14.6%) (Twene et al., 2018).

CHAPTER THREE

METHODOLOGY

3.0 Introduction

This chapter describes the methods that will be used to conduct this research. The chapter looked at key topics like; Study Area, Study Setting, Study Design, Study Population, Sample Size, Sampling Method, Study Variables, Data Collection Tools, Data Analysis and Presentation Methods, Data Quality Control Measures, Ethical Considerations, Study Limitations and Dissemination of Study Outcome.

3.1 Study Area

The Tamale Metropolitan Assembly was established by legislative instrument (LI 2068) which gave rise to the then Tamale Municipal Assembly to become a Metropolis in the year 2004 (GSS, 2010). It has Tamale as the Metropolitan Capital city as well the regional capital of the Northern Region (GSS, 2010). The Tamale metropolis is composed of the Tamale Central, the Tamale South and the Tamale North constituencies. The Tamale Metropolis is one of the 26 districts in the Northern Region. It is located in the central part of the Region and shares boundaries with the Sagnarigu District to the west and north, Mion District to the east, East Gonja to the south and Central Gonja to the south-west (Figure 3.1). The Metropolis has a total estimated land size of 646.90180sqkm (GSS-2010).Geographically, the Metropolis lies between latitude 9º16 and 9º 34 North and longitudes 0º 36 and 0º 57 West. Tamale is strategically located in the Northern Region and by this strategic location, the Metropolis has a market potential for local goods from the agricultural and commerce sectors from the other districts in the region. Besides the comparative location of the Metropolis within the region, the area stands

to gain from markets within the West African region from countries such as Burkina Faso, Niger, Mali and the northern part of Togo and also en-route through the area to the southern part of Ghana (GSS, 2010).

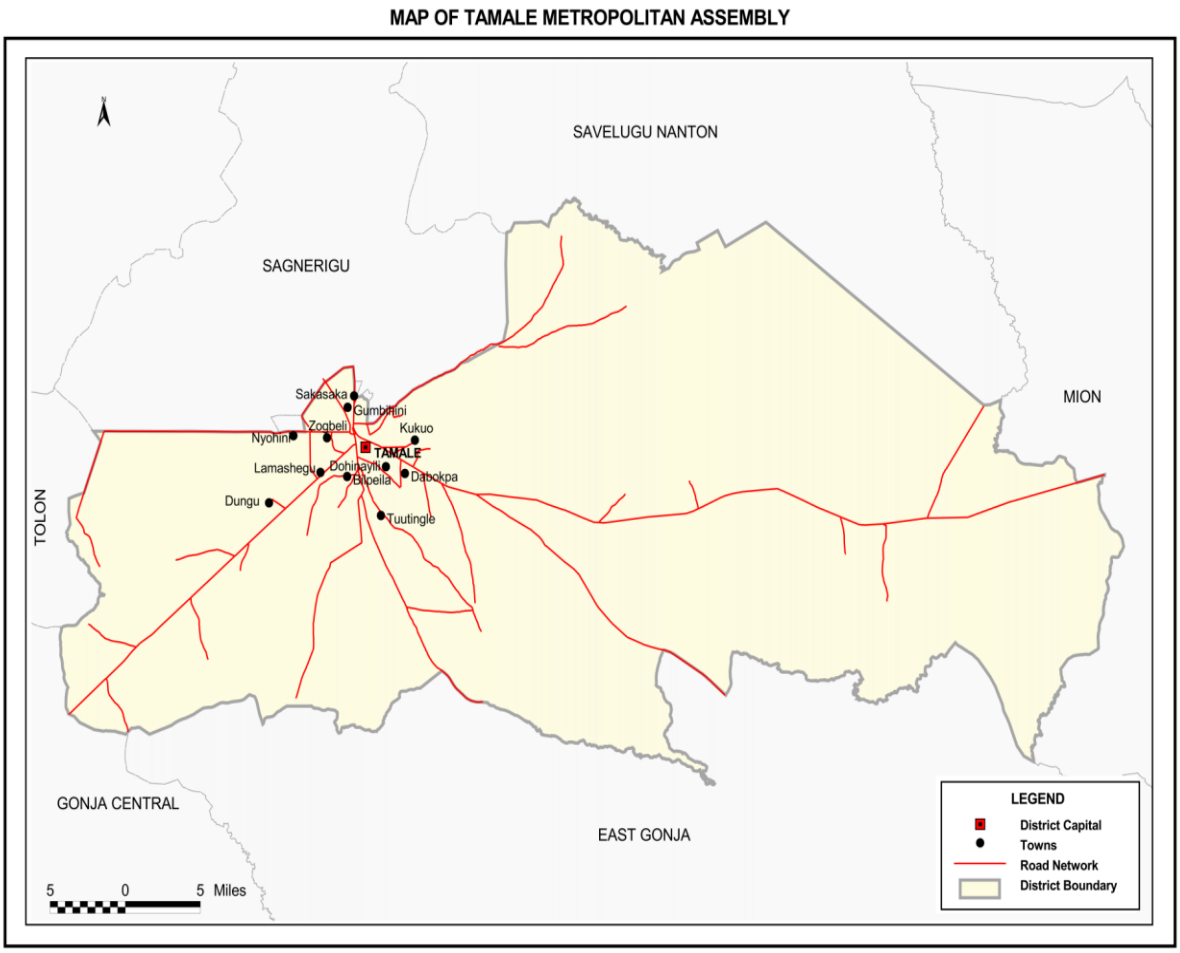


Figure 3.1 Map of Tamale Metropolis. (Source: GSS, 2010).

3.2 Study Setting

The study was conducted in Tamale Metropolis, specifically among the four sub-districts under the Tamale Metropolitan Health Directorate. Under the Health division, the Metropolis is demarcated into four (4) sub-districts; each sub-district has a management team that forms the

Sub-district Health Management Team (SDHMT) (Tamale Metropolitan Health Directorate, 2019). The various sub-districts are:

1. Bilpeila Sub-district
2. Nyohini Sub-district
3. Tamale Central Sub-district
4. Vitting Sub-district

The SDHMTs are responsible for programme planning and implementation of health activities in their various sub-districts. The SDHMT's conduct integrated static and outreach activities, immunization, reproductive health, disease control, growth monitoring, health education/promotion and clinical care. Training and supervision of community-based health workers such as traditional birth attendants (TBAs), Community Based Surveillance (CBS) volunteers, village Health Committees (Tamale Metropolitan Health Directorate, 2019).

3.3 Study design

The study was a cross sectional study, conducted in October 2019 to July 2020 among four sub-districts health facilities in the Tamale Metropolis. The study was a mixed method approach to research, thus both quantitative and qualitative methods. The study involved two categories of participants involving mothers of children < 5 years old who had been vaccinated at least once in the Tamale Metropolis and healthcare workers who are involved in the immunization/vaccination programmes of the health facilities.

The quantitative approach to the study mainly targeted mothers with children < 5 years and involved the administration of semi-structured questionnaires on AEFIs. The semi-structured questionnaire was developed to include both closed and open-ended questions to gather data on

AEFI among the participants. The use of the semi-structured type of questionnaire involving the opened and closed ended questions allowed the researcher to assess participants on both predetermined study characteristics and some other unknown characteristics from the participants' perspective(s). The qualitative approach to the study was used to collect data/views from the healthcare workers. The researcher employed a face-to-face interview guide to collect data on AEFIs in the various health facilities among key informants. Four main face to face interviews were conducted. The key informants in this study included (1) Diseases control officer (2) Head of the Facility (3) Community Health Nurse and (4) Health information officer.

The interview guide was designed to collect data on healthcare workers work experience, position, knowledge on AEFIs and challenges associated with the reporting of AEFIs in their facilities.

3.4 Study population

The study population for this study involved mothers presenting their children at the child welfare clinic at the four sub-districts health facilities in the Tamale Metropolis and healthcare workers in the four healthcare centres in the metropolis.

3.5 Sample size determination

Using the immunization coverage rate (79.8%) on the yellow fever immunization coverage in the Northern region as the baseline, the minimum estimated sample size was 247.7 which was approximated to 248.

The sample size was calculated using the Cochrane sample size determination formula (Bartlett, et al., 2001), given as:

$$n = \frac{pq(z)^2}{(d)2}$$

where,

n= estimated sample size

p + q =1

From the Ghana Health Services the Health Sector in Ghana Facts and figures (2018) report, the immunization coverage rate for yellow fever in 2017 was 79.8%, therefore "p" = 79.8/100 = 0.798.

Therefore p + q = 1,

0.798 + q = 1

Hence, q = 1 – 0.798 = 0.202

d= expected sampling or margin of error = 5% (0.05).

z= 1. 96 at 95% CI

computing for the values, **n** = $\frac{0.798\ x\ 0.202\ (1.96)^2}{(0.05)\text{^}2} = 247.7$

Therefore, the minimum estimated sample size is **248.**

3.5.1 Sampling for mothers with children under 5 years

The study used a quota system to determine the number of mothers from the various child welfare clinics based on the number of mothers on the facility's register. But due to COVID-19 restrictions the health facilities restricted the number of mothers who are to come for postnatal services to 25-30 mothers on clinic days to avoid overcrowding and the risk of Corona virus transmission. Therefore, the use of the quota system was modified to accommodate the restricted number of mothers allowed attend each day. During the data collection period, a simple random was used by recruiting every second willing and qualified mother in the cue to attempt the questionnaire. **Figure 3.2** shows the number of mothers attending the clinics during the period and the numbers sampled. All mothers coming to clinic had been advised on COVID 19 precautions including wearing of Face Masks. The daily tally of mothers interviewed was monitored continuously from all four clinics until the desired sample of 248 was attained.

3.5.1a Distribution of participants among the health facilities

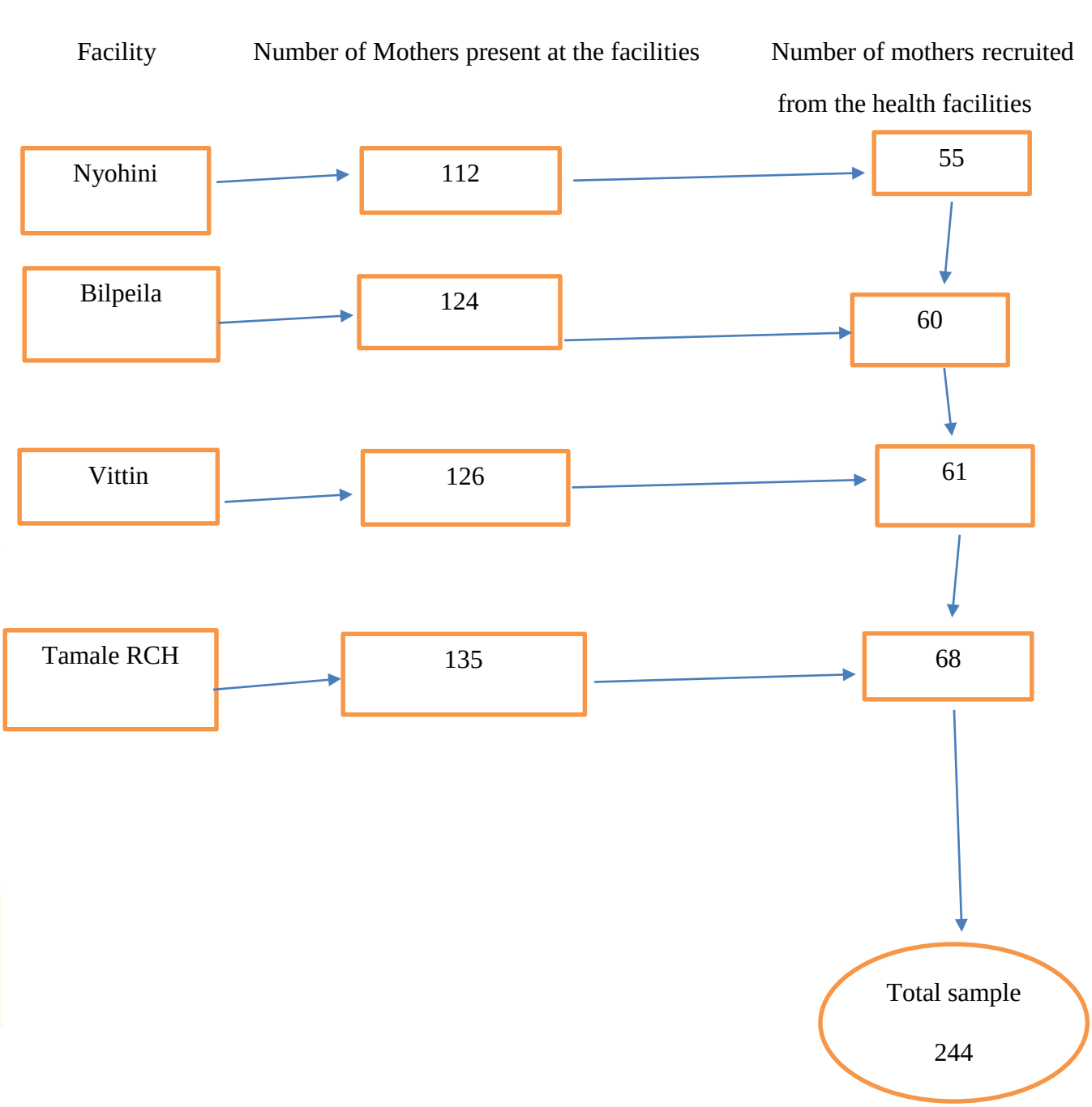


Figure 3.2 Distribution of participants among the health facilities

Source: Author, 2020.

3.5.1c Healthcare workers participants

Purposive sampling approach was used to select healthcare workers to conduct face to face interview from the four health facilities under Tamale Metropolitan Health Directorate. The researcher used face-to-face interview guide to interview one key informant (healthcare worker) from each of the four health facilities. The healthcare workers included Head of the Health Facility, Disease Control Officer, Community Health Officer, and a Health Information Officer who were directly involved in immunization/vaccination exercises in the various health facilities in the Tamale Metropolis.

3.5.1 Selection Criteria

The inclusion criteria set for this study were;

Mothers

1. Mothers or guardians of children < 5 years old who had been vaccinated at least once in the health facility.
2. Must consent to participate in the study

Healthcare workers

3. Healthcare workers who are directly involved in immunization/vaccination exercise
4. Must be in active service for more than a year at the clinic
5. Must consent to participate in the study

3.5.2 Exclusion criteria

For the purpose of this study, respondents were excluded based on:

Mothers

1. Refusal to consent to participate in the study by Mothers
2. Mothers' or guardians with sick child and cannot participate in the study
3. Mothers from outside the Metropolitan Area

Healthcare workers

4. Healthcare workers who were not directly involved in immunization programs
5. Healthcare workers who have less than one-year work experience
6. Refusal to consent to participate in the study

3.6 Study Variables

Explanatory Variables: This consisted of the demographic characteristics of participants (age, sex, marital status, income etc.)

Outcome variables: This consisted of AEFIs Knowledge and AEFIs reporting behaviours.

3.7 Data Collection Technique

A semi-structured questionnaire was designed to collect data on AEFIs among the participants by reviewing studies described elsewhere (Masika et al., 2016; Ankrah et al., 2018). The semi-structured questionnaire was developed using a closed and open-ended type of questions. The adoption of the closed ended type of questions was to allow the researcher to identify predefined questions related to self-report AEFIs, knowledge, AEFIs reporting behaviours and the associated factors AEFI reporting. Whereas the open-ended type of questions was to allow the researcher to collect information on AEFIs based on the perspectives of the participants. The prevalence of AEFI's was established from the mothers' together with the assessment of their knowledge on AEFIs, AEFIs reporting behaviours, as well as reasons for not reporting AEFIs and the challenges they encounter to report AEFI's.

The interview guide was semi-structured which allowed that guided the researcher to find out on AEFIs from the perspectives of the key informants (healthcare workers).

3.8 Data Quality Control

The researcher carried out the following measures: Pretesting of Study Instruments and Training of Research Assistants to ensure the quality of the data collection processes and study in general.

3.8.1 Pretesting of Study Data Collection Instruments

The researcher conducted pretesting of the study data collection instruments at the Kanvilli health facility in the Sagnarigu Municipal Assembly. About 5% of the study's sample size was estimated (12 pretesting participants) to pre-test the study data collection instrument. The Sagnarigu Municipal was considered because it has similar population characteristics as that of the Tamale Metropolitan Assembly. Based on the pretesting outcome, modifications were made to the study collection instrument where necessary to achieve the objectives of the study.

3.8.2 Training of research assistants

The research assistants recruited for this study included, one medical student, a community health nurse, and a general nurse to help in the data collection processes. A day training session with the research assistant was organized prior to the pretesting of the data collection instrument. The training was carried out to help the research assistants to enrich their data collection skills and introduce to them the main objectives of the study. The pretesting of the study data collection instrument was subsequently carried out with the research assistants. This enabled the research assistants and the principal investigator to identify the challenges and sections of the data collection instrument that needed attention and modification. Following the pretesting exercise, another meeting with the research assistants was organized, where challenges observed

during the pretesting period were made known and the necessary modification and answers were given to enhance the completeness of the study.

3.8.3 Data collection and handling/management

The items on the questionnaire were carefully explained to participants who could not read in a local language (such as Dagbaani etc.) to help them understand and make informed choices and answers. The researcher ensured that participants attempted almost all the items on the questionnaire. The research assistants forwarded the data collected after each session to the principal researcher for tallying toward the sample size. The collected data were subsequently cleaned and coded for analysis.

3.9 Data Analysis

Data obtained for the quantitative part of study was entered on Microsoft Excel 2010, validated, and later exported to SPSS (version 25) for further data management and analysis. The data was analysed descriptively, and a Pearson chi-square test was also performed to test associations. The data was presented in frequencies, percentages, graphs, and cross tabulations for clarity. Conventional statistical significance level of $p<0.05$ was be applied in statistical tests.

The qualitative data was analysed based on themes of the responses given by the key informants and triangulated with the quantitative data to better answer the research objectives.

3.10 Ethical Issues

Ethical approval for the study was obtained from the UDS Institutional Review Board (attached as appendix I). Likewise, permission was sought from the Regional and Metropolitan Health Directorate (attached as appendix II) as well as the heads of the various health facilities to conduct the study. Permission was also sought from the mothers and key informants to be

recruited on to the study. Both verbal and written consent were sought from the study participants. The scope and objectives of the study were carefully explained to the study participants. The explanation of the objectives of the study was carried out to aid study participants to make informed consent to either partake or not to in this study. The potential harms and benefits were made known to the potential study participants before recruiting them onto the study. The study participants were made to understand that participating in this study was voluntary and they can choose to redraw from the study at any point in time. Study participants were assured of their confidentiality and privacy and information gathered from them would not be used against them.

CHAPTER FOUR

DATA ANALYSIS AND RESULTS

4.1 Socio-demographic Characteristics of Study Participants

Tables 4.1 to 4.1.2 present detailed results on the socio-demographic characteristics of study participants. A total of 248 nursing mothers were recruited on the quantitative aspect of the study from four health facilities in the Tamale Metropolis, including Bilpeila Health Centre, Nyohini Health Centre, Vittin Health Centre, and Tamale Central Health Centre.

The mean age of the study participants was found to be 28.29 years (SD: 15.65). The findings of the study showed that a large proportion of the study participants were in the 20-24 age brackets 29.8% (74), followed by the 25-29 age brackets 29.0% (72) and 30-34 age brackets 17.7% (44).

Education: A large proportion of the study participants [33.9% (84)] did not have any form of educational qualification. About 19.8% (49) and 18.5% (46) of the study participants indicated that they have had senior high and junior high schools' education.

Religion: Majority [93.5% (232)] of the participants were Muslims with only 6.0% (15) indicating Christians.

Ethnicity: More than two-thirds of the study participants 83.5% (207) were Dagombas, followed by Mamprusis' 2.8% (7).

Table 4.1 Socio-demographic Characteristics of Study Participants

Variable	n=248 Frequency	(%)
Age		
15-19	16	6.5
20-24	74	29.8
25-29	72	29.0
30-34	44	17.7
35-39	31	12.5
40 and above	11	4.4
Sex /Gender		
Female	248	100
Educational Background		
Basic School	30	12.1
JHS	46	18.5
SHS	49	19.8
Tertiary	38	15.3
No Education	84	33.9
Non response	1	0.4
Religion		
Christian	15	6.0
Muslim	232	93.5
Traditionalist	1	.4
Ethnicity		
Akan	3	1.2
Dagomba	207	83.5
Hausa	5	2.0
Mamprusi	7	2.8
Others	26	10.5
Total	**248**	**100.0**

Source: Field Data, 2020. (Others= Fulani, Dagaati,Bimoba, Bulsa, Frafra, Gonja, Kasena, Konkomba, Yoruba, Kotokoli, Mossi)

Marital Status: 98.8% (245) representing the majority of the study participants were married, with only 0.8(2) and 0.4%(1) being single and co-habiting respectively.

Number of Childbirths: Approximately, 31.5%(78) of the participants were having only one child birth, followed by two childbirths 27.0% (67) and three childbirths 18.5%(46).

Number of Children Alive: About 32.3% (80) of the participants indicated that they have one child alive, followed by two 26.6% (66) and three 19.8% (49).

Occupation: Most of the study participants were informal sector workers, with a proportion of 75.8% (188), followed by formal sector workers 15.7 % (39) and about 8.5% (21) of the participants also indicated that they were not employed.

Table 4.1.1 Sociodemographic Characteristics of Study Participants Continuation

Variable	n=248 Frequency	(%)
Marital Status		
Single	2	0.8
Married	245	98.8
Co-habitation	1	.4
Number of Childbirths		
One	78	31.5
Two	67	27.0
Three	46	18.5
Four	25	10.1
Five	21	8.5
Six	8	3.2
Seven	2	0.8
Eight and above	1	0.4
Total	**248**	**100.0**

Source: Field Data, 2020.

Table 4.1.2 Sociodemographic Characteristics of Study Participants Continuation

Variable	n=248 Frequency	(%)
Number of Children Alive		
One	80	32.3
Two	66	26.6
Three	49	19.8
Four	25	10.1
Five	18	7.3
Six	7	2.8
Seven	1	0.4
Eight and above	1	0.4
No response	1	0.4
Occupation		
Civil Servant/Salary Worker	39	15.7
Farmer/Trader/Casual Worker	188	75.8
Unemployed	21	8.5
Total	**248**	**100.0**

Source: Field Data, 2020.

Description of Sociodemographic Characteristics of Key Informants

Table 4.1.3 gives a description of the sociodemographic characteristics of key informants for the qualitative aspect of this study. Majority of the key informants were females and have had working experience more than ten years. They included the heads of the facilities and disease control officer at the four health facilities under the Tamale Metropolitan Health Directorate.

Table 4.1. 3 Description of Sociodemographic Characteristics of Key Informants

Facility	Age	Sex/gender	Experience (years)	Rank/Position
Nyohini	45	Male	18	Head of facility
Bilpeila	40	Female	15	Head of facility
Vittin	37	Female	10	Disease Control officer
Tamale RCH	48	Female	20	Senior community health nurse

Source: Field Data, 2020.

4.2 Self-reported prevalence of Adverse Events Following Immunization

Figure 4.1 presents results on the self-reported prevalence of Adverse Events Following Immunization (AEFI's). The results showed that, out of the 248 study participants, a proportion of 85.9% (213) self-reported AEFIs with only 14.1 % (35) of the study participants not self-reporting on AEFI's.

To support the above findings, the qualitative study showed that mothers' who visit the various health facilities do give complains on AEFIs. As illustration all the interviewees from the various affirmed that mothers do complain about AEFIs.

Question: Have mothers who come here for vaccination for their children complained of AEFIs?

Response from an informant,

..oh! You know these our people they don't hide anything oo. They always report on AEFIs…

This response portrays that mothers indeed observe some AEFIs.

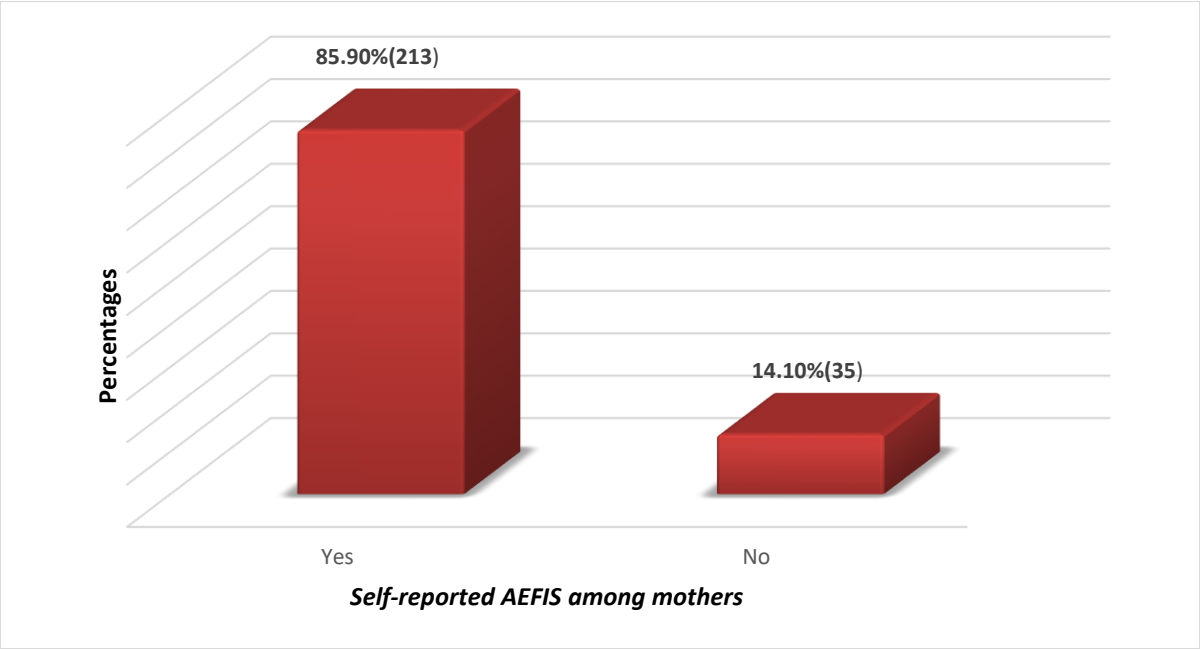


Figure 4.1 Prevalence of Self-reported AEFIS among mothers. *Source: Field Data, 2020.*

4.2.1. Self-reported Adverse Events Following Immunization

Tables 4.2 presents detailed results on the self-reported Adverse Events Following Immunization (AEFIs). From the results, most of the study participants [82.3% (204)] indicated that the AEFIs were observed within 24hours. Among the common self-reported AEFIs were as follows; Pain [8.9% (22)], Fever/High Temperature [63.7% (158)], Rashes **[**27.0% (67)] and Abscess/Swollen [33.1% (88)].

Corroborating the qualitative findings, it was acknowledged from the key informants that the common reported AEFIs included High Temperature/fever and Abscess. There were other AEFIs observed in other facilities which were not also observed by others. Though some mothers indicated headache as one of the observed AEFIs, it was not confirmed by the key informants.

Question: What are normally the complaints mothers' give on AEFIs about their children?

Response from an informant

"....mmmmm! I think since I started working here, the AEFIs mothers do complain consist of swollen thighs for the injections, fever, diarrhoea, vomiting, and body rashes..." Another response from an informant.

"...ooh! This facility at times mothers do complain that after the immunization, they saw some swollen at the site of injection and sometimes too they will tell you that their child was running high temperature.... Another response from an informant.

Findings from the face to face interviews affirms the reports by the mothers on the common vaccines they do observe AEFIs.

Question: Among the thirteen (13) vaccines preventable diseases (VPDs) which of them do you normally receive complaints on AEFIs?

Response from an informant.

"...ooh! Here, the common vaccine I normally hear mothers complain about on AEFIs is the Pentavalent Vaccine (thus a combination of DPT, HepB and Hib) and the IPV..."

Response from an informant;

".... If I remember very well, the common vaccines the parents do complain about is the Pentavalent Vaccine, measles vaccine and the IPV..."

Table 4.2 Self-reported Adverse Events Following Immunization

Variable	n=248 Frequency	%
Time taken to notice AEFIs		
Within 24 hours	204	82.3
After 24 hours	12	5.2
I do not remember	31	12.5
Observed/Reported AEFIs		
Local pain		
Yes	226	91.1
No	22	8.9
Fever/High Temperature		
Yes	158	63.7
No	90	36.3
Rashes		
Yes	67	27.0
No	181	73.0
Swelling		
Yes	82	33.1
No	166	66.9
Number of times AEFIs have been observed		
1-2 occasions	178	71.8
> 2 occasions	35	14.1
None	35	14.1
Number of Vaccinations		
Once	21	8.5
Twice	25	10.1
Three times	59	23.8
> Three times	135	54.4
None	4	1.6
No Response	4	1.6
Total	**248**	**100.0**

Source: Field Data, 2020.

Table 4.2.1 to 4.2.2 presents detailed results on vaccines and their associated AEFI as reported by mothers. From the results, it was indicated by mothers that Measles-rubella [21.8% (54)], Pneumonia [13.3% (33)]**,** Rotavirus vaccine [16.1% (40)], and Yellow fever [23.0% (57)] were reported to be associated with fever/high temperature.

Local Pain: Measles-rubella [20.2% (50)], Pneumonia [24.2% (60)], Rotavirus vaccine [18.1% (45)], and Yellow fever [27.0% (67)] were reported to be associated with local pain by mothers.

Rashes: Measles-rubella [12.1% (30)], Pneumonia [4.4% (11)], Rotavirus vaccine [7.7% (19)], and Yellow fever [2.8% (7)] were reported to be associated with rashes by mothers.

Swelling at site of injection: Measles-rubella [8.1% (20)], Pneumonia [9.7% (24)], Rotavirus vaccine [6.9% (17)], and Yellow fever [6.9% (17)] were reported to be associated with swelling by mothers.

Table 4. 2.1 Common AEFIs and associated vaccines

AEFI	**Vaccine(n=248)**			
	Measles-rubella	**Pneumonia**	**Rotavirus vaccine**	**Yellow fever**
	n (%)	**n (%)**	**n (%)**	**n (%)**
Fever/High temperature	54(21.8)	33(13.3)	40(16.1)	57(23.0)
Local Pain	50(20.2)	60(24.2)	45(18.1)	67(27.0)
Rashes	30(12.1)	11(4.4)	19(7.7)	7(2.8)
Swelling	20(8.1)	24(9.7)	17(6.9)	17(6.9)

Source: Field Data, 2020.

Table 4. 2.1 Common AEFIs and associated vaccines

	Vaccine (n=248)			
AEFI	**Meningitis**	**BCG**	**OPV/IPV**	**Penta**
	n (%)	**n (%)**	**n (%)**	**n (%)**
Fever/High temperature	56(22.6)	60(24.2)	35(14.1)	30(12.1)
Local Pain	65(26.2)	47(19.0)	33(13.3)	39(15.7)
Rashes	32(12.9)	28(11.3)	17(6.9)	23(9.3)
Swelling	16(6.5)	19(7.7)	16(6.5)	19(7.7)

Source: field Data, 2020. (BCG= Bacillus Calmette–Guérin, IPV = Inactivated Polio Vaccine, OPV = Oral Polio Vaccine)

4.3 Knowledge on Adverse Events Following Immunizations

Table 4.3 presents detailed results on the knowledge on Adverse Events Following Immunizations (AEFIs).

Out of the 248 study participants interviewed, approximately 89.9% (223) indicated of knowledge of AEFIs. Majority of the study participants [73.8% (223)] equally indicated that Child Welfare Center/Clinic/Hospital were their main source of information on AEFIs with another 16.1% (40) study participants indicating their source of information on AEFIs were from Family/Friends.

Additionally, to rate the level of knowledge on AEFIs, majority of the study participants [67.7 %(168)] indicated that they have good knowledge on AEFIs, followed by poor [26.6% (66)] and excellent [5.2% (13)]. Majority of the study participants equally indicated the desire to report on AEFIs [97.6% (242)].

Table 4. 3: Knowledge on Adverse Events Following Immunizations

	n=248	
Variable	**Frequency**	**%**
Knowledge of AEFIs		
Yes	223	89.9
No	25	10.1
Source of information on AEFIs		
Child Welfare Center/Clinic/Hospital	183	73.8
Family/Friends	40	16.1
None	25	10.1
Rating of Knowledge		
Poor	66	26.6
Good	168	67.7
Excellent	13	5.2
None	1	0.4
Desire to Report on AEFIs		
Yes	242	97.6
No	3	1.2
None	3	1.2
Total	**248**	**100.0**

Source: Field Data, 2020.

4.4 Adverse Events Following Immunization Reporting Behaviours

Table 4. 4 to 4.4.1 presents detailed results on Adverse Events Following Immunization Reporting Behaviours. From the results, it was found that about 80.2% (199) indicated that they have ever reported incidence of AEFIs to a health facility. Among the reported AEFIs to the facilities included local pain [10.9% (27)], Fever/High Temperature [52.4% (130)], Rashes [26.2 % (65)], and Swelling [30.2 % (75)]. The face to face interview findings indicates that mothers' indeed do report on AEFIs to the health facilities.

Question: Have mothers who come here for vaccination for their children complained of AEFIs?

Responses from informant.

"...oh! You know these our people they don't hide anything oo. They always report on AEFIs…"

Question: Do you record information on the complaints mother's make on AEFIs?

Response from an informant.

"...we are to record them when using a form but the issue is that most of our nurses do not fill the form because they feel that it can be used against them they don't know how to do injections and that caused the swollen…

….Another thing too is that some of the nurses claim that they don't know how to do filling and at same time it is cumbersome to fill…"

The assertions by the informant demonstrates that per the nurses work schedule, they are required to take notice or record any complaint on AEFIs but it is not always the case that these complaints go in to the complaint books of the facilities.

It is important noting that the nurses do profess some form of interventions or response when AEFIs are reported. As an observation from the question below.

Question: What have been your responses or reactions to the complaints mothers' make on AEFIs?

Response from an informant.

"…as I indicated earlier, we need to fill the AEFIs forms first and also consider if it serious adverse event or not. If it is serious normally a referral is given to a bigger facility like TTH or Central Hospital for admission and if it is also not serious, we do manage at our level here…"

Explaining further, below is also a response from another informant

"…here what we normally do is to reassure the mother that everything will be fine to calm the fears and anxiety of the mother and also fill a form which is a problem for my people... hahahaaha…hmmm asem oo…

…we then show them how to manage, like to do cold compress or sponging…"

The above response highlights that filling of the form on AEFIs (attached AEFI Form, Appendix IV) is indeed a challenge and may also be one of the contributing factors to the non-reporting of AEFIs at the Metropolitan Health Directorate. Again, it also shows that mothers are given some form of intervention including the management of AEFIs and consistent with the accounts given by the mothers as observed in the quantitative study.

AEFIs intervention provided by mother: Majority of the mothers [83.5 % (207)] indicated that they provide some form of interventions when they notice AEFIs on their children. Among the

reported interventions provided includes: Sponging [40.0 % (99)], Cold compress [27 % (67)], and Self-medication [15.3 % (38)].

Source of Advice for the intervention: majority of the mothers [56.4 % (140)] indicated that their source of advice for the given intervention was from healthcare providers, whereas [20.2 % (50)] also indicating it was a self-initiative.

Table 4.4: Adverse Events Following Immunization Reporting Behaviours

n=248		
Variable	**Frequency**	**%**
Ever reported AEFIs		
Yes	199	80.2
No	49	19.8
Adverse Event Reported to a Health Facility		
Pain		
Yes	27	10.9
No	221	89.1
Fever/High Temperature		
Yes	130	52.4
No	118	47.6
Rashes		
Yes	65	26.2
No	183	73.8
Swelling		
Yes	75	30.2
No	173	69.8
Total	**248**	**99.6**

Source: Field Data, 2020.

Table 4.4.1 Adverse Events Following Immunization Reporting Behaviours

Variable	*n=248* Frequency	%
AEFIs intervention provided by mother		
Yes	207	83.5
No	16	6.5
None	25	10.1
Form of Interventions Given		
Self-medicate	38	15.3
Sponging	99	40.0
Cold compress	67	27.0
None	44	17.7
Source of Advice for the intervention		
Self -initiative	50	20.2
Sibling/family/friends	16	6.5
Healthcare provider	140	56.4
None	42	16.9
Total	**248**	**100.0**

Source: Field Data, 2020.

4.5 Factors Associated with Reporting of AEFIs among mothers

Table 4. 5 and 4. 5.1 present detailed results on the factors associated with reporting of AEFIs among mothers.

Main information health workers give on AEFIs: Majority of the mothers [54.8 % (136)] indicated healthcare workers encourage them to report AEFIs to health worker/facility and 42.7% (106) also indicated that healthcare workers encourage them to mage AEFIs at home.

Frequency of education on AEFIs by health workers: on the frequency of education on AEFIs by given health workers, most of the mothers indicated that it was routine [49.6% (123)] and monthly [33.1% (82)].

Reasons for not Reporting AEFIs: The main reasons indicated by study participants included; Too busy [17.7% (44)], Long distance to the health facility [27.4% (68)], I do not think it was necessary to report [41.5%(103)], Health workers do not give me the needed attention [63.3% (157)], Condition not serious to report [65.3% (162)], I manage at home [53.2% (132)], I do not know how to report [44.4%(110)], Concerned about AEFIs [99.2% (246)] and Encourage others to report on AEFIs [99.6% (247)].

Additionally, findings from the face to face discussion on some of the factors that affect AEFIs reporting included; non-recording by healthcare workers, teaching mothers' on how to manage at home, cumbersome in the filling of the form and fear of being implicated in negligence. Below are some responses given by key informants on the challenges associated with AEFIs reporting.

Question: What challenges do you normally face in taking records of what mothers' come to complain about in your facility?

"…filling of the form the form entails a lot…" response from an informant

Equally, another response from an informant

"…almost all the staff do not document and follow-up on AEFIs…"

"…equally some also do not report because they think they would be blamed for the cause of the AEFIs…"

"…another important thing to is that because the nurses give the mothers' advice on the management of AEFIs, it discourages the mothers' to report to the facility when they observe any AEFI as they treat it at home…"

Table 4. 5 Factors Associated with Reporting of AEFIs among mothers

	n=248	
Variable	**Frequency**	**%**
Main information health workers give on AEFIs		
Manage at home	106	42.7
Report to health worker/facility	136	54.8
None	6	2.4
Frequency of education on AEFIs by health workers		
Routinely	123	49.6
Monthly	82	33.1
None	36	14.5
I do not remember	7	2.8
Reasons for not Reporting AEFIs		
Too busy		
Yes	44	17.7
No	204	82.3
Long distance to the health facility		
Yes	68	27.4
No	179	72.2
None	1	.4
I do not think it is necessary		
Yes	103	41.5
No	145	58.5
Health workers do not give me the needed attention		
Yes	157	63.3
No	91	36.7
Condition not serious to report		
Yes	162	65.3
No	86	34.7
Total	248	100.0

Source: Field Data, 2020.

Table 4.5.1 Factors Associated with Reporting of AEFIs among mothers

n=248		
Variable	**Frequency**	**%**
Manage at home		
Yes	132	53.2
No	116	46.8
I do not know how to report		
Yes	110	44.4
No	138	55.6
Concerned about AEFIs		
Yes	246	99.2
No	2	.8
Encourage others to report on AEFIs		
Yes	247	99.6
No	0	3.2
None	1	0.4
Total	248	100.0

Source: Field Data, 2020.

4.6 Chi square Test analysis between socio-demographic characteristics and reporting of AEFIs.

Table 4.6 to 4.6.3 present detailed results on the Chi square Test analysis between socio-demographic characteristics and reporting of AEFIs.

From the results, educational status was significantly associated with reporting of AEFIs among the mothers at a p-value of **0.017.** All the other sociodemographic characteristics of the participants did not demonstrate any significant association with the reporting of AEFIs.

Table 4. 6 Chi square Test analysis between socio-demographic characteristics and reporting of AEFIs

Variables	Frequency		P-value (x^2 d.f.)
Age	Yes	No	
15-19	5	11	0.752(2.660, 5)
20-24	26	45	
25-29	18	53	
30-34	16	28	
35-39	10	20	
40 and above	3	8	
Education			
Basic School	5	23	**0.017(13.813, 5)***
JHS	14	32	
SHS	23	25	
Tertiary	16	20	
No Education	20	64	
Total	**78**	**164**	

Source: Field Data, 2020. (Note * denotes statistically significant figure)

Table 4.6.2 Chi square Test analysis between socio-demographic characteristics and reporting of AEFIs Continuation

Variables	Frequency		P-value (x^2 d.f.)
	Yes	No	
Religion			
Christian	5	10	0.343(2.141, 2)
Muslim	72	155	
Traditionalist	1	0	
Number of Childbirth			
One	25	50	0.269(8.776, 7)
Two	28	39	
Three	9	36	
Four	9	16	
Five	5	15	
Six	1	7	
Seven	1	1	
Eight and above	0	1	
Total	78	165	
Number alive			
One	25	52	0.284 (8.585, 7)
Two	27	39	
Three	9	39	
Four	10	15	
Five	4	13	
Six	2	5	
Seven	0	1	
Eight and above	0	1	
Total	77	165	
Marital Status			
Single	0	2	0.216 (3.061, 2)
Married	77	163	
Co-habitation	1	0	
Total	**78**	**165**	

Source: Field Data, 2020.

Table 4. 6.3 Chi square Test analysis between socio-demographic characteristics and reporting of AEFIs Continuation

Variables	Frequency		P-value (x^2 d.f.)
	Yes	No	
Occupation			
Civil Servant/Salary Worker	18	21	0.116 (4.303, 2)
Farmer/Trader/Casual Worker	55	130	
Unemployed	5	14	
Total	78	165	
Time taken to notice AEFIs			
Within 24 hours	73	131	0.571 (1.121, 2)
After 24 hours	3	9	
11.0	0	1	
Total	**76**	**141**	

Source: Field Data, 2020.

CHAPTER FIVE

DISSCUSION

5.0 Introduction

This chapter discussed the results of the study. The discussions of the results were done in line with the objectives and other studies to confirm or to reject the assertions of such studies.

Discussion

The mean age of the study participants (28.29 years) was found to be slightly close with a similar study conducted by Afolaranmi et al. (2020) who reported a mean age of 29.0 years among mothers in Nigeria but much lesser than what was reported in a related study in Ghana (36.75s years) by Laryea et al. (2019). The observed differences can be attributed to the various sample sizes employed in these studies. Again, the mean age recorded in this current study can be said that most of the mothers in the metropolis give birth in their twenties, which some studies in reproductive health argue that it could promote healthy babies compared with children born by mothers in older ages (Moyer et al., 2013). The study participants were all females, though majority of them indicated that they were married (98.8%). This observation is not good, as at a time where there is a call for male participation in antenatal and postnatal services to ensure and promote good health for the mother and the baby as well as. Formal education among the mothers was extremely low with majority indicating no education (33.9%). The current study results was inconsistent with a similar study in Ghana by Twene et al. (2018) who reported a 10.0% no education among mothers. These findings were lower than the regional statistics on females without education in the Northern Region (65.8%) compared to 20.5% in the then Brong Ahafo where Twene et al. (2018) conducted their study. This observation can partially be

attributed to the study environments and the varying sample sizes. The findings on no education among some mothers visiting child welfare centres stresses the need to design health educational programmes in local languages, to target mothers with no education to increase their health literacy level, especially on immunization programmes.

It was obvious that majority of the study mothers were Muslims (93.5%) and Dagombas (83.5%) as was reported in the Tamale metropolis population and housing census (GSS, 2010). The implication of this observation is that healthcare providers in the metropolis should see the Muslim religious leaders and Dagomba chiefs or opinion leaders as key stakeholders in healthcare planning programs, especially in immunisation services. Nonetheless, the minority religious groups including Christians and the ethnic groups should equally be considered as stakeholders in the healthcare services of the metropolis. Considering these groups in the immunisation programs in the metropolis could increase immunisation coverage and boosting of public confidence on vaccines. A high proportion of the mothers (31.5%) had given birth for their first time. This observation is good for family planning purposes and therefore should be targeted.

The prevalence of self-reported AEFIs among mothers was observed to be high (85.9%) and was confirmed by the key informants that indeed, mothers do report observed AEFIs among their children. "*.oh! You know these our people they don't hide anything oo. They always report on AEFIs…*" Comparing these observations to the statistics (**figures 1.1-1.5**) given by the Tamale Metropolitan Health Directorate from 2015 to 2019 among the four healthcare centres may demonstrates two main things; thus non-reporting and under-reporting of the AEFI's among the healthcare workers in the metropolis. This may challenge the progress made against VPD's and EPI in the metropolis and Ghana at large as well as affecting the introduction of vaccine

acceptability among mothers, especially at a time the Ghana Health Service is considering the initiation of malaria vaccination among children under-five years. The emphasis must be made that when AEFIs are not reported or documented it may challenge the development of new vaccines and introduction of new vaccines. Learning from other studies, the current study self-reported AEFIs prevalence was higher than what was reported by Datta et al. (2017) among mothers (20.9%) and Aherkar et al. (2016) among mothers (22.71%) India. What was equally reported by Afolaranmi et al. (2020) in a cross-sectional study in Nigeria among mothers (46.5%) was inconsistent with the current study's prevalence of self-reported AEFIs. The observed differences could be attributed to the differences in the sample sizes. However, it also demonstrates that AEFIs are on the rise and could be a hindrance to immunization programmes. There should be concerted effort to addressing AEFIs to increase the public confidence in vaccines especially in Africa which is known to have increasing VPDs (Yenyi, 2019).

The current study observed that most of the mothers had appreciable knowledge (89.9%) on AEFIs. This was inconsistent with Twene et al. (2018) observation in Jaman North District (Ghana) with a proportion of 98.6% mothers showing knowledge of AEFIs. However, Datta et al. (2017) reported that about 90.0% of mothers were knowledgeable on AEFIs. Yousif et al. (2013) equally reported among mothers that the AEFIs knowledge to be 86.9% in Iran. However, in Nigeria Afolaranmi et al. (2020) observed a lower knowledge level (55.5%) among mothers on AEFIs compared to what was reported by Datta et al. (2017), Yousif et al. (2013) and the current study. Stressing the source of information on AEFIs among the mothers in the current it was observed most of the mothers had their information from the Child Welfare Centre/Clinic/Hospital. Similarly, the mothers indicated some of the facilities do give education on AEFIs routinely and monthly basis which can be said is welcoming with the importance of

health education or talks described in some studies. This observation was also acknowledged by Twene et al. (2018) in Ghana and reported more than half (61.7%) of the mothers indicated that they receive education on AEFIs on routine basis. As an illustration, the observation made by Olumuyiwa et al. (2008) demonstrated that mothers health talk on VPDs effectively arouse the interest of mothers without education to want to learn more about VPDs and apply they knowledge to improve the health of their children. This observation therefore presupposes that increasing health education especially on AEFIs and vaccinations in general is likely to increase vaccination coverage and identification of AEFIs as well the confident in immunization programs globally. As maintained in Olumuyiwa et al. (2008) study that the completeness of vaccination schedules by mothers was significantly associated with the level of knowledge of mothers on immunization.

As noted in other studies, both healthcare workers and mothers have important roles to play in the reporting and management of AEFIs, therefore becomes a necessary that both mothers and healthcare workers are partners in the healthcare delivery systems. In as much as healthcare workers play an important role in the reporting and documentation of AEFIs, it has been acknowledged that low knowledge as well as management of AEFIs has been the major challenges to the reporting of AEFIs (Muchekeza et al., 2014). As held by Yenyi (2019), in an effort to address the observed challenges among the health profession towards reporting of AEFIs, it is important to orient and train healthcare workers on key issues of AEFIs including; the definition, identification, treatment and management, documentation processes and notification to appropriate authority. These interventions, according to Yenyi (2019), would increase healthcare workers appreciation of AEFIs, documentation processes and vaccine safety in general. As asserted by Adedokun et al. (2017) and Muchekeza et al. (2014), parents or

caregivers' knowledge on AEFIs greatly influences the reporting of observed AEFIs on their children. A poor knowledge of AEFIs among caregivers has been observed to be associated with the low reporting of AEFIs in most countries (Adedokun et al., 2017; Muchekeza et al., 2014). As has been acknowledged by some studies on the reliance on caregivers or parents in spontaneous surveillance of AEFIs (Yun et al., 2012), it therefore becomes a good call to continually address the low knowledge level of AEFIs among caregivers or parents. To address the poor knowledge level of AEFIs among caregivers or parents Yenyi (2019) suggested a health talk on AEFIs at child welfare centers prior to immunization schedules. Importantly, the quality of information provided during the health talk sessions on AEFIs would impact positively or negatively on caregivers or parents' attitudes towards AEFIs (Adedokun et al., al., 2017; Aina et al., 2013).

The common reported AEFIs were non-serious AEFIs as they constituted temporary mild to moderate reactions (EPI-Ghana, 2014). The common AEFIs reported by mothers' included fever/high temperature, rashes abscess/swelling, pain and vomiting. The qualitative findings confirmed the assertions of the mothers. The current study's observation was also observed in a similar study in Ghana by Twene et al. (2018) who reported common AEFIs to include pain, swelling and redness. These findings was consistent with observations by Datta et al. (2017), who also reported common AEFIs in India to include low grade fever, pain, swelling and redness. Additionally, some of the current study's observation was consistent with the findings of Mohammad et al. (2010) on common AEFIs including fever, pain, swelling but was inconsistent with the observation of erythema, induration as well as ulceration. The given AEFIs by the mothers' according to Afolaranmi et al. (2020) in Nigeria also comprised of fever convulsions and weakness of the limbs. In another cross-sectional study in Nigeria, Ekwueme

(2009) reported that also indicated fever, pain and swelling, rashes, convulsion, boils, paralysis or weakness of limbs and ulcers. These observed AEFIs needs to be given the needed attention especially through surveillance systems to be able to report on every single AEFIs. In Ghana, as maintained by the EPI-Ghana (2014), the use of active and spontaneous systems of surveillance in the detection and reporting of AEFIs, there is the need to strengthen these areas of surveillance.

Factors that may affect the reporting of AEFIs among the mothers included too busy to report, long distance to the health facility, feeling of not necessary to report, and healthcare workers not given them the needed attention. Similarly, some mothers were of the view that if the condition is not serious there would not be any need to report, with some also indicating that they may manage at home. Furtherance to that, some also gave the reason of not knowing how to report. The findings from the face to face discussion on some of the factors that affect AEFIs reporting included; non-recording by healthcare workers, teaching mothers' on how to manage at home, cumbersome in the filling of the form and fear of being implicated in negligence.

"…filling of the form the form entails a lot…"

"…almost all the staff do not document and follow-up on AEFIs…"

"…equally some also do not report because they think they would be blamed for the cause of the AEFIs…"

"…another important thing to is that because the nurses give the mothers' advice on the management of AEFIs, it discourages the mothers' to report to the facility when they observe any AEFI as they treat it at home…"

The current study's observation on factors that are likely to be a hindrance to the reporting of AEFIs among mothers and healthcare workers have also been described in other studies. Muchekeza (2010) reported that assigned reasons for not documenting AEFIs among nurses included "not knowing the reporting procedure, fear of causing unnecessary harm. Other reasons were unavailability of stationary for reporting the cases and the absence of AEFI case definition and documentation procedure displayed (Muchekeza, 2010). The observations in Muchekeza, (2010) does not only show the knowledge gap on AEFIs among the nurses but also reflects the weak healthcare systems in Zimbabwe and most other African countries. Similarly, Yamoah et al. (2019) reported that most of the nurses were of the believe that reporting of AEFIs and surveillance systems would impact on increasing public confidence in immunization programs in Ghana. However, the question to ask is, does their belief really impact the documentation of AEFIs to improve surveillance? As was observed by Yamoah et al. (2019), it can be deduced that the nurses do not actually report AEFIs and assigned reasons such as lack of time to document resulting from busy work schedule. Yamoah et al. (2019) findings showed that most of the nurses indicated the lack of interest to know more AEFIs. The lack of interest to learn more about AEFIs indication by the healthcare workers could impact negatively on AEFIs surveillance, given the fact that knowledge on AEFIs could change overtime. Likewise, the challenges to reporting of AEFIs observed in Gidudu et al. (2019) study included fear of queries (44.1%), poor knowledge and training on AEFIs reporting (25.2%) together with AEFIs regarded as not being serious to report (22.2%).

Educational status was significantly associated with reporting of AEFIs among the mothers' ($p = 0.017$) in the current study. Previous studies have reported low immunization coverage in some parts of the world and have been associated with increasing false impression, AEFIs combined

with poor level knowledge and of education among healthcare workers and mothers (Masika et al., 2016). As observed in a study conducted by Smaillbegovic (2003) disclosed that 34% of mothers declined to make available their children for immunization programs and attributed this observation to the increasing misconception. Equally, other studies have reported that most education and information offered by healthcare workers on immunization programs including AEFIs are inadequate. This negatively impact the reporting and management of AEFIs. Therefore, much attention should be given to educating the populace especially among mothers on immunization programs.

CHAPTER SIX

SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.0 Introduction

The chapter six gives a summary of the study outcome, conclusion, key recommendations and study limitations and further research opportunities. The study aimed at assessing the adverse events associated with the current immunization programmes in the Tamale Metropolis and the specific objectives comprised of the following:

6.1 Summary

This was a cross sectional study, involving quantitative and qualitative approaches to research, conducted from October 2019 to July 2020 among four sub-districts health facilities in the Tamale Metropolis. The participants involved were mothers with children < 5 years old who had been vaccinated at least once in the Tamale Metropolis and healthcare workers who are involved in the immunization/vaccination programmes of the health facilities.

The mean age of the study participants was found to be 28.29 years (SD: 15.65) with majority (29.8%) in the 20-24 age brackets. A high proportion of the study participants (33.9%) did not have any form of educational qualification. About 93.5% of the participants were Muslims and 83.5% were Dagombas. 98.8% of the study participants were married. Approximately, 31.5% of the participants were having only one childbirth. Most of the study participants were informal sector workers (75.8%). (188), and about 8.5% were not employed.

The results showed that, out of the 248 study participants, a proportion of 85.9% self-reported AEFIs. Similarly, most of the study participants (82.3%) observed AEFIs within 24hours.

Among the common self-reported AEFIs were as follows; Fever/High Temperature (63.7%), Abscess/Swelling (33.1%), Rashes **(**27.0%) and Pain (8.9%). From the qualitative findings, it was acknowledged that the common reported AEFIs included High Temperature/fever and Abscess. There were other AEFIs observed in other facilities which were not also observed by others.

Approximately 89.9% of the participants had knowledge on AEFIs. Majority of the participants (73.8%) had information on AEFIs from the Child Welfare Centre/Clinic/Hospital. Additionally, to rate the level of knowledge on AEFIs, majority of the study participants (67.7 %) indicated that they have good knowledge on AEFIs and 97.6% reported the desire to report on AEFIs.

From the results, it was found that about 80.2% indicated that they have ever reported incidence of AEFIs to a health facility. Among the reported AEFIs to the facilities included Fever/High Temperature (52.4%), Abscess/Swelling (30.2 %), Rashes (26.2 %) and pain (10.9%),

Majority of the mothers (83.5%) provided some form of interventions when they notice AEFIs on their children. Among the reported interventions provided includes: Sponging (40.0 %), Cold compress (27%), and self-medication (15.3 %). Majority of the mothers (56.4 %) indicated that their source of advice for the given intervention was from healthcare providers, and 20.2 % also indicating it was a self-initiative.

Majority of the mothers (54.8 %) indicated healthcare workers encourage them to report AEFIs to health worker/facility with another 42.7% also indicating that healthcare workers encourage them to mage AEFIs at home. On the frequency of education on AEFIs by given health workers, most of the mothers indicated that it was routine (49.6%).

The common factors that may affect AEFIs reporting by mothers included, condition not serious to report (65.3%), health workers do not give me the needed attention (63.3%), I manage at home (53.2%), I do not know how to report (44.4%), I do not think it was necessary to report (41.5%), long distance to the health facility (27.4%), and too busy to report (17.7%). Similarly, findings from the face to face discussion on some of the factors that affect AEFIs reporting included; non-recording by healthcare workers, teaching mothers' on how to manage at home, cumbersome in the filling of the form and fear of being implicated in negligence. Educational status was significantly associated with reporting of AEFIs among the mothers at a p-value of **0.017.** All the other sociodemographic characteristics of the participants did not demonstrate any significant association with the reporting of AEFIs.

6.2 Study conclusion

From the study results, it is concluded that:

1. The prevalence of self-reported AEFIs among mothers with children under five years among the four health facilities in the Tamale Metropolis was 85.9%.
2. Knowledge of AEFIs amongst mothers with under-five years children among the health facilities in the Tamale Metropolis was 89.9%.
3. Reporting behaviours of mothers with under-five years children at health facilities in the Tamale Metropolis showed that 80.2% of mothers reported incidence of AEFIs to health facilities in the Tamale metropolis.
4. The major factors associated with reporting of AEFIs among mothers with under-five years children at health facilities in the Tamale Metropolis were found to include, condition not serious to report (65.3%), health workers do not give me the

needed attention (63.3%), I manage at home (53.2%), I do not know how to report (44.4%) and I do not think it was necessary to report (41.5%).

5. Factors that affect AEFIs reporting among healthcare workers included non-recording by healthcare workers, teaching mothers on how to manage at home, cumbersome in the filling of the form and fear of being implicated in negligence.
6. Educational status was significantly associated with reporting of AEFIs among mothers at a p-value of 0.017**.**

6.3 Study recommendations

From the results, it is recommended that:

1. Healthcare workers should continue to give health education or talk on AEFIs and management practices prior to immunizations or vaccinations at the child welfare centres.
2. Healthcare workers should encourage mothers to report on AEFIs even when they provide interventions at home.
3. Healthcare workers should report or document AEFIs as it is important for surveillance purposes and key in directing targeted interventions.
4. Healthcare workers should be given enough training on AEFIs and the need to report on AEFIs.
5. Inspection of AEFIs records at various health facilities should be conducted periodically or regularly by supervisors from the metropolitan health directorate.
6. Training on AEFIs identification and reporting for healthcare workers as well as a regular demand for AEFIs reports from the health facilities in the metropolis are required.

6.4 Study Limitations

Due to the COVID-19 restrictions on the number of mothers to receive postnatal services, the study could not use a proportionate sampling approach to get participants proportional to the facility's catchment or utilization population for postnatal services.

6.5 Dissemination of Study Outcome

The outcome of this study will be circulated among the following institutions: the UDS Graduate School, Department of Community Health and Family Medicine-School of Medical and Health Sciences and the Metropolitan Health Directorate. The findings of the study would equally be published in peer reviewed journals.

6.6 Opportunities for further research

The following research opportunities are recommended.

1. Assessing the Knowledge, attitudes, and practices towards AEFIs among healthcare workers involved in immunizations.
2. The study could be repeated in other parts of the region.

Reference

Aherkar, R. Y., Deshpande, P. K., & Ghongane, B. B. (2016). *IJBCP International Journal of Basic & Clinical Pharmacology Research Article Study of the pattern of adverse events following immunization of children in a tertiary care hospital*. *5*(3), 609–615.

Ankrah, D. N. A., Darko, D. M., Sabblah, G., Mantel-, A., Leufkens, H. M. G., Ankrah, D. N. A., Darko, D. M., Sabblah, G., & Mantel-, A. (2018). *Reporting of adverse events following immunizations in Ghana – Using disproportionality analysis reporting ratios*. *5515*. https://doi.org/10.1080/21645515.2017.1384105

Ankrah, D. N. A., Darko, D. M., Sabblah, G., Mantel-Teeuwisse, A., & Leufkens, H. M. G. (2018). Reporting of adverse events following immunizations in Ghana–Using disproportionality analysis reporting ratios. *Human Vaccines and Immunotherapeutics*, *14*(1), 172–178. https://doi.org/10.1080/21645515.2017.1384105

Article, O. (2020). *Knowledge of adverse events following immunization , its prevalence and actions of mothers of children aged 0 – 23 months in a tertiary health institution in Jos , North Central Nigeria*. 57–64. https://doi.org/10.4103/jomt.jomt

Borba, R. C. N., Vidal, V. M., & Moreira, L. O. (2015). *The re-emergency and persistence of vaccine preventable diseases*. *87*, 1311–1322.

Bosu, W. K., Ahelegbe, D., Edum-Fotwe, E., Kobina A Bainson, & Kobina Turkson, P. (1997). Factors influencing attendance to immunization sessions for children in a rural district of Ghana. *Acta Tropica*, *68*(3), 259–267. https://doi.org/10.1016/S0001-706X(97)00094-6

Brenzel, L., Wolfson, L. J., Fox-rushby, J., Miller, M., & Halsey, N. A. (2015). *Chapter 20*

Vaccine-Preventable Diseases. 389–412.

Datta, A., Baidya, S., Das, S., Mog, C., & Datta, S. (2017). *Assessment of Mother ' s Knowledge and Practices Regarding Adverse Events Following Immunization of Their Children in a Rural Area of Tripura*. *8*(4), 159–163.

Gidudu, J. F., Shaum, A., Dodoo, A., Bosomprah, S., Bonsu, G., Amponsa-achiano, K., Darko, D. M., Sabblah, G., Opare, J., Nyaku, M., Owusu-boakye, B., Oduro, A., Aborigo, R., Conklin, L., Welaga, P., & Ampadu, H. H. (2019). Barriers to healthcare workers reporting adverse events following immunization in four regions of Ghana. *Vaccine*, *xxxx*. https://doi.org/10.1016/j.vaccine.2019.11.050

Immurana, M., & Urma, A. (2016). Demand for measles and yellow fever vaccines for children in Ghana: are socio-economic, demographic and Geographic factors relevant? *International Journal of Accounting and Economics Studies*, *4*(2), 136. https://doi.org/10.14419/ijaes.v4i2.6526

Joshi, J., Das, M. K., Polpakara, D., Aneja, S., Agarwal, M., & Arora, N. K. (2018). *Vaccine Safety and Surveillance for Adverse Events Following Immunization (AEFI) in India*. *85*(February), 139–148.

Kai, B. (2012). *Impact of vaccination on vaccine-preventable disease burden in Croatia*. *114*(2), 141–147.

Kiptoo, E. (2015). Factors Influencing Low Immunization Coverage Among Children Between 12 - 23 Months in East Pokot, Baringo Country, Kenya. *International Journal of Vaccines & Vaccination*, *1*(2). https://doi.org/10.15406/ijvv.2015.01.00012

Lawan, U., Amole, G., Wali, N., Jahun, M., Jibo, A., & Nakore, A. (2016). Pattern of adverse events following immunization in nourished and malnourished infants in Kano, North-Western Nigeria. *Sahel Medical Journal*, *19*(3), 131. https://doi.org/10.4103/1118-8561.192394

Masika, C. W., Atieli, H., & Were, T. (2016). *Knowledge , Perceptions , and Practice of Nurses on Surveillance of Adverse Events following Childhood Immunization in Nairobi , Kenya*. *2016*.

Masuka, J. T., & Khoza, S. (2019). Adverse events following immunisation (AEFI) reports from the Zimbabwe expanded programme on immunisation (ZEPI): An analysis of spontaneous reports in Vigibase® from 1997 to 2017. *BMC Public Health*, *19*(1), 1–11. https://doi.org/10.1186/s12889-019-7482-x

Mehmeti, I., Nelaj, E., Simaku, A., Tomini, E., & Bino, S. (2017). Knowledge , practice and approaches of health professionals to adverse events following immunization and their reporting in Albania. *Heliyon*, *May*, e00331. https://doi.org/10.1016/j.heliyon.2017.e00331

Menezes, N. B., Wali, S., & Ganachari, M. S. (2020). *Pharmacist - led intervention on adverse events following immunization at a tertiary care hospital : A randomized controlled study*. 127–131. https://doi.org/10.4103/kleuhsj.kleuhsj

Moyer, C., Gyasi, R. K., Akosa, A. B., Tettey, Y., Akakpo, P. K., & Anim, J. T. (2013). *PREGNANCY RELATED CAUSES OF DEATHS IN GHANA : A 5-YEAR RETROSPECTIVE STUDY*. *47*(4), 158–163.

Parrella, A., Gold, M., Braunack-mayer, A., Baghurst, P., Parrella, A., Gold, M., Braunack-

mayer, A., & Baghurst, P. (2014). *Consumer reporting of adverse events following immunization (AEFI) Identifying predictors of reporting an AEFI*. *5515*. https://doi.org/10.4161/hv.27459

Poster, S., Laryea, E. B., Tengey, J., Kaburi, B. B., Asamoah, J., Ameme, D. K., Kenu, E., & Epidemiology, F. (2019). *Evaluation of Adverse Event Following Immunization*. 1–12.

President, S. V., Prescott, J., Services, C., Szwed, A., Zangari, D., Clinical, S., Managers, P., Delmendo, I., Mroz, D., Project, C., Burawski, L., Pigeon, T., Manager, P., Szeszko, A., Editors, A., Fahey, H., Pastor, J., Thomas, A., Writers, M., … Resources, H. (2020). *Assessing the Cost of Vaccine- Preventable Diseases*. 5–8.

Province, M. (2010). *Adverse Events Following Immunisation (AEFI) Surveillance in Kwekwe*. *5*(3), 3–6. https://doi.org/10.4172/2157-7560.1000232

Sally, E. T., & Kenu, E. (2017). Evaluation of access and utilization of EPI services amongst children 12-23 months in Kwahu Afram Plains, Eastern region, Ghana. *The Pan African Medical Journal*, *28*, 238. https://doi.org/10.11604/pamj.2017.28.238.11538

Suzuki, T., Osei, J. H., Sasaki, A., Adimazoya, M., Appawu, M., Boakye, D., Ohta, N., & Dadzie, S. (2016). Risk of transmission of viral haemorrhagic fevers and the insecticide susceptibilitystatus of aedes aegypti (linnaeus) in some sites in Accra, Ghana. *Ghana Medical Journal*, *50*(3), 136–141. https://doi.org/10.4314/gmj.v50i3.4

Tozzi, A. E., Asturias, E. J., Ram, M., Halsey, N. A., Law, B., & Zuber, P. L. F. (2013). Assessment of causality of individual adverse events following immunization (AEFI): A WHO tool for global use. *Vaccine*, *31*(44), 5041–5046.

https://doi.org/10.1016/j.vaccine.2013.08.087

Twene P, & Yawson, A. (2018). Adverse Events Following Immunization (Aefi) Reporting in a Rural District in Ghana. *Postgraduate Medical Journal of Ghana*, *7*(2).

Yamoah, P., Bangalee, V., & Oosthuizen, F. (2019a). *Knowledge and Perceptions of Adverse Events Following Immunization among Healthcare*. 1–15. https://doi.org/10.3390/vaccines7010028

Yamoah, P., Bangalee, V., & Oosthuizen, F. (2019b). Knowledge and perceptions of adverse events following immunization among healthcare professionals in Africa: A case study from Ghana. *Vaccines*, *7*(1), 1–15. https://doi.org/10.3390/vaccines7010028

Yenyi, S. E. (2019). *Influence of Low Rate of Reporting of Adverse Events Following Immunization on Immunization Dropout*.

Yun, I. S., Koo, M. J., Park, E. H., Kim, S. E., Lee, J. H., Park, J. W., & Hong, C. S. (2012). A comparison of active surveillance programs including a spontaneous reporting model for phamacovigilance of adverse drug events in a hospital. *Korean Journal of Internal Medicine*, *27*(4), 443–450. https://doi.org/10.3904/kjim.2012.27.4.443

Ventola, C.L. (2016). Immunization in the United States: recommendations, barriers, and measures to improve compliance: part 1: childhood vaccinations. P&T. 2016;41(7):426-436.

World Health Organization, AEFI Reports from Africa as of June 2015. Available online: https://www.who- umc.org/vigibase/vigilyze/ (accessed on 30th November, 2019).

Wharton M. Vaccine safety: current systems and recent findings. Curr Opin Pediatr 2010; 22:88-93; PMID:19952750; http://dx.doi.org/10.1097/ MOP.0b013e3283350425

Wolfson, L.J., Gasse, F., Lee-Martin, S.P., Lydon, P., Magan, A., Tibouti, A. et al. (2008). Estimating the costs of achieving the WHO-UNICEF Global Immunization Vision and Strategy, 2006-2015. Bull World Health Organ. 2008;86(1):27–39. PubMed | Google Scholar

World Health Organization. Global vaccine safety blueprint. The landscape analysis Global vaccine safety blueprint The landscape analysis Immunization. Vaccines Biol. 2012. Available online: http://whqlibdoc. who.int/hq/2012/WHO_IVB_12.04_eng.pdf (accessed on 30th November, 2019).

World Health Organization. (2015). World Health Statistics. 2015. Google Scholar

World Health Organisation. (2005)Immunization, vaccines and biologicals 2002-2003 highlights. 2005. Accessed July 2020

World Health Organization. (2012). World Health Statistics 2012. WHO. 2012. p176. Google Scholar

World Health Organization. (2014). Media centre. World health statistics 2014. 2014. Accessed July, 2020

Appendix I

Ethical Clearance

UNIVERSITY FOR DEVELOPMENT STUDIES

(Office of the Registrar)

Central Administration

Tel: +233-03720-93382, 26633, 26634
Internet: www.uds.edu.gh
Email: academicaffairs@uds.edu.gh
Fax: +233-03720-23957

P. O. Box TL 1350
Tamale
Ghana

Our Ref:

Your ref:

4TH April, 2020

MS. AGNES ALO

DEPARTMENT OF COMMUNITY HEALTH AND FAMILY MEDICINE

UNIVERSITY FOR DEVELOPMENT STUDIES
TAMALE

ETHICAL APPROVAL NOTIFICATION

With reference to your request for ethical clearance on the research proposal titled **'Reporting of Adverse Events Following Immunization'** I write to inform you that the University for Development Studies Institutional Review Board (UDSIRB) found your proposal including the consent forms to be satisfactory and has approved same. The period for the approval is six (6) months, starting from 4th April to 4th September, 2020.

Subject to this approval, you are please required to observe the following conditions:

1. That the anonymity of the respondents shall be guaranteed as mentioned in the consent forms.
2. That you will acknowledge the source of the data collected in any publication related to this research.
3. That you will submit a field report and a copy of the research report to the UDSIRB.
4. That you may apply to the UDSIRB for any amendments relating to recruiting methods, informed consent procedures, study design and research personnel.
5. That you will strictly abide by the code of conduct of this University.

Please do not hesitate to refer any issue (s) that you may deem necessary for the attention of the Board.

Thank you.

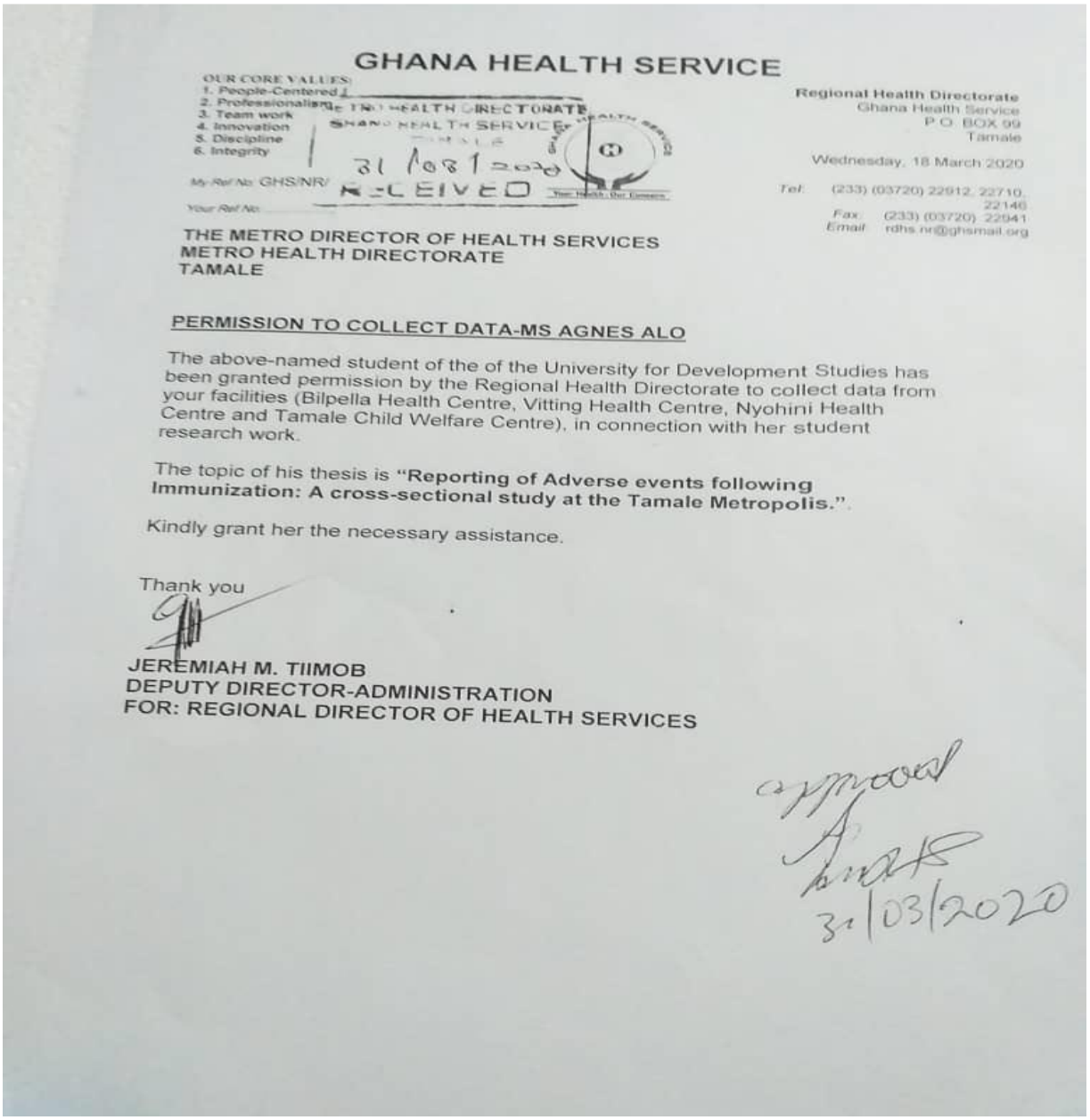
Prof. Herbert Kwabla Dei

Chairman, UDSIRB

Cc: file

Appendix II

Letter of Approval, Ghana Health Service, Tamale



GHANA HEALTH SERVICE

OUR CORE VALUES:
1. People-Centered
2. Professionalism
3. Team work
4. Innovation
5. Discipline
6. Integrity

METRO HEALTH DIRECTORATE
GHANA HEALTH SERVICE
TAMALE
31/03/2020
RECEIVED

My Ref No: GHS/NR/
Your Ref No:

Regional Health Directorate
Ghana Health Service
P.O. BOX 99
Tamale

Wednesday, 18 March 2020

Tel: (233) (03720) 22912, 22710, 22146
Fax: (233) (03720) 22941
Email: rdhs.nr@ghsmail.org

THE METRO DIRECTOR OF HEALTH SERVICES
METRO HEALTH DIRECTORATE
TAMALE

PERMISSION TO COLLECT DATA-MS AGNES ALO

The above-named student of the of the University for Development Studies has been granted permission by the Regional Health Directorate to collect data from your facilities (Bilpella Health Centre, Vitting Health Centre, Nyohini Health Centre and Tamale Child Welfare Centre), in connection with her student research work.

The topic of his thesis is **"Reporting of Adverse events following Immunization: A cross-sectional study at the Tamale Metropolis."**.

Kindly grant her the necessary assistance.

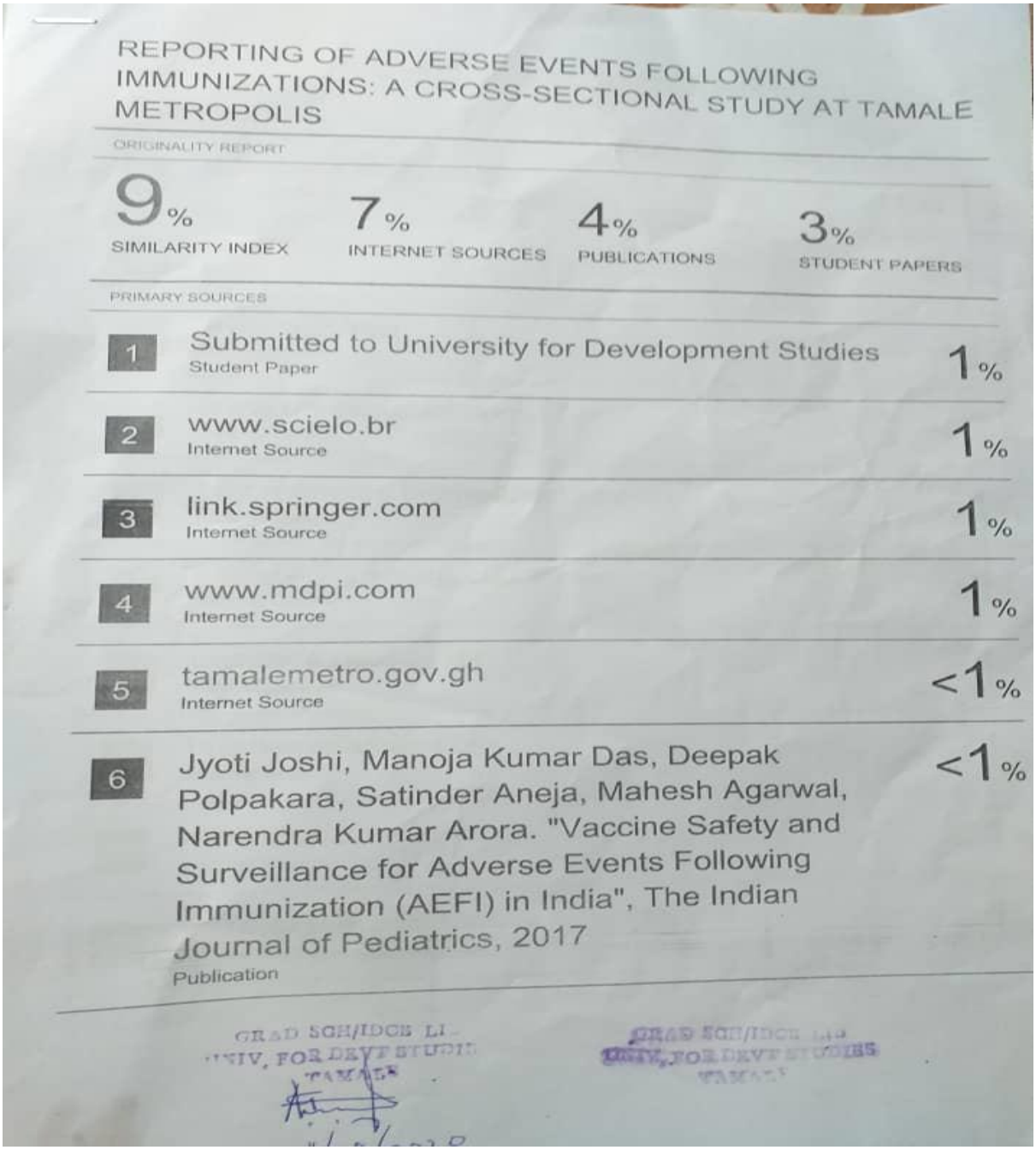
Thank you

JEREMIAH M. TIIMOB
DEPUTY DIRECTOR-ADMINISTRATION
FOR: REGIONAL DIRECTOR OF HEALTH SERVICES

approved
31/03/2020

Appendix III

Plagiarism Report



REPORTING OF ADVERSE EVENTS FOLLOWING IMMUNIZATIONS: A CROSS-SECTIONAL STUDY AT TAMALE METROPOLIS

ORIGINALITY REPORT

9%	7%	4%	3%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

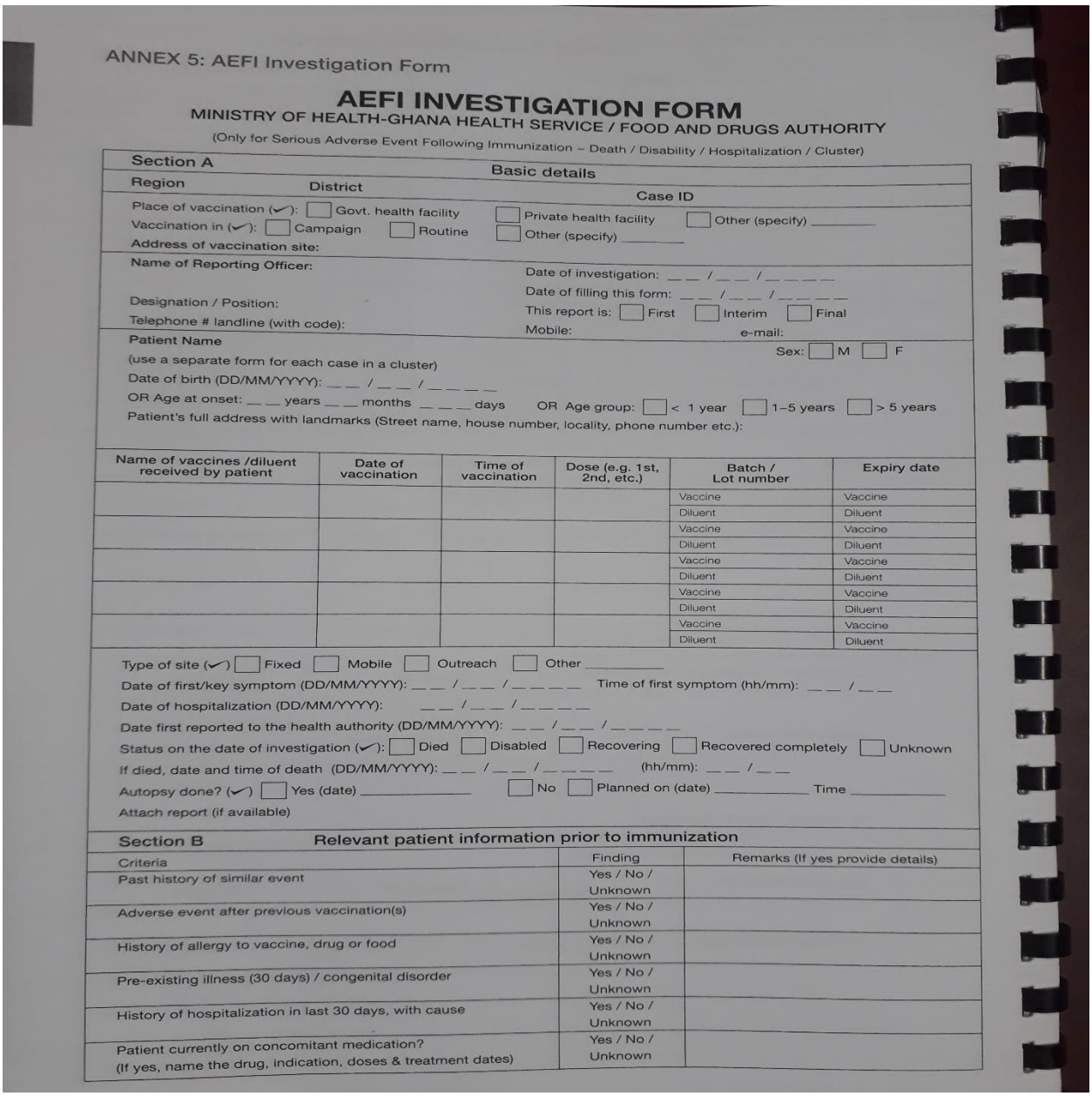
1	Submitted to University for Development Studies Student Paper	1%
2	www.scielo.br Internet Source	1%
3	link.springer.com Internet Source	1%
4	www.mdpi.com Internet Source	1%
5	tamalemetro.gov.gh Internet Source	<1%
6	Jyoti Joshi, Manoja Kumar Das, Deepak Polpakara, Satinder Aneja, Mahesh Agarwal, Narendra Kumar Arora. "Vaccine Safety and Surveillance for Adverse Events Following Immunization (AEFI) in India", The Indian Journal of Pediatrics, 2017 Publication	<1%

GRAD SCH/IDCE LI... UNIV. FOR DEVT STUDIES TAMALE

GRAD SCH/IDCE LIB UNIV. FOR DEVT STUDIES TAMALE

Appendix IV

AEFI Report Form



ANNEX 5: AEFI Investigation Form

AEFI INVESTIGATION FORM

MINISTRY OF HEALTH-GHANA HEALTH SERVICE / FOOD AND DRUGS AUTHORITY

(Only for Serious Adverse Event Following Immunization – Death / Disability / Hospitalization / Cluster)

Section A Basic details

Region District Case ID

Place of vaccination (✓): ☐ Govt. health facility ☐ Private health facility ☐ Other (specify) _____

Vaccination in (✓): ☐ Campaign ☐ Routine ☐ Other (specify) _____

Address of vaccination site:

Name of Reporting Officer: Date of investigation: __ __ / __ __ / __ __ __ __

Designation / Position: Date of filling this form: __ __ / __ __ / __ __ __ __

Telephone # landline (with code): This report is: ☐ First ☐ Interim ☐ Final

Mobile: e-mail:

Patient Name Sex: ☐ M ☐ F

(use a separate form for each case in a cluster)

Date of birth (DD/MM/YYYY): __ __ / __ __ / __ __ __ __

OR Age at onset: __ __ years __ __ months __ __ __ days OR Age group: ☐ < 1 year ☐ 1–5 years ☐ > 5 years

Patient's full address with landmarks (Street name, house number, locality, phone number etc.):

Name of vaccines /diluent received by patient	Date of vaccination	Time of vaccination	Dose (e.g. 1st, 2nd, etc.)	Batch / Lot number	Expiry date
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent
				Vaccine	Vaccine
				Diluent	Diluent

Type of site (✓) ☐ Fixed ☐ Mobile ☐ Outreach ☐ Other _____

Date of first/key symptom (DD/MM/YYYY): __ __ / __ __ / __ __ __ __ Time of first symptom (hh/mm): __ __ / __ __

Date of hospitalization (DD/MM/YYYY): __ __ / __ __ / __ __ __ __

Date first reported to the health authority (DD/MM/YYYY): __ __ / __ __ / __ __ __ __

Status on the date of investigation (✓): ☐ Died ☐ Disabled ☐ Recovering ☐ Recovered completely ☐ Unknown

If died, date and time of death (DD/MM/YYYY): __ __ / __ __ / __ __ __ __ (hh/mm): __ __ / __ __

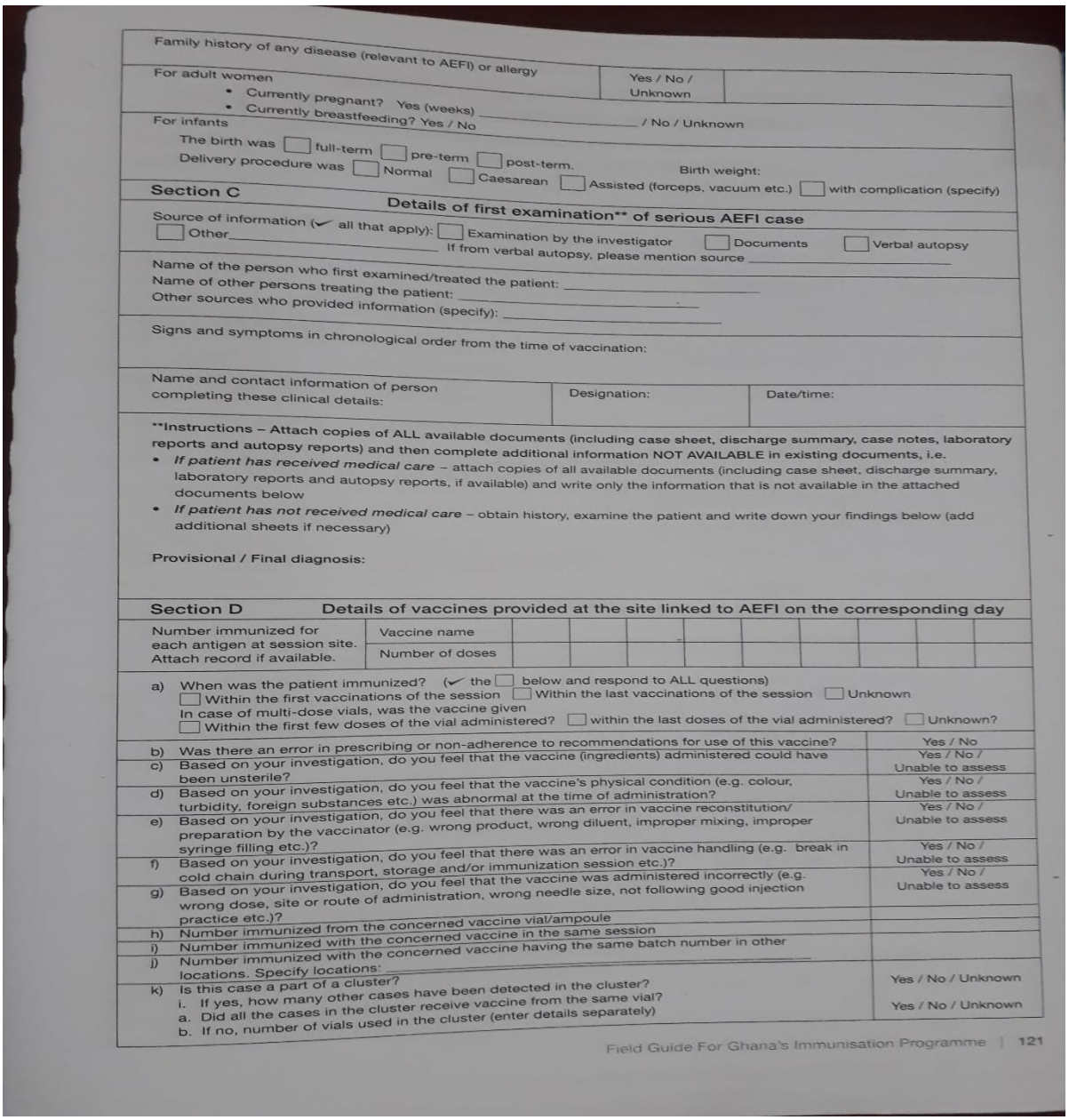
Autopsy done? (✓) ☐ Yes (date) _____ ☐ No ☐ Planned on (date) _____ Time _____

Attach report (if available)

Section B Relevant patient information prior to immunization

Criteria	Finding	Remarks (If yes provide details)
Past history of similar event	Yes / No / Unknown	
Adverse event after previous vaccination(s)	Yes / No / Unknown	
History of allergy to vaccine, drug or food	Yes / No / Unknown	
Pre-existing illness (30 days) / congenital disorder	Yes / No / Unknown	
History of hospitalization in last 30 days, with cause	Yes / No / Unknown	
Patient currently on concomitant medication? (If yes, name the drug, indication, doses & treatment dates)	Yes / No / Unknown	

Appendix IV continuation (AEFI Report Form)



Family history of any disease (relevant to AEFI) or allergy	Yes / No / Unknown	
For adult women • Currently pregnant? Yes (weeks) _____ / No / Unknown • Currently breastfeeding? Yes / No		
For infants The birth was ☐ full-term ☐ pre-term ☐ post-term. Birth weight: Delivery procedure was ☐ Normal ☐ Caesarean ☐ Assisted (forceps, vacuum etc.) ☐ with complication (specify)		

Section C — **Details of first examination** of serious AEFI case**

Source of information (✓ all that apply): ☐ Examination by the investigator ☐ Documents ☐ Verbal autopsy
☐ Other_____ If from verbal autopsy, please mention source _____

Name of the person who first examined/treated the patient: _____
Name of other persons treating the patient: _____
Other sources who provided information (specify): _____

Signs and symptoms in chronological order from the time of vaccination:

Name and contact information of person completing these clinical details:	Designation:	Date/time:

**Instructions – Attach copies of ALL available documents (including case sheet, discharge summary, case notes, laboratory reports and autopsy reports) and then complete additional information NOT AVAILABLE in existing documents, i.e.

- *If patient has received medical care* – attach copies of all available documents (including case sheet, discharge summary, laboratory reports and autopsy reports, if available) and write only the information that is not available in the attached documents below
- *If patient has not received medical care* – obtain history, examine the patient and write down your findings below (add additional sheets if necessary)

Provisional / Final diagnosis:

Section D — **Details of vaccines provided at the site linked to AEFI on the corresponding day**

Number immunized for each antigen at session site. Attach record if available.										
	Vaccine name									
	Number of doses									

a) When was the patient immunized? (✓ the ☐ below and respond to ALL questions)
☐ Within the first vaccinations of the session ☐ Within the last vaccinations of the session ☐ Unknown
In case of multi-dose vials, was the vaccine given
☐ Within the first few doses of the vial administered? ☐ within the last doses of the vial administered? ☐ Unknown?

b)	Was there an error in prescribing or non-adherence to recommendations for use of this vaccine?	Yes / No
c)	Based on your investigation, do you feel that the vaccine (ingredients) administered could have been unsterile?	Yes / No / Unable to assess
d)	Based on your investigation, do you feel that the vaccine's physical condition (e.g. colour, turbidity, foreign substances etc.) was abnormal at the time of administration?	Yes / No / Unable to assess
e)	Based on your investigation, do you feel that there was an error in vaccine reconstitution/ preparation by the vaccinator (e.g. wrong product, wrong diluent, improper mixing, improper syringe filling etc.)?	Yes / No / Unable to assess
f)	Based on your investigation, do you feel that there was an error in vaccine handling (e.g. break in cold chain during transport, storage and/or immunization session etc.)?	Yes / No / Unable to assess
g)	Based on your investigation, do you feel that the vaccine was administered incorrectly (e.g. wrong dose, site or route of administration, wrong needle size, not following good injection practice etc.)?	Yes / No / Unable to assess
h)	Number immunized from the concerned vaccine vial/ampoule	
i)	Number immunized with the concerned vaccine in the same session	
j)	Number immunized with the concerned vaccine having the same batch number in other locations. Specify locations: _____	
k)	Is this case a part of a cluster?	Yes / No / Unknown
	i. If yes, how many other cases have been detected in the cluster?	
	a. Did all the cases in the cluster receive vaccine from the same vial?	Yes / No / Unknown
	b. If no, number of vials used in the cluster (enter details separately)	

Field Guide For Ghana's Immunisation Programme | 121

Appendix V

Face to face interview guide

UNIVERSITY FOR DEVELOPMENT STUDIES

SCHOOL OF MEDICAL SCIENCES

DEPARTMENT OF COMMUNITY HEALTH AND FAMILY MEDICINE

Dear Respondent,

I am a final year Master of Public Health student at the University for Development Studies (UDS) Graduate School.

I am conducting a research on the topic "REPORTING OF ADVERSE EVENTS FOLLOWING IMMUNIZATIONS: A CROSS-SECTIONAL STUDY AT TAMALE METROPOLIS"

The purpose of this study is purely academic and policy direction.

Remember your answers will be kept confidential

You have been given a copy of questionnaire and a pencil. Please use the pencil to tick the answers provided corresponding to the questions. If you make a mistake, carefully erase/rub out the pencil marks that were made incorrectly and then tick the answer you now choose.

Please **do not write your name** on the questionnaire sheets given to you. Your information is confidential..

…….

Please sign

1. Please what is your rank? .....
2. How many years have you been working as healthcare provider? …….
3. Do know the meaning of AEFIs? …… please tell me the full meaning
4. Have mothers' who come here for vaccination for their children complain of any AEFIs?
5. What are normally the complaints mothers give on AEFIs?
6. What have been your reactions/responses to the complaints mothers make?
7. Do you record information on the complaints mothers' make?
8. What are some of the major complaints you often record
9. Among which of the vaccines do you normally receive complaints on AEFIs?
10. What challenges do you normally face in taking records of what mothers' come to complain about in your facility?

Appendix VI

Questionnaire

UNIVERSITY FOR DEVELOPMENT STUDIES

SCHOOL OF MEDICAL SCIENCES

DEPARTMENT OF COMMUNITY HEALTH AND FAMILY MEDICINE

Dear Respondent,

I am a final year Master of Public Health student at the University for Development Studies (UDS) Graduate School.

I am conducting a research on the topic "REPORTING OF ADVERSE EVENTS FOLLOWING IMMUNIZATIONS: A CROSS-SECTIONAL STUDY AT TAMALE METROPOLIS"

The purpose of this study is purely academic and policy direction.

Remember your answers will be kept confidential

You have been given a copy of questionnaire and a pencil. Please use the pencil to tick the answers provided corresponding to the questions. If you make a mistake, carefully erase/rub out the pencil marks that were made incorrectly and then tick the answer you now choose.

Please **do not write your name** on the questionnaire sheets given to you. Your information is confidential.

INSTRUCTIONS

Please answer all the questions.

PLEASE TICK (√) OR WRITE WHERE APPROPRIATE IN THE BOX FOR ANSWER.

…….

Please sign

code	Questions	Response
Social demographic characteristics		
1	What is your age? Write age in years in the box provided	……
1a	Sex of Guardian	Male 1[ ] Female 2[ ]
1b	What is your highest level of education?	Basic School 1[ ] JHS 2[ ] SHS 3[ ] Tertiary 4[ ] No education 5[ ]
1c	Religious Denomination	Christian 1[ ] Muslim 2[ ] Traditional 3[ ] No Religion 4[ ] Other, specify 10
1d	Ethnicity	Hausa 1[ ] Dagomba 2[ ] Mossi 3[ ] Other, specify 10
1e	Please, how many times have you given birth?	Specify:
1f	Please kindly specify how many are alive?	
1g	What is your marital status?	Single 1[ ] Married 2[ ]

		Divorced 3 [ ] Widowed 4[ ] Co-habitation 5[ ] Others specify……..... 10
1h	Please what is your occupation/Profession?	Specify:
Self-reported prevalence of AEFIs		
2a	Please, have you ever seen/noticed any reaction/event on your child after receiving an immunisation?	Yes 1 [ ] No 2 [ ]
2b	How long did it take you to see/notice the reaction/event on your child?	Within 24hours 1[ ] After 24hours 2[ ]
2c	What reaction/event did you see on your child after the immunization?	Specify:
2d	Please among which of the following vaccines did you see/notice the reaction/event? Please tick/indicate where appropriate	Bacillus Calmette-Guerin (BCG) 1 [ ] Oral/Inactivated Polio Vaccine 2 [ ] Diphtheria Toxoid Vaccine 3 [ ] Tetanus Toxoid Vaccine 4 [ ] Pertussis Vaccine 5[ ] Hepatitis B Vaccine 7 [ ] Hib conjugate Vaccine 8 [ ] Pneumococcal Vaccine 9 [ ] Rotavirus Vaccine 10[ ] Measles-Rubella 11[ ] Yellow Fever Vaccine 12[ ] Conjugate Meningococcal A Vaccine 13 [ ]
2d	How many times have you witnessed or seen the AEFIs on your child?	Specify:

2e	Number of times child has been vaccinated	Once 1[ ] Twice 2[ ] Three times 3[ ] More than three times 4[ ]
2f	Among which of your children did you see the AEFIs?	First child 1[ ] Second Child 2[ ] Third Child 3[ ] All my Children 4[ ] None of my Children 10[ ]
AEFIs knowledge		
3a	Are you aware that after immunisation(s) you can or likely to develop AEFIs?	Yes 1 [ ] No 2 [ ]
3b	Have you ever heard about AEFIs before?	Yes 1 [ ] No 2 [ ]
3c	Where did you hear about AEFIs?	Specify:
3d	How would you rate your knowledge/awareness level on AEFIs?	Poor 1[ ] Good 2[ ] Excellent 3[ ]
3d	Do you desire to learn more about how to detect and report AEFIs?	Yes 1 [ ] No 2 [ ]
AEFIs reporting behaviours		
4a	Have you ever reported any AEFIs to a health facility?	Yes 1 [ ] No 2 [ ]
4b	Which health facility do you normally report observed AEFIs to?	Specify:

4c	Which of the AEFI (event) did you report to the health facility? Eg. Fever, headache etc.	Specify:
4d	Did you provide any form of intervention to the child when you observed the reaction (AEFIs)	Yes 1 [ ] No 2 [ ]
4e	What form of intervention did you give to your child?	Specify:
4f	Who advised you to provide the intervention in **item 4e**?	Self -initiative 1[ ] Sibling/Family/Friend 2[ ] Healthcare provider 3[ ]
Factors associated with reporting of AEFIs among mothers'		
5a	What information does health workers give to mothers when their children experience AEFIs?	Manage it in the home 1 [ ] Report to health worker or health facility 2[ ]
6b	How often do healthcare workers educate you (mothers) about AEFIs?	Routinely 1[ ] Monthly 2[ ] None 3[ ]
6c	Reasons for not reporting AEFIs. Please tick/indicate where applicable	Too busy 1[ ] Long distance to facility 2[ ] I don't think it is necessary 3[ ] Condition was not serious 4[ ] Healthcare workers do not give my child the needed attention 5[ ] Was asked to manage it at the home 6[ ] I did not know how to report 7[ ] Others, please write;

6d	Are you concerned about AEFIs?	Yes No	1[ ] 2[ ]
6e	Would you encourage other mothers to always report any case of AEFIs?	Yes No	1[ ] 2[ ]

THANK YOU