SCHOOL OF PUBLIC HEALTH
COLLEGE OF HEALTH SCIENCES
UNIVERSITY OF GHANA

ADVERSE EVENTS REPORTING FOLLOWING IMMUNIZATION AMONG
MOTHERS WITH CHILDREN 0-5 YEARS AND HEALTH WORKERS IN
SELECTED HEALTH FACILITIES IN GREATER ACCRA REGION.

BY

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DISSERTATION SUBMITTED TO UNIVERSITY OF GHANA, LEGON IN
PARTIAL FULFILLMENT FOR THE AWARD OF THE MASTER OF PUBLIC
HEALTH (MPH) DEGREE.

JULY, 2019
DECLARATION

I, Enyonam Aku Duah, declare that except for other peoples investigation which has been fully acknowledged, this work is the result of my own original research with the supervision of my supervisor Dr. Augustina Koduah and this proposal either in part or in whole has not been presented elsewhere for another degree.

Enyonam Aku Duah  Signature  ………………… Date: …………..

(Student)

Dr. Augustina Koduah Signature: ………………… Date: ……………

(Academic Supervisor)
ABSTRACT

Introduction: Adverse event reporting remains a major public health concern. Vaccination, an essential component of the public health programme was introduced to save lives and preserve health. Unlike medicines, the expectations from vaccination are much higher and problems arising from the vaccine or vaccination may be less acceptable to the general public. Adverse events (AEFI) is defined as any unwanted medical occurrence which follows immunization and does not necessary have a causal relationship with the use of the vaccine. The identification, recording, reporting and monitoring of adverse event following immunization (AEFI) is essential to the investigation and reduction of such cases. Spontaneous reporting system is a commonly used system to report AEFIs by health workers as well as caregivers. Spontaneous and prompt reporting of AEFIs is an important activity of pharmacovigilance that help in ensuring medicine safety.

Aim: To explore factors and barriers associated with adverse event reporting following immunization among mothers with children aged 0-5 years and health workers in three selected health facilities in Greater Accra Region.

Method: This is a mixed method study design which involved both qualitative and quantitative approaches. Health facilities were conveniently sampled and health workers purposively sampled to partake in the studies. Mothers were randomly selected from the three selected health facilities and secondary data was obtained from 2016-2018 ascertain the most causal vaccines reported, the common AEFIs in three selected health facilities in the Greater Accra Region.

Results: Qualitative: A total of 17 interviews were conducted, 17 (100%) being females with age ranging between ≤ 30 representing 3 (17.6%) and ≥ 30 representing 14 (82.4), 10
(58.8%) have had tertiary education, 5 (29.4%) secondary education and 2 (11.8%) primary education. A total of 7 (41.1%) were health workers whiles 10 (58.9) were mothers. Barriers identified in the study included inadequate staff, heavy workload, fear of criticism, lack of adequate knowledge about AEFI and who to report to. Factors were identified based on three main factors (health worker factors, mothers’ factors and health system factors) availability of forms, adequate training, built feedback system, education and sensitization, familiarity of the reporting system and monitoring and supervision.

Quantitative: A total of 33 AEFI cases (34.6 per 100000 children vaccinated) was identified at the three facilities. In 2016, seven AEFI cases (22.4 Per 100000 children vaccinated), in 2017 26 AEFI cases (82.6 per 100000 children vaccinated) and one AEFI case in 2018 (3.0 per 100000 children vaccinated). This indicates underreporting as compared to the WHO recommended rate of AEFI reporting. 15 (45%) represented males as compared with 18 (55%) females. The most common AEFI identified was Injection site abscess with most causal vaccine being yellow fever.

**Conclusion:** It is necessary to develop training and educational programs to increase awareness in both mothers and health workers towards reporting of AEFIs. The information generated from this study is valuable for the public health regulators to generate new guidelines for AEFI surveillance.
ACKNOWLEDGEMENT

I firstly want to thank God Almighty for the grace to successfully see me through this MPH program; I also want to thank my supervisor Dr. Augustina Koduah for her enormous contribution and support throughout my program to carefully go through my work and make her contribution towards my thesis.

Also my sincere thanks goes to the Accra metro Health Directorate for their immerse support during my data collection process to assist with study sites and numbers of health workers. My sincere gratitude also goes to Kaneshie polyclinic, Adabraka polyclinic and Mamprobi Polyclinic for their immerse support for allowing me conduct my study in their facility and help during the data collection process.

In addition, I would also like to thank my bosses Dr. Raymond Aborigo and Dr. Nathan Mensah for their contribution and guidance during my masters’ programme.

Lastly I also want to thank my family for all the help and support for they have given me throughout my studies and stay on campus.
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**DEFINITION OF TERMS**

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<th>Definition</th>
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<tbody>
<tr>
<td>Adverse event following immunization (AEFI)</td>
<td>Any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine.</td>
</tr>
<tr>
<td>Causal association</td>
<td>A cause and effect relationship between a causative factor and outcome. This usually occurs after a vaccine is administered.</td>
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<tr>
<td>Causality assessment</td>
<td>In the context of AEFI surveillance it is a systematic review of data about AEFI case to determine the association between the event and the vaccine received.</td>
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<tr>
<td>Coincidental events</td>
<td>An AEFI that is caused by something other than the vaccine product, by immunization error or immunization anxiety.</td>
</tr>
<tr>
<td>Contraindication</td>
<td>A situation where a particular treatment or procedure, such as vaccination with a particular vaccine, must not be administered for safety reasons.</td>
</tr>
<tr>
<td>Immunization anxiety-related reaction</td>
<td>An AEFI arising from anxiety about the immunization.</td>
</tr>
<tr>
<td>Immunization error-related reaction</td>
<td>An AEFI that is caused by inappropriate vaccine handling, prescribing or administration, and thus by its nature is preventable.</td>
</tr>
<tr>
<td>Immunization safety</td>
<td>The process of ensuring the safety of all aspects of immunization, including vaccine quality, adverse events surveillance, vaccine storage and handling, vaccine administration, disposal of sharps and management of waste.</td>
</tr>
<tr>
<td>Immunization safety surveillance</td>
<td>A system for ensuring immunization safety through detecting, reporting, investigating and responding to AEFI.</td>
</tr>
<tr>
<td>Non-serious AEFI</td>
<td>An event that is not serious and does not pose a potential risk to the health of the individual.</td>
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recipient.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Vaccine product-related reaction</td>
<td>An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product, whether the active component or one of the other components of the vaccine (for example, adjuvant, preservative or stabilizer).</td>
</tr>
<tr>
<td>Vaccine quality defect-related reaction</td>
<td>An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration device, as provided by the manufacturer.</td>
</tr>
<tr>
<td>Vaccine reaction</td>
<td>An event caused or precipitated by the active component or one of the other components of the vaccine. It may also relate to a vaccine quality defect.</td>
</tr>
<tr>
<td>Vaccine safety</td>
<td>The process, which maintains the highest efficacy of, and lowest adverse reaction to, a vaccine by addressing its production, storage and handling. Vaccine safety is a part of immunization safety.</td>
</tr>
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LIST OF ABBREVIATIONS

AEFI- Adverse Events Following Immunization

AEs- Adverse Events

EPI-Expanded Programme on Immunization

FGD- Focus Group discussion

IDI- In-depth Interviews

Hib- Hemophilus influenzae type b

WHO- World Health Organization
CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Among the most cost effective and safest public health interventions to prevent diseases and death is vaccination. Vaccination is among the most cost effective and safe public health interventions available to prevent diseases and death (Adokiya, Baguune, & Ndago, 2017; Kagoné et al., 2018; WHO, 2009). Three quarters of the world's children are protected against major childhood illnesses and an estimated two million deaths are averted each year through vaccination (Danova, Kocourkova, & Celko, 2017). “The Expanded Programme on Immunization (EPI) was launched by WHO in 1978 with the aim to protect every child against the six specific vaccine preventable diseases: diphtheria, pertussis, tetanus, measles, poliomyelitis, and tuberculosis” (Adokiya et al., 2017; Keja K, Chan C, Hayden G, 2015; World Health Organization et al., 2000).

Ghana’s EPI was launched in 1978 and became operational nationwide in 1985 which was aimed at increasing immunization coverage from 6% to 80% among children under one year of age against six target diseases. The target was in response to reduce morbidity and mortality of vaccine preventable diseases which contribute significantly to both infant and child mortality in the country (Benjamin Baguune, Ndago, & Adokiya, 2017).

After immunizations some people may experience adverse events ranging from mild adverse reactions to life threatening events. Usually, these adverse events may be caused by the vaccine, or by an error during administration while in majority of the cases is just coincidental(National Pharmacovigilance Centre (NPC) NAFDAC, 2014).
Mass vaccination may lead to more vaccine related adverse events or immunization errors, therefore early reporting and investigating of adverse events following Immunization (AEFI) is advocated since it can be useful in identifying and correcting immunization-error related reactions and may help in distinguishing coincidental events, program errors from vaccine-related adverse events (National Pharmacovigilance Centre (NPC) NAFDAC, 2014).

The success of immunizations in reducing childhood infections has paradoxically led to rising concerns about safety of vaccines (Asuman, Ackah, & Enemark, 2018). The decline in vaccine preventable diseases, however, has led to media focus and heightened public concerns on adverse events associated with these vaccines. Hence, adverse events associated with vaccines are a critical theme in both routine and mass immunizations (Larson, Cooper, Eskola, Katz, & Ratzan, 2011; S. Tafuri et al., 2014).

1.2 Definition of Adverse Event Following Immunization

Adverse events (AEs) occurring after immunization, regardless of whether they were or were not caused by the vaccine, are referred to as ‘AEFI (D’alo et al., 2017; Di Pasquale et al., 2016).

“AEFI is any untoward medical occurrence which follows immunization and which may not necessarily have an unpretentious relationship with the usage of the vaccine” (D’alo et al., 2017; National Pharmacovigilance Centre (NPC) NAFDAC, 2014; Puliyel & Naik, 2018)

According to WHO there are three key aspects to the definition of an AEFI. The definition is deliberately loose to encourage reporting of events. This is because it does not restrict the type of event (other than being a health consequence) nor limit the time window after immunization, nor attempt to determine whether the immunization may have been responsible. That is, it is events not reactions that are reported (Puliyel & Naik, 2018).
Secondly, AEFI is described as a belief of causality that usually requires investigation. Sometimes the belief that immunization was responsible for the adverse event may turn out to be correct, incorrect or probably impossible to assess. Adverse events could occur as a result of the way the immunization was carried out during the vaccination process.

Thirdly, describing an AEFI event may not necessarily imply causality, its only after investigation that causality can be ascertained (Konnyebal, 2014). Usually within the framework of, causality an AEFI can be caused either by;

1. The vaccine, which is the event being caused as a result of the inherent properties of the vaccine.
2. Immunization process, which is usually an error, occurs during vaccination.
3. Coincidence, which usually occurs by chance after the immunization is given and may not have any relationship with the vaccine administered (Stefanizzi et al., 2017).

1.3. Classification of AEFI
AEFI can be classified according to the frequency of occurrence and may range from very common to very rare (National Pharmacovigilance Centre (NPC) NAFDAC, 2014) as shown in Table 1.1.

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Measures of AEFI</th>
</tr>
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<tbody>
<tr>
<td>Very common</td>
<td>&gt; 1/10</td>
</tr>
<tr>
<td>Common</td>
<td>&gt; 1/100 and &lt; 1/10</td>
</tr>
<tr>
<td>Uncommon</td>
<td>&gt; 1/1000 and &lt; 1/100</td>
</tr>
<tr>
<td>Rare</td>
<td>&gt; 1/10,000 and &lt; 1/1,000</td>
</tr>
<tr>
<td>Very rare</td>
<td>&lt; 1/10,000</td>
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(Schumacher, Bourquin, & Heininger, 2010)
AEFI may also be classified as expected or unexpected. Expected AEFIs are those that the manufacturer is aware of and documents. These AEFIs are observed with determined rates of occurrence (Puliyel & Naik, 2018).

1.3.1. Impact of AEFI on immunization programmes

Adverse events following immunization remain a major challenge to immunization programmes because of the awareness and emergence of vaccine safety issues which could potentially erode the gains made by immunization programmes (McClure, Cataldi, & O’Leary, 2017).

A perceived or real adverse event following Immunization has the potential to undermine the credibility and acceptance of the vaccine and the programme itself. In other words AEFI may lead to loss of public trust in immunization and a vaccine with short term or long lasting consequences such as parents refusing to send their children for vaccination, loss of confidence in vaccines. They could influence public health policy change or result in resurgence of vaccine–preventable diseases (Serpell & Green, 2006).

1.4 Problem statement

Despite the undoubted public health benefits of routine vaccination, AEFI remains a major concern to public health. As most AEFIs may be mild, it is usually underreported which affects AEFI reports in literature (Danova et al., 2017).

Even though AEFIs are well known, little is known about health workers and mothers recognizing and reporting. Poor knowledge of AEFI among health workers and mothers will result in many causes of AEFI going underreported and unaddressed (R. A. Ogunyemi & Odusanya, 2016).

The reliance of the system on spontaneous reporting of AEFI by mothers to the facility and/or looking out for selected conditions by health workers at health facilities during vaccination
campaigns opens it to under and biased reporting. Mothers may not report mild AEFIs to the facility and health workers may fail to capture AEFIs not included in the list of AEFI to look out for (Konnyebal, 2014).

Setting up awareness on the importance of the reporting AEFI and the vaccine safety monitoring is important for sustaining National immunization programmes and increasing vaccine coverage (Mehmeti, Nelaj, Simaku, Tomini, & Bino, 2017).

This study is therefore designed to explore factors associated with AEFI Immunization among mothers with children aged 0-5 years and health workers in 3 selected health facilities in Greater Accra region.

1.5 Justification

Patient safety is necessary when vaccines are administered. Detection, documentation, reporting and management of vaccine related issues are inclusive in ensuring the overall safety of the patient. Unlike drugs, the expectations from vaccinations are much higher but problems arising from vaccines or vaccinations are less acceptable to the general public. There is therefore the need to actively monitor all AEFIs and respond to them appropriately. This study will provide data on factors associated with adverse event reporting, barriers to reporting, description of AEFI, Seriousness and outcome of AEFI among mothers with children 0-5 years and health workers in Adabraka Polyclinic, Mamprobi Polyclinic and Kaneshie Polyclinic in Greater Accra Region of Accra.

1.6 Research Question

- What is the common type of AEFI and causal vaccine in the three selected facilities?
- How is AEFI reporting detected and reported?
- What are the barriers to reporting of AEFI among mothers with children 0-5 and health workers?
What are the factors influencing AEFI reporting health workers and mothers reporting?

1.7 General Objective
To explore factors and barriers to AEFI among mothers children aged 0-5 years and health workers in three selected health facilities in Greater Accra Region of Ghana.

1.8.1 Specific Objectives
- To assess the common type of AEFI reported in the three health facilities in Greater Accra.
- To assess detection of reporting among mothers with children 0-5 years and health workers in selected health facilities in Greater Accra.
- To identify barriers of adverse event reporting following immunization among mothers with children 0-5 years and health workers in selected health facilities in Greater Accra.
- To explore factors associated with adverse event reporting following immunization among health workers and mothers with children 0-5 years in selected health facilities in Greater Accra.

1.8 Conceptual framework
Reporting of AEFI is influenced by factors that are related to health staff, care givers, health system and others. The level of knowledge, practice of reporting of AEFI and socio-demographic characteristics of health staff and care givers could facilitate reporting of AEFI. Both health system and health staff factors are interrelated in reporting of AEFI and health staff factors influence care givers to report an AEFI. Feedback promotes the interest of both reporting staff and care giver to report subsequent AEFI for action. The availability of logistics such as the AEFI reporting tools also determine reporting of AEFI. A cumbersome
and complex reporting system may discourage some staff from reporting AEFI. The factors are interlinked with the barriers to reporting which are either individual barriers or health system related.

Figure 1: Conceptual framework on barriers and factors affecting adverse event reporting following immunization.
CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

In the last 10 years, major advances have been made in the development and introduction of new vaccines and expanding immunization programmes. According to D’alo et al., the access and use of vaccines is expanding which has led to more people being vaccinated (D’alo et al., 2017).

An essential component of the public health programme which is vaccination was introduced to save lives and preserve health, unlike medicines, the expectations from vaccination are much higher and problems arising from the vaccine or vaccination may be less acceptable to the general public. Like medicinal products, vaccines which help people stay healthy; is not free from adverse events with a small number of persons experiencing mild adverse events which may also be serious (Maman et al., 2016).

According (WHO) data, vaccination prevents 2-3 million deaths every year worldwide (D’alo et al., 2017) while at the same time WHO warns that 22 newborns do not receive vaccinations globally (D’alo et al., 2017). Around 1.5 million children die each year from vaccine-preventable infectious diseases (Burghouts et al., 2017). Vaccines have reduced the incidence of many vaccine-preventable diseases in the United States by more than 98% compared to the pre-vaccine era.

Studies conducted in Spain and USA showed that AEFI rate varies between 11.9-19% per 1000 doses (Pate, Shah, Desai, V Kalaiselvan, & G.N Singh, 2018). Surprisingly studies conducted in India, 54 deaths were reported by Pentavalent vaccine in 2014. Among them, three deaths were causally associated with vaccination, while one death has been placed
under “Vaccine Reaction” by AEFI. According to recent media report up to August 2016 there have been 237 deaths reported within 72 hour of vaccination with Pentavalent vaccine (Pate et al., 2018)

Studies done by D’alo et al., and WHO showed that the scientific knowledge of AEFI is limited due to the detection rate and usually identification is overlooked by physicians and the available reported AEFI data only shows a relationship between the vaccination and the onset of the AEFI (D’alo et al., 2017).

In an India published article in 2003, AEFI forms a critical component of immunization program. The risk of AEFI is being weighed against the risk of not immunizing a child it is only then that a vaccine can be considered safe However even at a low rate, because of the high beneficiaries, there is still a risk of a few serious adverse events among vaccinated children (Joshi et al., 2018).

2.2 Reporting system

Spontaneous reporting system is the known accepted method used worldwide for reporting AEFIIs (Kumar, Singh, Gupta, Rao, & Taneja, 2016).

Studies have shown that underreporting is a known limitation of spontaneous reporting all over the world (Brickel et al., 2017; Mendes Marques, Polónia, Figueiras, Costa Santos, & Herdeiro, 2016). Another study has shown that lack of knowledge in AEFIIs and its reporting may have led to inconsistent adverse events data collection which may have also lead to inaccurate calculation of incidence of AEFIIs, by delaying or missing important vaccine safety concerns (Mehmeti et al., 2017).

Spontaneous reporting system has many benefits (cover large population, may generate rapid alerts, low setup/costs) along with some limitations (under reporting, incomplete data, bias).
The most important function of the spontaneous reporting system is the early detection of signals which leads to confirmatory investigations or sometimes regulatory warnings that lead to the changes in product information leaflets or manuals (Kumar et al., 2016).

All AEFIs reporting is encouraged but that depends on whether the individual makes a report or not which is usually influenced by the severity of the AEFI, media reports, temporal relationship of the event with immunization and the knowledge or ease of access to reporting forms.

AEFIs usually lead to public concerns and this may have serious implications for public health if not dealt with accurately and such issues should be considered when immunization programs are established (WHO, 2018b).

The use of AEFI forms is encouraged to facilitate the reporting of certain events such as local site abscess which is usually seen as a result of an immunization error (WHO, 2018a, 2018b).

Various studies from literature have argued that most reportable AEFI events are the serious and events that may cause public concern whiles mild AEFIs are not usually reported or documented which usually differs from spontaneous reporting which focuses more on even mild case detection. Assessment of a causal relationship between the administration of the vaccine and the occurrence of the event can be difficult. (Mehta, Milstien, Duclos, & Folb, 2000)

2.3. Passive surveillance of AEFI

Passive surveillance is a type of surveillance system and source for post licensure safety information which relies on individuals to make such reports when they become aware of it. (Di Pasquale et al., 2016; Shimabukuro, Nguyen, Martin, & DeStefano, 2015).
From literature many countries have regional or centralized procedures in place to receive AEFI reports from the health workers that are queried regularly for signal detection and evaluation (Williams et al., 2013).

Alternatively, when knowledge of the background rates of disease is known (i.e., the incidence of the disease in the general population), ‘Observed-versus-Expected’ analyses can be used to determine if the AEFI is occurring at a higher rate in vaccines than expected in the general population’ (Di Pasquale et al., 2016).

2.3.1 Active surveillance of AEFI

According to a study conducted by (Schumacher et al., 2010), Active surveillance is developed and maintained to be able to better quantify risk associations between administered vaccines and a potential AEFI whiles passive surveillance is important to generate and generate new safety signals.

From previous studies the active surveillance system was initially designed with the focus of building upon existing infrastructure and capacity so it could reliably identify AEFIs. Therefore, the identification and evaluation of existing longitudinal demographic, health and vaccination program information and data collection systems (e.g. Birth cohorts, morbidity surveillance and vaccination registries) are crucial in monitoring active surveillance.

Active surveillance system in the long term perspective should be well integrated into the national health system for effective vaccine safety monitoring. (Sri Lanka FMoH Epidemiology unit, 2012).

As suggested by (Parrella, Gold, Braunack-Mayer, Baghurst, & Marshall, 2014b) immunization safety reporting system should be built and mutually strengthen any existing system of reporting of AEFIs (e.g. immunization coverage reports, disease incidence reports,
and adverse drug reaction reports). The best AEFI reporting system is the one which encourages a high level of appropriate reporting and takes timely action in response to reports.

2.4 Vaccine Safety

No drug or immunization can be attributed to be risk free. (Di Pasquale et al., 2016). In the context of vaccine safety, the benefits of immunization such as prevention of epidemics, reductions in cost associated with treatment should outweigh the risk the individual might suffer from (WHO, 2018b).

According to a critique done by Puliyel and Naik on a WHO causality assessment document most vaccines are provided as injections and the most common AEFI are symptoms that occur at the injection site (pain, redness, swelling), or common systemic symptoms such as fever or myalgia. These events are reported as side-effects of most injected vaccines and are generally mild and self-limiting. Occasionally, unexpected AEs or rare serious AEs may occur. Some events, such as anaphylaxis, usually occur rapidly after immunization and require swift recognition and management. Others may occur days or weeks after immunization; these require comprehensive investigation to distinguish those events that can be potentially causally related to immunization, and those which are merely coincidental to immunization (Puliyel & Naik, 2018).

In studies conducted the possible causes of an AEFI are not clearly identified, or if the event occurred in temporal association with immunization, the patient who experiences the event may assume that the vaccine was the cause. Allegations that vaccines may cause an AEFI must be dealt with diligently and either confirmed or refuted based on scientific evidence (Puliyel & Naik, 2018; Su, Duffy, & Shimabukuro, 2019).
Misleading data can rapidly undermine confidence in an individual vaccine, or can lead to groundless suspension or withdrawal of the product from the market; ultimately having dramatic consequences for public health including decreased coverage and disease resurgence. (Grignolio, 2018b, 2018a, 2018d, 2018c).

2.5 Barriers to reporting adverse events following immunization reporting

Some barriers that affect AEFI reporting may be related to health worker, the health systems, the patient and the severity of the adverse drug reaction (Silvio Tafuri et al., 2018).

2.6.1 Health worker factors

In a studies conducted by Parelle in 2014 on health worker factors that could affect the reporting of AEFI; it included sex, age, years of practice, specialty and the location of the health worker. It is expected that the health workers’ age and years of practice are correlated (Parrella Adriana, 2014).

Studies have found opposing results with regards to the association between age of the health worker and reporting of AEFIs. A number of studies found that health workers who reported AEFIs were younger than the non-reporters whereas other studies showed that health workers who reported AEFIs were older and had more years of practice than non-reporters (Parrella Adriana, 2014).

2.6.2 Health systems factors

Various studies have found out that some of the health systems factors that affected the reporting of AEFIs include the availability of reporting tools, training of health workers, feedback from the national medicines regulatory authority on adverse drug reactions reported previously and the workload of health workers (Westhoff, 2015).

Unavailability of reporting tools was found to be a major deterrent to reporting of AEFIs (B. Baguune & B., 2017; Samsiah, Othman, Jamshed, & Hassali, 2016). Health workers cited
lack of feedback from the medicines regulatory authority on previous reports sent as a reason for not sending reports subsequently (Al Dweik, Stacey, Kohen, & Yaya, 2017; De Vries et al., 2017; Rolfes, van Hunsel, van der Linden, Taxis, & van Puijenbroek, 2017; Terblanche, Meyer, Godman, & Summers, 2017). Training health workers on AEFI reporting had a positive influence on reporting. There was an increased tendency to report AEFIs if the health worker received training (Kaur, Kosey, Mehra, & Kumar, 2015; Terblanche et al., 2017). Education and training were found to be positive predictors in influencing Health providers to report AEFIs as found (Terblanche et al., 2017). Majority of studies have found that there is an association between the health workers’ workload and reporting of AEFIs. Studies by (Chimusoro A, 2014; Mehmeti et al., 2017; Parrella, Braunack-Mayer, Gold, Marshall, & Baghurst, 2013) have found that an increase in workload reduces AEFI reporting by health workers. High workload was as a result of writing more prescriptions in the case of general practitioners, spending more time in clinical practice in the case of consultants or other clinical priorities and from this study by high workload led to lack of time to report AEFIs.

2.6.3 Patient factors

From literature, the willingness of patients to discuss AEFIs with their health provider affects the reporting of AEFIs (Parrella, Gold, Braunack-Mayer, Baghurst, & Marshall, 2014a; Strategy, 2016).

In a study it was found that 25% of outpatients did not discuss AEFI symptoms with their providers. In another study, it was discovered that 42.9% of patients would not consult their General practitioner for serious AEFI caused either by conventional medicine or herbal products (R. A. Ogunyemi & Odusanya, 2016). If a patient does not discuss an AEFI with the health worker, then the health worker will not know that the patient experienced the AEFI and therefore will not be able to report it (Mehmeti et al., 2017).
2.7. Knowledge of definition of adverse events following immunization

A number of studies conducted asked health workers to correctly define Adverse Events Following Immunization. Three of the studies used open-ended questions (Chopra et al., 2011; Oreagba et al., 2011; Toklu and Uysal, 2008), while in one study the questions were multiple choice (Su et al., 2010).

In one study 17% and 26% of the health workers could correctly define pharmacovigilance and an AEFI respectively (Toklu and Uysal, 2008). In a study carried out in India 38% of the health workers could correctly define pharmacovigilance, 66% could correctly define an AEFI and 40% could correctly define a serious AEFI (Chopra et al., 2011). There was another study that used multiple-choice question to define AEFI, 69.5% of the health workers could correctly identify the definition of an AEFI. This higher percentage obtained in the multiple-choice question compared with the results obtained from the open-ended studies.

2.7.1. Awareness on the existence of adverse events following immunization reporting schemes

Majority of the studies that assessed the knowledge of health workers on AEFI reporting schemes assessed whether the workers knew about the existence of an AEFI reporting scheme in their country and its functions, where to get the reporting tools and the procedure for reporting. In studies that investigated the awareness of the existence of a national AEFI reporting scheme, the proportion of health workers who were aware of the existence of the scheme ranged from as low as 12% in one study (Pérez García & Figueras, 2011) to as high as 99.6% in another (Passier et al., 2009). In majority of the studies more than half of the respondents were aware of the existence of the national pharmacovigilance Centre which is responsible for collecting AEFI reports (Chopra, Wardhan, & Rehan, 2011).
A study carried out in Venezuela showed that only 12% of physicians and 20.5% of the pharmacists knew about the existence of the national AEFI reporting scheme, and 2.1% of the physicians and 1.3% of the pharmacists knew where to get the AEFI reporting tools (Pérez García & Figueras, 2011).

In studies that were determining the correct procedure for reporting AEFIs, majority of the health workers knew the correct procedure for reporting AEFIs. In a study carried out in China, 78% of the health workers knew the correct procedure for reporting AEFIs; similarly the correct procedure for reporting AEFIs was identified by 70% of health workers in two studies in Germany and Italy and 97% of health workers in a study that was carried out in Netherlands (R. Ogunyemi & Odusanya, 2016). In a Venezuelan study, only 20% of the participants were aware of the correct procedure for reporting AEFIs (Pérez García & Figueras, 2011). In a study carried out in the UK, 97% of pharmacists were aware that they could participate in the Yellow Card Scheme (Green, Mottram, Rowe, & Pirmohamed, 2001).

2.7.2 Knowledge about the kind of information that should be reported to the AEFI reporting scheme

A number of studies investigated whether health workers have adequate knowledge regarding the kind of information that should be reported to the national pharmacovigilance centres. In a study done on pharmacists in the UK, 97.7% of pharmacists were aware that all adverse reactions for newly marketed agents should be reported, 91.4% were aware that all serious reactions for established products should be reported and 94% knew that the Committee of Safety of Medicines did not only want reports of only proven AEFIs but those where the causality between the drug and the AEFI remained unknown. However, smaller numbers of pharmacists knew that all reactions should be reported for vaccines (56.3%) and herbal medicines (36.2%) (Green et al., 2001). A study carried out in India showed that 74.4% of doctors knew that they should report adverse reactions to a new drug. However, only 15%
and 10.6% knew that they should report serious reactions and unusual reactions respectively (Chopra et al., 2011; R. Ogunyemi & Odusanya, 2016).

2.7.5. Knowledge about the purposes of the AEFI reporting scheme

A number of studies have investigated whether the health worker had knowledge about the purposes of the AEFI reporting scheme (Chopra et al., 2011; R. Ogunyemi & Odusanya, 2016). A study carried out on pharmacists in Iran revealed that knowledge on the purposes of the AEFI reporting scheme was low. Less than half of the pharmacists could correctly identify these purposes of the AEFI reporting scheme: to identify factors which may predispose to AEFI, to compare AEFIs for drugs in similar therapeutic classes and to compare AEFIs from the same drug from different manufacturers. Approximately half (49%) of the pharmacists erroneously thought that one of the purposes of the AEFI reporting scheme was to enable safe drugs to be identified (Suyagh, Farah, & Abu Farha, 2015). A similar study carried out in the UK showed that the knowledge of the purposes of the AEFI reporting scheme was high, whereby more than half of the doctors surveyed could correctly identify the purposes of the AEFI reporting scheme such as identification of bizarre reactions to drugs and previously unrecognized reactions to drugs and the identification of factors which may predispose to toxicity. However, majority of the doctors erroneously believed that the purposes of the AEFI reporting scheme was to enable safe identification of drugs (R. Ogunyemi & Odusanya, 2016).

A study in Venezuela that identified lack of knowledge as a major cause of under-reporting of AEFIs showed that less than a quarter of the pharmacists and physicians surveyed could correctly identify pharmacovigilance as associated with the surveillance of AEFIs (Pérez García & Figueras, 2011)
CHAPTER THREE

3.0 METHODOLOGY

3.1 Study Area

The study was carried out in the Accra Metropolis. Greater Accra has a population of 4,010,054 (Ghana Statistical Service, 2010). At the regional level, Greater Accra is the most densely populated region with a density of approximately 1,236 persons per square kilometer. The region therefore currently has six administrative districts: Accra Metropolis, Tema Municipality, Ga West, Ga East, Dangme East and Dangme West (Ghana Statistical service, 2014). Accra Metropolis is divided into 6 sub-metros namely Ablekuma, Ashiedu-Keteke, Ayawaso, Kpeshie, Okaikoi, and Osu-Clottey. The study site included Mamprobi polyclinic, kaneshie polyclinic, and Adabraka polyclinic (Ghana Statistical service, 2014).

Figure 2: Map of Accra.

Source: (Ghana Statistical Service, 2014)
The study population were mothers of children aged 0-5 years and health workers who conduct EPI services.

3.3 Sampling Procedure

All outreach points in the various sub districts were selected using the sub district’s immunization itinerary and three facilities were conveniently sampled based on the most AEFI cases. The list of all health workers who conduct EPI services and their respective health facilities was obtained from the district EPI coordinator. At the health facilities all eligible health workers who conduct EPI services and are present during the study period will be consented prior to participation in the study. The number of mothers that were included in this study was randomly selected. Health workers who conducted immunization services and had at least one year working experience at the facility were purposively selected to partake in the study and consented prior to participation in the study.

The quantitative component involved the use of existing data of all reported AEFI in 2016 to 2018 in all the three selected health facilities. The data was extracted from the AEFI forms from the respective health facilities.

3.4 Study Design

This was a mixed method study involving both qualitative and quantitative approaches. The qualitative component consisted of using one-on-one in-depth interviews to explore how AEFI is detected and reported among mothers with children aged 0-5 and health workers and the quantitative component consisted of using existing data on AEFI from 2016 to 2018 to identify the most occurring AEFI and evaluate the seriousness of AEFI and also to support the qualitative on underreporting.
3.5 Sample Size

Participants were selected from three health facilities in the Greater Accra Metropolis. The health facilities included polyclinics that offer major immunization services. Mothers who indicated they had experience an AEFI were included in the study and the health workers were selected based on their work experience and whether they had reported an AEFI or not. A total of 17 interviews were conducted comprising of 6 health workers and 11 mothers/caregivers. Data analysis started during conducting the 17 interviews and the selection process continued until no themes emerged reaching data saturation.

3.6 Inclusion Criteria

1. Health workers who conduct EPI services (Vaccination)
2. Mothers of children with at least one child who has experienced AEFI.

3.6.1 Exclusion Criteria

3. Health workers who decline to participate in the study.
4. Health workers who were not directly involved in offering EPI services to patients.
5. Mothers who decline to be part of the study.

3.7 Data collection and Analysis

A research assistant was recruited and taken through a two day training to familiarize himself with the study guide, interview guide and tools. This was to sharpen the skills of the research assistant to effectively moderate the discussions and produce verbatim transcripts. The training was facilitated by the principal investigator and one health worker from the three health facilities were included to assist with the selection of the right participants mothers and pre informing them of the study.
3.7.1 In-depth Interviews

A guideline was generated for the in-depth interviews. The guideline consisted of background information and questions based on the four general themes which are knowledge of AEFI, Factors associated with AEFI reporting, Barriers to AEFI reporting, detection and reporting of AEFIs; a final theme on pharmacovigilance and monitoring were inductively generated during the interview process. The interview guide comprised of information about previous knowledge and experience of an AEFI in practice, awareness and experience of AEFI reporting, facilitators’ or barriers to AEFI reporting and previous training received and knowledge about vaccine safety. An in-depth interview discussion was organized at quiet location in the health facilities to prevent interference. The interview questionnaire was pretested to determine its appropriateness and suitability for the study. Written consent was sought from the participants prior to the interview. The consent form was read to participants in the language they understood in the presence of a translator and participants who agreed to partake in the study signed the consent sheet. The interviewer asked follow-up questions if necessary for clarification. Each participant was interviewed once with the interviews ranging between 10 and 30min. All interviews were electronically recorded and transcribed verbatim by the research assistant. The principal investigator assisted in transcribing the interviews conducted in local languages (There was a back translation done). Quality checks were conducted after the interviews to check for completeness and accuracy before transcriptions were done. Completed interviews were transcribed, coded and organized into themes using NVIVO 10 (QSR).

3.7.2 Quantitative data

For the quantitative data, relevant information on the 2016 AEFI to 2018 from each facility was extracted using a generated data extraction sheet adopted from the Ghana Health Service reporting form; data extracted for the study included socio-demographic history of both the
child and mother, AEFI reporting ID number, Description of AEFI, Seriousness and outcome of AEFI, details of all vaccines administered and Reporters details.

3.8 Data Analysis

The transcripts from the qualitative component were later prepared and imported into QSR Nvivo 10 software to facilitate data coding and analysis. The coding process involved a critical review of each transcript and coding of the data into emerging themes. These codes were generated inductively from participants’ descriptions of their experiences in responding to and reporting an AEFI, and awareness of vaccine safety surveillance. Memos were created in the Nvivo 10 software and attached to themes during the coding process. This was to help put down preliminary ideas and observations from the data and patterns that emerged from the data for thematic content analysis. The results were presented as narratives and supported by relevant quotes from the transcripts. Following initial coding of transcripts, preliminary themes that captured information relevant to the research questions were generated. The thematic analysis process involved identifying patterns in the data: recurring ideas, perspectives and descriptions that depicted each participant’s context and perspective. The final analysis for this study focused on the key themes, narratives, and professional histories emerging from the interviews. Data concordance was verified by a trained qualitative researcher with extensive experience in medical and public health qualitative research. Thematic saturation was achieved as similar themes that emerge from various participants from each target group after preliminary analysis of initial interviews. Quotes that best illustrate important representation of participants’ views and experiences were identified through our iterative process of review and discussions were presented in the results section.
3.8.1 Quantitative data Analysis

The quantitative data was entered into an excel spread sheet, the number of cases got was not substantive to look at any relationship between the variables so a descriptive analysis was done to ascertain the most common AEFIs, the common casual vaccine and month wise distribution of the cases. Also reporting rates was ascertained looking at the number of AEFI cases per 100,000 doses administered.

3.9 Ethical Consideration

The research protocol was reviewed and approved by the Ghana Health Service Ethics Committee with reference number GHS-ERC066/02/19. A cover letter from the District health Directorate was obtained and distributed to the various facilities and approval was obtained from the various heads of health facilities where the study was conducted.
CHAPTER FOUR

4.0 RESULTS

4.1. DEMOGRAPHIC CHARACTERISTICS

A total of 17 interviews were conducted, All 17(100%) being females with age ranging between less than 30 representing 3(17.6%) and greater than 30 representing 14(82.4).10 (58.8%) have had tertiary education, 5(29.4%) secondary education and 2(11.8%) primary education. A total of 7(41.1%) were health workers whiles 10 (58.9) were mothers. Health workers with less than 6 years’ experience represented 2(33.3%) as compared with those more than 6 years’ experience 4(66.7%). Mothers with children less than three represented 8(72.7%) as compared with mothers with more than three children 3(27.3%)

<table>
<thead>
<tr>
<th>Background variable</th>
<th>Characterization of category</th>
<th>Frequency</th>
<th>Percentage%</th>
</tr>
</thead>
<tbody>
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<td>3</td>
<td>17.6</td>
</tr>
<tr>
<td></td>
<td>&lt;30</td>
<td>14</td>
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<td>sex</td>
<td>Female</td>
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<td>100</td>
</tr>
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<td>Education</td>
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</tr>
<tr>
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<td>Secondary</td>
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</tr>
<tr>
<td></td>
<td>Primary</td>
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<td>11.8</td>
</tr>
<tr>
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<td>5.9</td>
</tr>
<tr>
<td></td>
<td>Disease control Officer</td>
<td>2</td>
<td>11.7</td>
</tr>
<tr>
<td></td>
<td>Community health worker</td>
<td>3</td>
<td>17.6</td>
</tr>
</tbody>
</table>
4.2 Findings from Quantitative

4.2.1 Nature of adverse events reported

A total of 33 AEFI cases (34.6 per 100,000 children vaccinated) was identified at the three facilities. In 2016, 7 AEFI cases (22.4 per 100,000 children vaccinated), in 2017 26 AEFI cases (82.6 per 100,000 children vaccinated) and 1 AEFI case in 2018 (3.0 per 100,000 children vaccinated). This indicates underreporting as compared to the WHO recommended rate of AEFI reporting.

Table 3: AEFI rate

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of children vaccinated</th>
<th>AEFI cases</th>
<th>Rate per 100,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>31315</td>
<td>7</td>
<td>22.35</td>
</tr>
<tr>
<td>2017</td>
<td>31478</td>
<td>26</td>
<td>82.60</td>
</tr>
<tr>
<td>2018</td>
<td>32450</td>
<td>1</td>
<td>3.08</td>
</tr>
<tr>
<td>TOTAL</td>
<td>95243</td>
<td>33</td>
<td>34.6</td>
</tr>
</tbody>
</table>
4. 2.2 Age and Gender

Out of the 33 AEFI reports identified at the facilities, 15(45%) represented males and 18(55%) females. The age of children less than one represented 7(21.2%) whiles’ children greater than one represented 26(78.8%).

![Figure 3: Sex wise distribution of cases.](image)

4.2.4 Clinical presentation

The most common type of AEFI was injection site abscess representing 27(71%), followed by severe local reaction 4(10%), vomiting 2(5%) and inability to walk 2(5%), fever 1(3%), swollen eyes 1(3%) and inability to walk 1(3%). Most AEFIs were mild with just a few serious cases. They were cases mostly reported after static clinics and usually reported to the facility where the vaccinations were taken.
4.2.5 Causal vaccines

Yellow fever was the common causal vaccine 16(44%) followed by Pentavalent vaccine 6(17%) (DPT/Haemophilus influenza type B/Polio), Rubella/Measles 5(14%) and DPT/Haemophilus influenza type B/Hepatitis B vaccine 4(11%), Polio 1(3%).

Figure 5: Percentages of vaccines administered.
4.2.6 Completeness of forms

15 out of the 33 forms were not complete, information such as landmark and address of parents were not captured at all, and the name of the manufacturer of the vaccines were not also captured making the form in complete in accessing AEFI according to WHO guidelines for causality. This according to WHO is necessary for accessing the causality and classify the type of AEFI as well.

4.3 Findings from in-depth interviews

A total of 11 mothers and six health workers comprising of two disease control officers, one public health nurse and three Community health nurses. A total of 7 themes were generated and 1 inductive theme on pharmacovigilance came about from the interviews. These themes had various questions under them which sought to answer the main themes

4.3.1 Job description

Most health workers interviewed were either a community health nurse or a disease control officer with only one been a public health nurse, their jobs were directly related to EPI services, they were involved in offering immunization service to children aged 0-5 years. The disease control officers and public health nurse provide vaccines and logistics to the community health nurses, monitor EPI activities, organize trainings, as well as monitor and supervise other health workers under their catchment areas.

4.3.2 AEFI Reporting and Detection

AEFIs are to be reported whether mild or serious. According to the health workers, reporting of AEFI report within the health system is spontaneous. Health workers solicit the events from their clients with the expectation that the clients will comply. All reported events are captured using a specially designed form from the Ghana Food and Drugs Authority (FDA). Disease control officers at the various health facilities have the primary responsibility of
collating all reported events, which are then forwarded to the District health Directorate which is then forwarded to FDA office within the region for advice. The FDA is required to examine the report and feedback to the health facility for any follow up visits to the patients.

“They first report to us, the parent will report to where they go for the immunization and then the community health nurses, they will examine and then if it is true that because of this; some there is vomit but some times in recent cases it is, you see that it is not the vaccine that causes it but it maybe coincident maybe malaria or something because they do the check and they realize that it wasn’t the vaccine” ( Participant 4)

“It’s from mother, the mother normally they bring it to us because we do the immunization, yes, we do the immunization so they will bring it to us, and then if it is above us, we just refer them. Sometimes it is something little you can help them, you can tell them what to do but if it is above us, you just report them, refer them to the disease control officer” ( Participant 8)

4.3.2 Knowledge of AEFI

Most health workers were aware of the reporting process in their hospitals; however, they were not well informed of reporting guidelines on AEFI reporting and were therefore not too conversant. They could not provide a comprehensive definition of AEFI in accordance with the national guideline for reporting AEFI’s. Here are some few quotes to support:

“Most of the time, the place becomes reddish, swollen and fever, there is fever, they cry a lot” (Participant 17).

“I know the AEFI is the outcome of, the outcome of, or the occurrence after vaccinations are given” (Participant 9).
Most health workers had also reported an AEFI during their number of years worked at the facility and were aware of the reporting process. They were able to account of the AEFIs that occurred and the medication and reporting process that went on.

“They first report to the parent will report to where they go for the immunization and then the community health nurses, they will examine and then if it is true that because of this; some there is vomit but some times in recent cases it is, you see that it is not the vaccine that causes it but it maybe coincident maybe malaria or something because they do the check and they realize that it wasn’t the vaccine.” (Participant 10)

Also, in terms of health workers encountering an AEFI during their working experience; majority of them stated they had ever encountered an AEFI.

“Yes yes, yes yes especially during general immunization, national immunization, we have few cases” (Participant 15).

“Yes, I have. Umm, this baby was between three months, umm the last immunization she had, the side of immunization. So the mother had to bring her here. I wasn’t here but I came to meet it when they were (CH 1:57) the mother had to report to us and then we referred her to seek a doctor. That was the errh, it was the second dose PENTA and second dose PCV plus the OPV and then Vitamin A the but those ones are not injections, it is the PENTA and the PCV that are injections” (Participant 13)

Meanwhile for most mothers they were not too conversant with the definition and couldn’t provide a comprehensive definition; they didn’t know what a reportable AEFI was and who to report to when an AEFI occurs.
“I think it is something being advise on parent to partake in, in order to give out children healthy living from disease and all kinds of rashes and a lot of things that happens to children they don’t know much about. It has helped a lot. Mostly when you partake in them, there is less sickness, they don’t fall sick most of the times and if there is any changes in the body you will know and when it happens like that, you just rush to the hospital and you will be attended to”. (Participant 5)

“What I know is after they give the children the vaccines, as a mother if you really take a critical look you will realize the place becomes swollen with pus, then afterwards it becomes a sore”. (Participant 2)

4.3.3 Barriers to reporting

Some of the barriers identified on the part of the health workers were fear of criticism for wrongly giving injection, others talked about the cumbersome way of reporting as reported by one Community health officer;

“Oh yes it was difficult because one when the mother came she was tensed up because she didn’t know much about the vaccine that was given and the adverse events that follows; and when she came and we were like we have to fill a form before she goes to see the doctor, she was complaining because she thought when she comes she has to go and see the doctor immediately but we had to take her through that process before seeing the doctor”. (Participant 4)

Also another barrier was not getting feedback from the responsible authority. usually after the report is made there is no feedback received and this makes it frustrating anytime the health workers had to report and that prevented them from reporting anytime an AEFI report came in, but other health workers taught otherwise and said since it was necessary to make the reports it was equally important to go through the process of reporting;
“For the reporting process what I know is to report to the disease control officer, but normally after there we don’t get any feedback even though we have handed over the person to them” (Participant 7)

Another barrier identified by one particular nurse was the way documentation was done in the facility. Documentation is key to determine the quality of information been generated to inform policy

“I think the problem here is documentation, from what I know when the cases come we fill the form and give it to the disease control officer but we don’t know what happens there whether they have a different way of documenting because we have been told about the AEFI forms, we pick it up fill it and take it back we don’t know what really goes on there” (Participant 16)

Another barrier identified on the part of mothers was the event was not considered serious enough to be reported, most mothers were of the view that the cases they experienced were mild and didn’t see the importance of reporting back to the health worker. In addition, lack of availability of AEFI reporting form decrease of AEFI events during the last years;

“Most of the time from the field, the community health nurses don’t see the cases we. It is the sever cases that they bring in. You see, and sometimes the demand they are few as compared to the number of people they see so they don’t get the time to fill these things, you see, it’s also a barrier. The stuff they are not enough to meet the needs of the, those coming for the vaccination”. (Participant 15)
4.3.4 Factors associated with reporting

Health worker factors, mothers’ factors and health system factors were the major factors identified to be responsible for low reports of AEFIs in the study area.

4.3.5 Health worker factors

The health workers reported that, heavy workload and inadequate number of stuff sometimes made it difficult for them to report AEFI cases when they happen, because they had to go for home visits and when that happens they do not readily have reporting forms. They had to combine field visit with static vaccinations

“Most of the time the AEFI cases are from the field, It is the sever cases that they bring in to the hospital. You see, and sometimes the demand they are few as compared to the number of people they see so they don’t get the time to fill these things, you see, it’s also a barrier. The stuff they are not enough to meet the needs of the, those coming for the vaccination” (participant 90)

“Like I said, inadequate stuff so even the vaccine they withdraw sometimes the ermm the work load make them instead of withdraw and then give they withdraw the vaccines into the syringes put it in the this thing before so that when you come nor they take it when you come nor, it’s not the best. So the work load made them to do that” (Participant 14)

Another factor was that most health workers had training whenever a new vaccine was introduced but had not have training specifically on AEFI alone and there were no refresher training unless a mass immunization campaign was about to take place, most health workers were of the view that having adequate training was crucial in knowing the types of AEFI and what should be reported
“No, let say the time, maybe it should have been training on its own, so you show us pictures of AEFI's so we know. So let’s say, even if you are in the community and someone is experiencing that thing but the person doesn’t know that it’s because of the immunization you the nurse you will know it then you report and then further investigations will be done” (Participant 6).

“Hmmm we had training longtime, very longtime, It was about reporting; it was about how to report it when we have issues like that, CHN’s were involved in the training and we would be glad if we had more training”. (Participant 3).

Another factor identified was the cumbersome process of reporting AEFI cases, after the cases were reported. Forms had to be filled before patients were attended to:

“Oh yes it was difficult because one, when the mother came she was tensed up because she didn’t know much about the vaccine that was given and the adverse events that follows; and when she came and we were like we have to fill a form before she goes to see the doctor, she was complaining because she thought when she comes she has to go and see the doctor immediately but we had to take her through that process before seeing the doctor” (Participant 7).

4.3.6 Mothers’ factors

Mothers are usually not motivated to come back and report adverse events especially if the side effects are those already known to be associated with the drug. Mothers perceived such side effects as normal and reporting them held no relevance to them. Mothers preferred to endure such side effects at home rather than report them to the health facility with the reason that every drug has a side.
“For instance, after all the event has happened already so what is the need for reporting like mine that happened and I decided to manage it myself so I didn’t see the need to come back to report to the nurse” (Participant 8)

“Yes, but after I applied the ice cube I didn’t see the need to report so I didn’t bother to report to the nurse during my next visit” (Participant 12)

Mothers also identified long queues at the OPD that led to long waiting-time before receiving care as a critical factor that affect the reporting of adverse events. To them, such experiences were not worth repeating just to report an adverse event. Patients preferred to spend time on their businesses than to traveling to health facilities to report adverse events.

“It is because of the long queues at the health facilities where we usually have to go and spend the whole day before seeing the doctor makes it difficult for us to go back when we get some of these problems after using the drugs” (Participant 5)

The majority of mothers felt uneducated and under informed about immunizations and vaccinations as a whole. When asked why they were so concerned about having their children immunized, many mothers said they were simply lacking enough knowledge about vaccines to make them comfortable with their decision to immunize. Some mothers seemed to lack an accurate perception of what the actual risks and benefits of vaccination were. Concerns about adverse reactions and the necessity of vaccines could also be attributed to a lack of parental education about the safety and necessity of immunization. Several mothers expressed a need for better communication to assuage their concerns. Criticisms ranged from not having any of their questions answered to not being able to understand their provider’s medical terminology. Also related to poor communication and lack of information was what a number of participants expressed concern about the process of immunization.
“It is because they are not being educated on it. If they have much idea about it and the importance of it, the outcome of taking it, I don’t think they will have any problem when given even ten at a time. So I think the only thing they have to do is educate the mother much on it so that they will not have any different idea or they will not panic about given to their children.” (Participant 16)

“Most of them, according to the work, the field you have to be, the best thing is communication, if you communicate with the mother you educate the mother on the reason of giving such, I don’t think, even the mothers will even sell it outside. But if they do not know much idea about it, umm they give some kind of injection bi, I don’t know they will just say it as normal biaa, but if you tell them, they will even educate their fellow women to go for it if none of them have been, so I think they should put much effort in it. Most of the nurses when giving the vaccines, they don’t explain anything. They just give it to you like that. Most of them do not even communicate because you are supposed to come; you have come so let me give you. But I think they should keep on whilst giving, and then they will be educating asking questions about, with the mothers so that they will know much about it. So that is it” (Participant 4)

Mothers were uncomfortable about their children “getting so many shots at one time” and usually because of the pain the child goes through they are not fully aware of the adverse events associated with all the different shots given to the children. This does not incite them to come back to the facility to report.

“Hmmm, I sometimes pity the child because of the pain the child goes through, I can see the child is in so much pain that is because the child hasn’t felt pain before. And because of time the community health nurse does not have time to explain why those shots are given at a time” (Participant 4)
“I think that is the dosage, if it not prescribed dosage, how will they give. Do you understand? It is their work, so they know the number of times they should give to the children. If it is normal, I think they will keep. If it is not normal then they would not give it” (Participant 8)

4.3.7 Health system factors

Health system factors identified during the study included challenges health workers faced in filling the forms, availability of reporting forms, appropriate feedback channels and monitoring and supervision. Most disease control officers in the facility were responsible for making sure that most vaccines are kept under the right temperature and also responsible for AEFI reports, they are also responsible for training staff on vaccine safety but an issue came up as to how the disease control officer in a particular facility were not doing the duties as supposed which even causes fear among health workers on the safety of the vaccines

“Yes that is why we have the disease control officers they monitor. They take care of the vaccines. They have a thermometer they know the vaccines and err their temperatures that will make the vaccines to remain potent so they have thermometer a type of thermometer to monitor it. They make sure that it remains within the temperature that is needed to maintain the vaccine”. (Participant 4)

In addition, enough information was communicated to the health workers on vaccine safety, the disease control officer gave health workers the necessary information they needed to know

“for that one, the safety they do it and they also make sure that when they are bringing the vaccines to us, we have enough, we have errm ice park, frozen ice parks that what they normally make sure that we have frozen ice parks to take it from them,
to take the vaccines from them, so and they provide the frozen ice parks too”

(Participant 8)

Also, the health directorate visited quarterly to monitor the activities of the facilities but the health workers suggested that it was not enough since reports had to be done frequently especially in terms of logistics.

“Oh Yes, yes, they do it like I said especially during national immunization, because we do not want trouble where the public will say this errr they heard somebody is dead because of this, so we make sure that we monitor well if there is anything like that we find, look at the batch we find that those vaccines and then we draw it then take care of whatever has happened make sure that everything is fine” (Participant 11)

Also another factor was not getting feedback from the responsible authority. usually after the report is made there is no feedback received and this makes it frustrating anytime the health workers had to report and that prevented them from reporting anytime an AEFI report came in, but other health workers taught otherwise and said since it was necessary to make the reports it was equally important to go through the process of reporting:

“For the reporting process what I know is to report to the disease control officer, but normally after there we don’t get any feedback even though we have handed over the person to them”(Participant 7)
CHAPTER FIVE

5.0 DISCUSSIONS

Surveillance of AEFI is the bedrock to the sustenance of quality immunization services in any country. The sensitivity of any AEFI surveillance lies in the awareness, knowledge and reporting practices of healthcare workers, consumers and manufacturers of vaccines. The availability of knowledgeable healthcare workers on the subject, who pay enough attention to observing and reporting AEFIs, is important to assuring continuing public confidence in immunization programmes.

From the rate of AEFI cases, there was underreporting of cases to the appropriate authorities and this was supported by the qualitative component that seeks to identify the barriers and factors associated with reporting. AEFI cases were seen more in males as compared to females. The common clinical symptoms of AEFI identified were injection site abscess, followed by fever, pain at injection site, vomiting and difficulty in walking. The vaccine that was identified to have caused this AEFI was Yellow fever followed by PENTA, DPT, measles and yellow fever. Most clinical symptoms occurred between 24-48 hours after vaccination with just a few occurring within a month after immunization.

Forms retrieved from the facilities were not completely filled leaving out the most important information to be captured such as location to patient’s house and the manufacturer of the vaccine. This is necessary to be able assess the causality of AEFI according to WHO guideline. Other studies that also looked at completeness of form found a similar findings as compared to this study which suggested that documentation was not been done accurately which leads to inadequate data contributing to health care decisions. Intervention should be targeted at educating health care workers on the importance of completing AEFI case forms.
Another observation made during data collection was that some facilities did not report or did not have zero reporting (Sri Lanka FMoH Epidemiology unit, 2012). To improve this there would be the need to introduce electronic reporting system which has been done by other studies. Other methods, such as using modern technology, could make AEFI reporting easier. For instance, one study observed that online computer applications enhanced the reporting of AEFIs more than paper forms, which were considered cumbersome by many of the study participants. These web-based computer programmes could be developed and simplified as smart phone applications, to make reporting easier and more convenient for health workers by way of reporting with their smart phones (Pillsbury, Quinn, Cashman, Leeb, & Macartney, 2017).

On the topic of knowledge of AEFI, health workers were not too conversant with the definition of what an AEFI according to WHO definition of AEFI. They instead gave examples as definitions which are suggestive that they had not familiarized themselves with what AEFI really was and could not explain it to even report. Most mothers did not know the definition of AEFI and couldn’t give a definition to it. Participant’s low knowledge of AEFIs could be as a result of unfamiliarity with the guidelines. Interventions should be aimed at targeting special training education and guidelines that are printed out and this includes posters that are visibly pasted around vaccination points as compared to most studies that were conducted to access the knowledge of health workers; their results showed similar results compared to this study where health workers had low percentages in reporting rates and were not aware of the guidelines for identifying what is really supposed to be considered an AEFI and when to report it this was because most caregivers resorted to self-management and did not have adequate information from the health workers as to what to consider an AEFI whether it is a common AEFI or serious AEFI and when to report (Mehmeti et al., 2017). Some also gave prophylaxis before coming to the facility so to prevent the children
from getting an AEFI. This practice should be looked into to be able to provide adequate information to mothers/caregivers on what AEFIs are. With studies that looked at knowledge among caregivers/mothers, most caregivers did not have adequate information on vaccinations, the benefits and risks associated with it and suggested adequate information by the health workers which will make them comfortable for going to vaccinations (Shui, Kennedy, Wooten, Schwartz, & Gust, 2005).

Barriers to reporting

Some of the barriers that were identified during this study were distance from home to facilities, some caregivers had to travel long distances for vaccination services which is suggestive that they trust certain facilities more than others and even if those facilities are far away from them they would still attend for vaccinations, however health workers did not see it to be a barrier in providing services to children and this is because of the concept of community health based and planning services that has helped to bridge the gap of providing health care services to the doorsteps of individuals. Comparing this study to a particular study conducted by Malande et al., in Uganda they found out that distance was a barrier for caregivers accessing immunization services due to the geographical location and the terrain of the immunization point. Most health workers had to use their own monies for means of transport which was not the case found in our studies (Malande et al., 2019).

Also another barrier that was identified was the cumbersome process it takes for reporting an AEFI which usually discourages them, generally most health workers pointed out this as a major barrier, this was found to be similar to a study conducted by Farriba et al., stated that “complicated and time-consuming administrative procedures in reporting process and limited access to appropriate equipment and resources for submitting ADE reports” (Mirbaha, Shalviri, Yazdizadeh, Gholami, & Majdzadeh, 2015) Also the mothers found this to be true
since when they come to report, a form is to be filled, sometimes when the mother come they are anxious about the health of their children and wish to be attended to early but then they are sent to join the queue to see the physician which usually doesn’t encourage them to report.

In addition, not getting feedback from the right authorities was another barrier that came up in the study, most health workers who had reported an AEFI do not receive any feedback and this could be suggestive of the delink between health workers and disease control officers making the flow of communication between these two category of staff difficult. This was also suggestive of no team work between the health workers as such interventions should target setting up and building team work to improve AEFI reporting; this was seen in a similar study by Farradi et al. (Mirbaha et al., 2015) which realized that good relation between staff and supervisors increased adverse drug reaction reporting.

Another barrier was the work load on health workers, in some facilities the health workers are under staffed which put pressure on only one health worker to vaccinate and also fill report forms when AEFI cases come in which makes it quite tedious. As a motivational factor, incentives should be attached to the reporting to encourage health workers to report having a positive impact on AEFI reporting. This factor has been seen in previous studies according to (P. et al., 2017)

Factors associated with AEFI

Factors identified by the health workers included bureaucracy in reporting AEFI; this has been found in most studies conducted in other parts of the world (Mohammed, Aliyu, Maiha, & Isa, 2018), not receiving feedback from authorities when AEFI cases are reported, this is suggestive that there is no relationship between reporting authorities and health workers and this gap can be bridged by organizing more intensive workshops and sensitizations on
communication strategies to improve feedback process (WHO, 2014). Another factor identified was lack of motivation received when reports were done and this is because of the huge workload on them and if they are able to take time off to fill these forms then some form of motivation should be given them; this finding was similar to other studies done in (Patricia, Hugo, & Date, 2015), fear of being criticized was another factor that was identified, some health workers were of the view that they might be criticized if they report especially if they were the ones who gave the injections, this has been found to be consistent with findings from most studies that suggested that the fear of being criticized after reporting an AEFI was a factor according to calistus et al.. It was important that there be the need to reassure nurses that reporting is not meant to be punitive or to apportion blame since half of the respondents in this study believed that reporting AEFI could lead to personal consequences.

Unavailability of AEFI guideline was cited by most participants as a factor to not reporting this goes to say that the clear AEFI may be missed out or totally under reported but may also not bring out the consequences of the various vaccines, the pharmacovigilance system in the country to take it up to make sure periodic monitoring checks are done on availability of AEFI guidelines which could be translated into hard facts sheets at every work station.

Training

Training is an important component of the EPI, according to WHO several training guidelines has been developed to assist with monitoring and reporting AEFI’s. Most health workers reported they had received training on EPI services and any time new vaccines are introduced with AEFI chipped in but training on AEFI alone hasn’t been done and advocated that more frequent trainings should be done as it helps them to understand the importance of AEFI reporting and the appropriate ways of reporting. The similar performance on knowledge
between healthcare workers who had received training on AEFIs and those who had not been 
trained contrasts with a study on AEFI study among nurses in Kenya (Adedeji et al., 2014) 
where respondents with previous training on AEFI were more likely to have good knowledge 
on AEFI.

WHO specifies that health workers involved in providing immunization services should be 
trained in order to have accurate information and provide information about the vaccines and 
diseases to their patients(WHO, 2014).

In a study by Hutchinson et al. (2007) it was found that the familiarity of health workers with 
the AEFI surveillance system was dependent on training in AEFI. Training was associated 
with higher reporting rates amongst health workers, especially nurses. Although training is 
essential for health care only; 35% of 26 studied European Union countries had developed a 
training program or manual for nurses on prevention, identification and treatment of AEFI.

A study conducted by Doodo et al. (2007) which was a ten month prospective study, noted a 
six hundred increase that occurred in AEFI reporting following training, monitoring visits 
and provision of AEFI reporting forms. Vaccine safety plays a crucial role in the acceptance 
of vaccinations as a whole; mothers are particularly concerned about what vaccines are made 
of and the benefits their children get out of them. From this study a few mothers suggested 
that less information was provided to them at the vaccination centres about the names of the 
vaccines, they were only told what the vaccines prevent compared to a similar finding from a 
previous study; a vast majority believed in the positive impact of AEFI reporting on building 
public trust in immunization programs. Steps must be taken by regulatory authorities and 
managers of immunization programs to make reporting easier for health workers as well as 
mothers/caregivers while ensuring all vital AEFI information is still collected.
The healthcare professionals’ vaccination, their knowledge about the subject and their own confidence in vaccines are essential to guide their behavior when indicating vaccines to their patients. A review of 185 articles on vaccination hesitancy among health professionals carried out in 2016 by (Paterson et al., 2016) showed that knowledge about vaccines, their efficacy and safety increase the professionals’ confidence and the prescription of these immune biological agents; most articles revealed that an appropriately vaccinated professional is more likely to prescribe vaccines, which makes more evident the need for continuing education and training.

In addition to vaccine safety, cold chain management and storage came up, most health workers knew of the cold chain management but advocated for more logistics like the cold box that helps to keep vaccines safe

5.1 Limitation

This study faced some limitations, the first was low reporting of AEFI among most facilities in Accra metro which made it difficult to report any relationship between the various outcomes. There was also an inherent limitation to using a qualitative method such as IDIs and the results may not be generalizable to a larger population. It could be possible findings from other regions may say otherwise. Although the numbers of IDIs were sufficient to reach thematic saturation with participants randomly and conveniently sampled, this study was conducted in only three facilities in the Greater Accra Region. During data collection some facilities were not willing to give out data. There was no proper documentation which made it difficult to access information.
6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

Under reporting remains a major concern in terms of adverse event reporting following immunization. Spontaneous reporting of AEFI is the first step to making sure vaccine products are safe. Pooling of information is important so that signals of rare and very rare adverse events are identified. From this study we can conclude that even if an AEFI would be detected there are a few barriers to reporting, however despite the barrier to reporting under reporting might be attributed to less reactive vaccines over the years. This decreases the awareness of health workers towards reporting. Most health workers had inadequate knowledge of what an AEFI was and could not provide an adequate definition according to WHO guidelines, most listed examples as a definition. Most mothers couldn’t define what an AEFI was. More education should be given to health workers and mothers to increase awareness irrespective of the outcome and type of AEFI.

Barriers identified in this study were similar to other studies conducted in different settings; some were Fear of criticism after reporting, Lack of time because of workload and inadequate number of staff available, lack of feedback from the necessary authorities which discourages them from reporting. Most of the mothers also gave the cumbersome process of reporting discourages them.

Strengthening reporting systems by increasing health worker participation and knowledge about AEFI can enhance surveillance efforts during real time events such as mass immunization.
Another important practice to be implemented in daily work practice of health workers is the screening of children for possible contra-indications prior to immunization.

Vaccine safety raises a lot of concerns when it comes to immunization and this could contribute to vaccine refusal. Negative impact of vaccines especially from the media could send out wrong information about vaccines. Addressing mothers concerns about vaccines will improve both the available information given to mothers as well as patient health worker communication. Health workers should play a major role in disseminating information about the components of a vaccine so mothers understand the benefits and risks.

The findings from this study is aimed to be used as a base to enhance safety surveillance by health care authorities and immunization authorities to improve detection and reporting of AEFI.

6.2 Recommendations

AEFIs should be reported even if there is delay in submission of information by field staff. Interventions to increase reporting AEFI such as wall mounted AEFI reporting cards should be placed at working sites to promote awareness and reporting. Also the introduction of the mobile reporting system should be established to improve pharmacovigilance; this initiative was done in a study in Cameroon which had seen massive improvement in AEFI reporting.

It is necessary to develop training programs, staffs at all levels should be trained in diagnosing, treating and reporting of AEFIs to prevent underreporting and increase trust in vaccinations. Proper training modules might prevent a substantial number of AEFIs which result from immunization error.

Feedback system should be developed to provide timely and accurate feedback of investigations and action taken appropriately for reports received. Good trainings and
communication should be done periodically in order to maximize benefits and develop a strong surveillance system to encourage reporting of AEFI’s. An electronic form should be created to assist with data entry and data quality since most of the facilities had only hard copies.
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APPENDIX

Appendix 1: Adverse events following immunization reporting among Mothers with children 0-5 years and health workers in some selected facilities in the Greater Accra.

**Health worker Interview guide.**

Facility code: Participant code:

**Socio-demographic information**

1. How old are you? 19-24 [ ] 25-29 [ ] 30-34 [ ] 35-40[ ]

2. How long have you worked in the service?

3. How long have you worked in this institution?

4. What is your highest level of education?

**A. Knowledge about AEFI**

1. Can you please describe your current job position? And how is it related to EPI services?

2. Can you please describe an AEFI and give some examples?

3. Have you ever reported an AEFI?

Probe: If yes 3a. What types of AEFI was experienced?

3b. If No: Why haven’t you reported?

4. Was it a difficult process to report? Why?

5. Have you ever encountered an AEFI?
Probe: If yes 4a. Can you please describe what AEFI it was and the symptoms?

**B. Detection of AEFI**

6. How is AEFI detected in your facility?

7. Are you please aware of how AEFI to be reported?

If yes 6a. Could you please List them

If No, what are the AEFI you consider an AEFI?

8. Are you aware of the reporting format?

probe: If yes

7a. Can you please tell me how the reporting format is done?

9. What are some of the reasons that would incite you to report?

10. Where are your completed report forms sent to and do you receive feedback?

11. Do you have an instruction manual to deal with AEFI or are you aware of the protocol on how to deal with AEFIs?

**C. Barriers to reporting**

12. Can you please tell me some of the barriers to reporting?

13. Can you please tell me factors that could affect reporting?

14. Can you please tell me some of the reasons why health workers who encounter AEFI may not report?

15. What are some of the challenges you face in reporting?
D. Training

16. Have you ever been trained on AEFI?

17. Can you please describe the training you had?

18. What was involved in the training?

19. What suggestions would you give to improve reporting?

E. Surveillance of AEFI

20. Could you describe your understanding of how vaccines are monitored for safety after they are released to the public?

21. Who do you think should be responsible for monitoring vaccine safety in Ghana?

22. How do you access communication regarding vaccine safety issues?

23. Is there sufficient information available to you from surveillance authorities or other sources? Explain.

24. In your opinion, who should be responsible for monitoring the ongoing safety of vaccines?

25. What do you think happens after an AEFI report is made?

26. What is your impression of how safety is monitored?
Appendix 2: Adverse Event reporting Following Immunization among mothers with children 0-5 years and Health workers in selected health facilities in the Greater Accra Region.

**Mother’s Interview Guide**

**Socio demographic Characteristics**

1. How old are you? 19-24 [ ] 25-29 [ ] 30-34 [ ] 35-40[ ]

2. Can you please tell me your highest level of education?

3. Can you please tell me your occupation?

4. What is your marital status?

5. How many children do you have?

**A. Knowledge on AEFI**

6. Can you please tell me your knowledge about an AEFI?

7. Has your child ever experienced an AEFI?

8. Has any of your children ever experienced an AEFI?

9. What did you do about the AEFI experienced?

10. Did you report the AEFI to your health worker?

Probe: if yes how did you report?

If no: why didn’t you report?

11. Are you aware of a reporting system?

**B. Barriers to reporting**
12. Can you please tell me some of the barriers to reporting?

13. Can you please tell me factors that could affect reporting?

14. Can you please tell me some of the reasons why mothers who encounter AEFI may not report?

15. What are some of the challenges you face in reporting?

C. Hesitancy about vaccine confidence

16. Have you or someone you know ever had a bad reaction to a vaccine which made you reconsider getting your children vaccinated?

17. Do the vaccinators indoor to door or mass immunization campaigns provide you with sufficient information to address your concerns around vaccination? If yes, what information do they provide you?

18. Do you think vaccines are still needed even when the disease is no longer prevalent? Why?

19. Do you think that most parents like you have their children vaccinated with all the recommended vaccines?

20. Do you think receiving too many vaccines at one time actually help your child?

21. Does having the same provider give all the infant vaccines make you more likely to accept vaccines than having a different provider each time vaccinations are due?