IMMUNISATION SAFETY SURVEILLANCE IN ASOSA ZONE, ETHIOPIA

by

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DEDICATION

In remembrance of my passed father, Reverend Asres Alemu, and late mother Alemitu Engidaw, wishing they were able to see my long journey and success, specially my father who was a strong pillar of the family and always motivating me to work hard to achieve the maximum academic status. My mother was highly overloaded in taking her own workload and her husband’s responsibility to keep the momentum of my academic achievement. This degree is therefore dedicated to the memory of my loved parents.

DECLARATION

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I declare that the above thesis is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references.

I further declare that I submitted the dissertation to originality checking software and that it falls within the accepted requirements for originality.

I further declare that I have not previously submitted this work, or part of it, for examination at Unisa for another qualification or at any other higher education institution.

15 January 2021

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SIGNATURE **DATE**

Muluken Asres Alemu

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ABSTRACT

Background

Surveillance for immunisation safety is a scheme for guaranteeing immunisation safety through identifying, reporting, investigating and countering to adverse events following immunisations (AEFIs). Most of the AEFI surveillance reports are delivered through health care providers, it is imperative to be clear not only about the factors such as awareness and incidence of reporting, rather the health care providers' knowledge, perceptions and practice regarding AEFIs.

Purpose of the study

The purpose of this research was to assess immunisation safety surveillance in Asosa zone, Ethiopia, detect barriers in the health care providers' existing guidelines, and develop an immunisation safety surveillance pocket manual for health care providers.

Methods

A convergent parallel mixed research method was used. Three hundred respondents participated for the quantitative design and nine participants were included for the qualitative design. Data were analysed through the Statistical Package for Social Sciences (SPSS) 25.0 version and Atlas ti 8 for quantitative and qualitative approaches, respectively.

Results

Of the total sample, (94.7%) had heard about AEFI, but only (22.3%) were able to define AEFI as per WHO standard definition. Some (45.7%) of the respondents were not informed that AEFI surveillance had to be practised in each health facility. Most respondents, (90.7%) were not trained in immunisation safety surveillance. Nearly, (42%) of the respondents had below the average value and (56%) had more than mean value of knowledge indicators. Respondents, (56%) agreed and (32.7%) strongly agreed that detecting, reporting and investigating AEFI is not within their job description. The respondents overall mean value for all the perception indicators of immunisation safety surveillance were, (44.7%), (41.3%) which was below mean value and above the mean value respectively. Only 5.7% respondents had ever reported to higher level and (23%) had treated an AEFI case. The mean values of all the practice indicators of immunisation safety surveillance scored by respondents were (46.7%) below mean and (31.3%) above the mean. Challenges impacting on effective immunisation safety surveillance were outlined. The findings from the qualitative design, confirmed the quantitative results on knowledge, perceptions including challenges of health care providers regarding immunisation safety surveillance. These results were merged to provide a concrete analysis of the research problem. Gaps were identified from the national guidelines for AEFI and recommendations proposed. The investigator developed immunisation safety surveillance pocket manual for health care providers.

Conclusion

The overall detecting and reporting rate of AEFI cases was very low, implying that a concerted effort of health care providers and stakeholders' partnership is important to enhance immunisation safety surveillance.

Key words

Adverse events following immunisation safety surveillance, knowledge, perceptions, pocket manual, practice, vaccination.

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LIST OF ABBREVIATIONS

ACIP	Advisory Committee on Immunisation Practice
ADR	Adverse drug reactions
AOR	Adjusted odds ratio
AEFI	Adverse events following immunisation
AIDS	Acquired Immuno-deficiency Syndrome
ANC	Antenatal care
BCG	Bacillus Calamite Guerin
CC	Contingency coefficient
CDC	Centre for Disease Control
CI	Confidence interval
CIOMS	Council for International Organisation of Medical Practice
DHO	District health office
DIO	District immunisation officer
DPT	Diphtheria-Pertussis-Tetanus
EFMHACA	Ethiopia Food Medicine Health Administration and Control Authority
EHS	Environmental health science
FDA	Food and Drug Authority
EPI	Expanded programme on immunisation
FMoH	Federal Ministry of Health
GBS	Guillain-Barre Syndrome
GP	General practitioner
HC	Health centre
HCPs	Health care providers
HEW	Health extension programme
Hib	Hemophilus influenza type b
HIT	Health information technology
HMIS	Health management information system
H1N1	Hemophilus Influenza 1
HO	Health officers
HP	Health post
HPV	Human Papiloma Virus
IPC	Inter-personal communication
ISS	Immunisation safety surveillance
IT	Information technology
KAP	Knowledge attitude practice
KPP	Knowledge perception practice
KMO	Kaiser-Meyer-Olkin
LMIC	Low-middle-income country
MD	Medical doctors
MMR	Measles mumps rubella
MPH	Master in Public Health
NGO	Non-governmental organisation
NID	National immunisation day
NIP	National immunisation programme
NRA	National regulatory agency
OPD	Out-patient department
OPV	Oral polio vaccine

OR	Odds ratio
PC	Principal component
PCA	Principal component analysis
PMS	Post marketing surveillance
PV	Pharmacovigilance
RET	Reportable events table
RIO	Regional immunisation officer
SD	Standard dethroughtion
SPSS	Software Package for Social Sciences
STI	Sexually transmitted infection
Td	Tetanus diphtheria toxoid
TPB	Theory of planned behaviour
TRA	Theory of reasoned action
TV	Television
UK	United Kingdom
UNICEF	United Nation Internationals Children Fund
UNISA	University of South Africa
USA	United States of America
VAERS	Vaccine adverse events reporting system
VIS	Variance inflation factors
VPD	Vaccine preventable diseases
VSS	Vaccine safety surveillance
WHO	World Health Organization
ZHD	Zonal Health Department

CHAPTER 1

ORIENTATION TO THE STUDY

1.1 INTRODUCTION

This chapter focuses on justification of the research, the problem statement, the research questions, aim and objectives, null hypothesis, philosophical worldview, and ethical considerations. Also, significance of the study, definition of key terms, scope of the study and briefly research methods were highlighted.

1.2 BACKGROUND INFORMATION ABOUT THE RESEARCH PROBLEM

Immunisation is the most globally recognised public health indicator which has produced the major public health effect by reducing the burden of illnesses (Paterson, Meurice, Stanberry, Glismann, Rosenthal & Larson 2016:6700) and mortality from vaccine preventable diseases (VPDs), particularly in childhood (Dube, Laberge, Guay, Bramadat, Roy & Bettinger 2013:1763). With the introduction of vaccines, approximately 5 million smallpox deaths, 2.7 million cases of measles, 2 million cases of neonatal tetanus, 1 million cases of pertussis, 600,000 cases of paralytic poliomyelitis and 300,000 cases of diphtheria have been prevented yearly (Rémy, Zöllner & Heckmann 2015:1). Childhood immunisation has been indicated as one of society's most cost-effective health care investments (Wonga, Liao, Guo, Xin & Lam 2017:3155). In spite of vaccines successfulness in protecting and eradicating disease, routine child vaccine utilisation continues to be sub-optimal. Due to parent's rejection of the vaccines, VPDs like measles and whooping cough epidemics have been contributed (Glanz, Kraus & Daley 2015:2; Maglione, Das, Raaen, Smith, Chari, Newberry, Shanman, Perry, Goetz & Gidengil 2014:326).

Immunity refers to a multifaceted biological system gifted with the capability to distinguish and endure whatever belongs to the self, and to distinguish and discard what is foreign (non-self) (BC Centre for Disease Control 2009:2). It boosts through vaccines by making the receiver's immune system to respond to the vaccine (WHO 2016:15). Active immunity denotes the process of making the body to generate antigen-specific humoral (antibody)

and cellular immunity. Passive immunity implies giving produced antibodies to human or animal rather than producing their immunity system. Vaccines function in a similar process through making the immune system to defend a specific illness. More or less, a vaccine comprises constituents that are similar to the disease-causing microorganism, and hence the immune system reacts as it would to an infection with that microorganism (WHO 2015b:3).

The population attention has been progressively shifted from the benefit of the vaccine to the safety of the vaccine following the dramatic progresses in immunisation coverage and the considerable drops in VPDs (Gattás, Braga, Koike, Lucchesi, Oliveira, Piorelli, Queiroz & Precioso 2018:2). As compared to the magnitude of the problems, vaccines effectively protect rare AEFIs, obtain unequal public and media focus because of the clear sequential probably coincidental occurrence of adverse events but often not due to vaccines (Singh et al 2017:1). Adverse events following immunisation (AEFI) refers to "any undesirable medical occurrence following vaccination and which does not essentially have a cause and effect association with the utilisation of the vaccine'' (Sebastian, Gurumurthy, Ravi & Ramesh 2019:1). An AEFI can be any unwanted signs, uncharacteristic laboratory findings, symptoms or diseases (Tozzi, Asturias, Balakrishnan, Halsey, Law & Zuber 2013:2). AEFI may be local (e.g. redness, swelling, pain) or systemic (e.g. fever, exanthema), and acute (within minutes of vaccination) or chronic (many hours or days following vaccination) (Danova, Kocourkova & Celko 2017:1; Meng, Sun, Shen, Pan, Tang, Wang, Wu & Ye 2017:2).

Generally, an AEFI is classified into five categories (Mohammed, Aliyu, Maiha & Isa 2018:81; WHO 2016:13; Yenyi 2019:24) as:

- Vaccine product-related reaction: An AEFI that is caused by a vaccine due to one or more of the inherent properties of the vaccine product, known vaccine side effects.
- Vaccine quality defect related reaction: An AEFI caused by a vaccine that is due to one or more quality defects of the vaccine product as provided by the manufacturer.
- Programme errors caused by errors in vaccine handling, prescribing or administration.
- Coincidental event unconnected to vaccination, happening at or immediately after vaccination.
- Anxiety-related reaction: An AEFI arising from anxiety about the immunisation.

AEFIs are influenced by individuals' features (age, pre-existing sickness, genetic makeup, social situations and environmental situations), vaccine connected aspects (quality, vaccine product, and manufacturer), and the immunisation courses (cold chain and handling, dosage given, type of vaccine in mix or solo) (Singh, Wagner, Joshi, Carlson, Aneja & Boulton 2017:2).

In line with the Hippocratic oath "First do no harm ", any medical intervention including vaccines should be proven to be safe and effective prior to widespread adoption. However, interventions are rarely 100% safe. The decision to immunise must therefore balance the risks versus the benefits within an appropriate context. For preventive public health interventions such as immunisations, this context includes the incidence and severity of the target disease as well as the real AEFI (Bonhoefer, Kohl, Chen, Heijbel, Heininger, Jefferson& Loupi 2002:298).

Decreasing the undesirable outcomes on vaccination programmes and the well-being of vaccines is the major aim of surveillance of an AEFI prompt tracing and proper early response to adverse events (Muchekeza, Chimusoro, Ncube & Pomeria 2014:1; Ogunyemi & Odusanya 2016:79). According to Ethiopia Food Medicine Health Administration and Control Authority (EFMHACA) (2016:4), AEFI surveillance system efforts on vaccine safety uses instruments such as manuals and procedures focused to guarantee public health prevention by using vaccines with proven safety profile. AEFIs surveillance is an effective strategy of watching immunisation safety and pays to the trustworthiness of the immunisation programme. The district health office (DHO) and Zone Health Department (ZHD) are responsible for training, supportive supervision and communication to the public using different modalities (Amarasinghe 2012:14; FMoH Ethiopia 2015:52). Mühlhans and Radebeul (2016:4) urge that correct and real-time reporting of AEFI is vital to vaccine safety surveillance (VSS). In addition, a VSS system is among the types of public health surveillance whose goals are monitoring entire matters of vaccination programmes and ensures the security of entire antigens given to the population. To maintain public health immunisation programme and vaccines victory in eliminating vaccine preventable diseases (VPDs), the acceptability of a strong surveillance system that identifies safety conditions as they happen during the prompt and continual utilisation of vaccines is very important (Ali, Rath & Thiem 2015:61; Parrella 2014:1). According to Bok (2014:4), vaccines pre-licensure trials are often very small to

trace rare occurrences and special populations may be insufficiently represented, thus immunisation safety surveillance (ISS) is vital to identify adverse events following immunisations (AEFIs). Masuka and Khoza (2019:2) refer to vaccine or immunisation safety surveillance as a strategy for safeguarding safety of immunisation through tracing, reporting, investigating and responding to AEFIs.

One of the strategies to respond to AEFI is behaviour change communication, to increase vaccination knowledge and usefully leverage perceptions and habit of individuals and groups related to vaccination. This could be addressed targeted at caretakers, health care providers and other crucial actors. A combination of various communication means: group media, such as (television, radio), minor media (leaflets, flipcharts and road plays) and interpersonal communication channels (health care providers, spiritual leaders, valued community members) have been utilised to bring behavioural change communication (UNICEF 2005:12).

AEFI reporting has improved for the past 16 years globally, but needs reinforcing in most of low-middile-income-countries (LMICs) including Ethiopia. Extra energies highlighted by Lei, Balakrishnan, Gidudu and Zuber (2018:1577) are needed to guarantee and enhance data quality, AEFI reporting and surveillance of immunisation care in each country. AEFIs are well known, however, health care providers do not know much about how to identify or report them. Reporting AEFIs is important in recognising the occurrence of rare events for new vaccines, which may not be known during clinical trials, or to monitor the rates of such events for well-established vaccines. Poor knowledge of AEFI among health care workers often results in many cases of AEFI going unreported and unaddressed, which may undermine confidence (Ogunyemi & Odusanya 2016:80). Agreed that health professionals deliver the main AEFI reports to surveillance systems, it is imperative to know not only the variables such as cognisance and reporting regularity, but what health care providers know, perceive and practise regarding AEFI. Many antigens are underutilised and the competence for ISS is normally diverse (Mehmeti, Nelaj, Simaku, Tomini & Bino 2017:3).

Since the outbreak of COVID-19 was declared as a pandemic by the WHO in March 2020, statistics of people contracting and succumbing to the virus are escalating at a fast pace in most countries worldwide. Chang (2020:814) found that the pandemic situation triggered by COVID-19 has caused great harm worldwide, adding that the development

of vaccines could help to reduce the impact of the pandemic. At the time of writing this report, global statistics reflected 74,662,468 million coronavirus cases, 52,489,966 million recoveries and 1,658,69 deaths (From: http://www.worldometer.info/coronavirus accessed 17 December 2020).

Scientists and professionals in different countries have been working tirelessly to develop the vaccine against COVID-19 and some countries such as the UK, USA and UAE had already started rolling out the new vaccine against COVID-19. It therefore becomes crucial that immunisation surveillance systems must be strengthened to protect the public, ensure trust and safety amongst all regarding the new vaccine/s.

1.3 STATEMENT OF THE RESEARCH PROBLEM

Vaccines are inoculated to healthy individuals for the protection of disease whereas majority of drugs are used to manage disease in ill persons. An instinctive threat is believed as more than a threat taken willingly. Thus, the scheme has to be too active to the specificity of vaccines (WHO 2016:38). Under normal situations, vaccines should not cause adverse events and should protect people fully from the intended infections. However, according to the WHO (2013a:21), the existing technologies do not allow for such precision. In the United States of America, every 10,000 cases of vaccination, 1.14 cases of AEFIs were reported and deaths accounted for 1.4% of such AEFIs (Puliyel 2013:144). In Zhejiang province of China, the total rate of reporting for AEFI was 9.2 per 100,000 doses of vaccination (Hu, Li, Lin, Chen, Chen & Qi 2013:211-217), and in 2009 AEFI reporting rate was 14.1 cases per 100,000 doses in Australia (Mahajan, Roomiani, Gold, Lawrence, McIntyre & Menzies 2010:259). Furtheremore, in a tertiary hospital in Ilorin, Kwara State of Nigeria, 19.3% was reported in 2010 (Aderibigbe, Osagbemi & Bolarinwa 2010:70-73). Of the studied 26 European Union countries 35% had ready knowledge enhancing mechanism such as training schedule or manual for nurses on prevention, differentiation and management of AEFI (Kurstak 2009:3380; Masika, Atieli & Were 2016:15). However, no related information or scientific study could be found in Ethiopia, hence the need for this research.

The researcher has been working in the CORE Group Polio project for the last 10 years overseeing the polio campaign, routine immunisation and surveillance activities, and have observed the immunisation coverage in the country with large immunisation dropout rate

which could be attributed to inadequate immunisation safety surveillance. Despite its significance, immunisation safety surveillance is very low in Ethiopia (FMoH Ethiopia 2015:48). In this relation, the Federal Ministry of Health of Ethiopia (FMoH) warned in a letter dated 5 February 2018 about the weak immunisation AEFI safety surveillance at ground level, and that it affected routine immunisation coverage (Worku 2018). It also became evident that there have been AEFI cases due to any of the five causes, since the immunisation programme was implemented (WHO 2016:13). Furthermore, no information or study was done which addressed the following problems; Why are AEFI cases not reported by the primary health care providers (HCPs)? What seems to be the overall status of immunisation safety surveillance? Have communities been made aware by HCPs to report any AEFI? Are HCPs informed about raising awareness regarding AEFIs to mothers or care takers? Do HCPs working at different levels know who are the AEFI cases, when, where and how AEFI should be reported? Do the HCPs positively perceive the occurrence of AEFIs, as the cases have to be reported to higher levels for further investigation? Do health facilities have the standard AEFIs reporting forms? Do the HCPs have the experience of AEFI reporting? Is AEFI reporting system established in the study area? Do HCPs have sufficient and clear standard immunisation safety surveillance guidelines and training manual? Why is immunisation safety/AEFI surveillance not done properly? What challenges hinder health care providers to implementing AEFI surveillance in Asosa Zone?

Furthermore, in Ethiopia in 1980 the expanded programme on immunisation (EPI) was started with the aim of 10% coverage increment yearly. Although, the achievement in the first 20 years was extremely minimal but during the 1990s, encouraging achievements were obtained through universal child immunisation (FMOH Ethiopia 2015:viii). However, health care providers' knowledge, attitudes and practice related to immunisation safety surveillance is unknown. In addition, health facilities in the study region do not have the immunisation safety surveillance pocket manual for guidance when HCPs are faced with AEFI. It is on the basis of these factors that the researcher embarked on this study.

1.4 PURPOSE OF THE RESEARCH

The purpose of this research is to assess immunisation safety surveillance in Asosa Zone, Ethiopia, with the aim of detecting barriers in the health care providers' existing

guidelines, and develop an immunisation safety surveillance pocket manual for health care providers.

1.4.1 Research questions

- How much knowledge do health care providers have about immunisation safety surveillance in Asosa Zone, Ethiopia?
- What are health care providers (HCP)s' perceptions and practices regarding immunisation safety surveillance?
- What are the factors affecting HCPs' immunisation safety surveillance?
- What are the challenges experienced by HCPs in immunisation safety surveillance?
- What are the gaps in the existing AEFI surveillance guidelines of the country?
- How could the AEFI surveillance guidelines be modified to be in line with the WHO standard AEFI surveillance guidelines?
- What should be incorporated in the immunisation safety surveillance pocket manual for health care providers?

1.4.2 Research objectives

The current study is divided into two phases with the following objectives:

Phase 1 addresses the following three objectives (one to three):

Objectives are to:

- Assess health care providers' knowledge, perceptions and practice about immunisation safety surveillance in Asosa Zone, Ethiopia.
- Establish factors affecting immunisation safety surveillance.
- Describe the challenges, which affect immunisation safety surveillance.

Phase 2 addresses the last two objectives mentioned in this study:

- Identify gaps in the existing AEFI surveillance guidelines of Ethiopia in view of the latest WHO AEFI surveillance standard guidelines.

- Develop an immunisation safety surveillance pocket manual for HCPs.

1.4.3 Null hypotheses

- HCPs knowledge, perceptions and practice working in the study area have no relationship towards immunisation safety surveillance.
- Socio demographic variables have no relationship with status of HCP AEFI surveillance.
- Availability of standard reporting system has no relationship with immunisation safety surveillance.
- The existence of immunisation safety/AEFI surveillance guidelines has no relationship with immunisation safety surveillance.

1.5 SIGNIFICANCE OF THE STUDY

The outcome of this study could provide major insight on the status of HCP knowledge, perceptions and practice and the challenges related to immunisation safety surveillance for decision makers. Based on this insight, the decision makers will take corrective action to strengthen immunisation safety surveillance. This in turn, will help to improve the weak immunisation performance and improve public trust on vaccines. In addition, it will become the basis for policy designers, decision makers and planners, and will serve as a pilot study for the country. This study provides an opportunity for reviewing the existing AEFI surveillance guidelines, identify gaps, and recommend improvements in immunisation safety surveillance. Moreover, the investigator developed an immunisation safety surveillance pocket manual, which could be used for quick referral to address problems during practice.

1.6 OPERATIONAL DEFINITIONS

1.6.1 Adverse events following immunisation (AEFI)

AEFI refers to any unfortunate medical incidence (unwanted or unexpected sign, unusual laboratory outcomes, symptom or disease) that follows vaccination and that does not fundamentally have a cause- effect association with the utilisation of the antigen (EFMHACA 2016:17).

1.6.2 Challenge

A challenge refers to the condition of being confronted with something that requires excess mental or physical energy, in order to be conducted fruitfully and hence confronts an individual's capacity. Challenges in the context of this study, entail barriers or problems that impacted negatively on immunisation safety surveillance (*Cambridge English Dictionary* 2020).

1.6.3 Health care provider (HCP)

A person certified by a licensing body, facilitating and or providing health care services and reporting the health information to the health system. For the purpose of this study, health care providers are licensed professionals working in the government systems. They include nurses, doctors, health officers, environmental health officers and health extension workers assigned in departments linked to immunisation safety surveillance (https://en.wikipedia.org/wiki/Health_care_provider accessed 6 June 2018).

1.6.4 HMIS focal person

Any person in charge of data compiling and reporting in Regional Health Bureau, ZHD, district health office and health facility level. They are experts usually in information technology (IT) and statisticians by profession (FMOH Ethiopia 2010:54).

1.6.5 Immunisation safety surveillance (ISS)

ISS is the method of guaranteeing and watching the safety of entire issues of immunisation, comprising the identification and investigation of adverse events, vaccine storage and handling, vaccine quality, vaccine administration, and disposal of sharps and management of waste (Masuka & Khoza 2019:2).

1.6.6 Immunisation safety surveillance pocket manual

A pocket manual readily available and portable that could be used for immediate reference in relation to basic concepts and ideas related to immunisation safety surveillance (*Cambridge English Dictionary* 2020).

1.6.7 Vaccine

A vaccine is a substance that enhances a body's capacity to prevent specific VPDs (Mandala 2018:1-4). A vaccine classically comprises disease-causing germs, or part of it, and is usually prepared from either live-attenuated or killed type of the microorganism, its toxin or one of its surface proteins (WHO 2015a:4).

1.7 FOUNDATION OF THE STUDY

1.7.1 Research Paradigm

This study is based on a philosophical approach that allows the investigator to choose which technique should be accepted and why (Chetty 2016:1-2). According to Creswell (2018:40), philosophical worldviews continue to be mainly concealed in research, yet they impact the practice of research and require to be recognised. Others have called them paradigms, epistemologies and ontologies, or broadly conceived research methodologies.

1.7.2 Theoretical framework

The theory of reasoned action (TRA) was deemed ideal for this study. First, in 1967 Fishbein introduced it in an initiative to realise the association between behaviour and attitudes. The theory clarifies the connection among beliefs, attitudes, intentions and behaviour. According to the TRA, Fishbein and Ajzen (2010:59), the main driving factor of behaviour is behavioural intention. The exact driving factors of people's behavioural intentions are their attitudes towards accomplishing the behaviour and the subjective norms related with the behaviour. Attitude is driven by a person's beliefs about the outcomes or attributes of accomplishing a unique behaviour (that is, behavioural beliefs), weighted by evaluations of those outcomes or attributes (Tlou & Dyk 2009:16). An individual's choice to engage in a special behaviour is grounded on products the individual imagines will come as a result of acting the behaviour (Gillmore, Morrison, Wilsdon, Wells,

Hoppe, Nahom & Murowchick 2002:886). According to Fishbein and Ajzen's (1991:188) theory of planned behaviour, attitudes have two constituents, the assessment and power of belief. The power of belief influencing behavioural intent, which has two constituents: normative beliefs and motivation to comply. HCPs spend most time in the care of patients and are solely responsible for actual administration of medicines to patients in health care facilities. The outcome they may think of could be either good or bad. Once a HCP is sure of a positive outcome of safety surveillance and vaccine reporting after immunisation, he/she is likely to go ahead and provide the service.

1.8 RESEARCH DESIGN AND METHODS

1.8.1 Research design

A convergent parallel mixed method of quantitative and qualitative research design was employed for this study (Creswell 2018:12). A cross sectional quantitative approach was employed to measure HCPs' knowledge, perceptions and practice on immunisation safety surveillance in Asosa Zone, Ethiopia. Qualitative research is an interpretative methodological approach that is thought to yield a subjective science. It developed from the Behavioural and Social Sciences as a method of realising the specific, changing and rounded nature of human beings. Therefore, in qualitative design, researchers are expected to put altogether a multifaceted array of data drawn from sources (Tarcy 2013:32) as was practical in this research. In this study, an eclectic type of mixed method research design on which the quantitative part was used to triangulate and strenghten the qualitative section of the study (Mehdi [s.a.]).

1.8.2 Sampling

1.8.2.1 Sample size for quantitative design

Since the target population was small, Yamane 1967 formula, was used for the sample size calculation (Israel 2013:4), $n=N/1+N\ (e)^{2}$ where n is the sample size, N the population size, and e, level of precision.

The distributions of total study population (N) in each facility were as follows:

For hospitals, N=8, for health centres (HCs), N=64, for health posts (HPs), N=541. The total number of the target population in the hospital and health centres was estimated based on FMoH Ethiopia manpower structure and the number of HPs workers from the 2018 Asosa Zone Health Department manpower profile.

Therefore, the expected sample size (n) was based on the formula n=N/1+N (e) ^{2} and considered 5% as the level of precision:

- Hospital, n=8/1+8*0.0025=8
- HCs, n=64/1+64*0.0025=64
- HPs, n=541/1+541*0.0025=230
- The total sample size for the quantitative approach is 8+64+230=302

In each health centre and hospital: there were four respondents (disease surveillance, immunisation, paediatric treatment focal persons and medical director) and in the health post level, 2 respondents (outpatient department nurse and health extension workers) all expected to have a mandate to contact for any AEFI related cases. In every hospital and HC, there were four respondents and in each HPs, two respondents. To get 302 respondents, all hospitals and all HCs and randomly selected HPs were included as a sampling unit. When more than one health extension workers (HEWs) were available in HPs, one of them was selected randomly by using lottery method.

Number of facilities required to get the study unit or sample size were:

- All hospitals were taken to get 8 respondents.
- Required HCs were 64/4=16.
- Required HPs were, 230/2=115, where 230 is the total sample size in all HPs based on sample size formula calculation and 2 was number of respondents required per health post.
- The 115 HPs were proportionally allocated in all the seven woredas/districts (Asosa, Bambasi, Homosha, Kurmuk, Menge, Oda and Sherkole) found under Asosa Zone. Two respondents expected to be taken per HP. The total number of proportionally allocated HPs versus total number of HPs per woreda after exclusion of some HPs

were Asosa (38/69), Bambasi (23/42), Homosha (8/15), Kurmuk (9/16), Menge (13/24), Oda (14/25), and Sherkole (10/19).

Therefore, 133 (2+16+115) HFs were included for a total number of the planned respondents in this study.

1.8.2.2 Sample size for qualitative design

In Asosa Zone, all the districts were stratified in to two groups (near and distant), based on their distance from the zone town. One district was selected in each group. Two districts in the zone were part of the study. Therefore, the Asosa Zone and two districts were included and 3 participants from the zone and 6 (3 per district) from the districts were part of the study. In general, zone health departments and selected district health offices' surveillance, immunisation and health-management-information-system (HMIS) focal persons were included for the face-to-face interview.

1.9 ETHICAL CONSIDERATIONS

Ethical concerns were followed prior and during the process of this study to defend the rights of the participants. Written ethical approval was obtained from UNISA (Annexure A) and Asosa Zone Health Department (Annexure C). These comprised the right to provide informed consent, dignity for the human being who has the right not to be harmed or abused, un-forced consent to take part in a specific portion of research, the right to privacy, and the right to confidentiality and/or anonymity usually summarised as the ethical principles of autonomy, justice, beneficence and non- maleficence (Saxena 2015:6-9).

1.10 SCOPE OF THE STUDY

Geographically, the research was conducted in Asosa Zone hospitals and all woredas of the zone. It assessed the KAPs, factors and challenges affecting HCP's immunisation safety surveillance in the study area. The research involved HCP working in the zone, woreda and HFs as immunisation, surveillance, HMIS, paediatric treatment, medical

director, OPD nurse and HEW for complete information about the research under problem.

1.11 STRUCTURE OF THE THESIS

Chapter 1: Comprises an orientation chapter. It incorporates the research background, statement of the problem, research questions, aim and objectives, null hypothesis, significance, definition of terms, paradigm, theoretical frameworks and scope of the study.

Chapter 2: Presents the theoretical framework, reviewed literature and summarises studies related to immunisation safety surveillance. It includes vaccines, adverse drug reaction surveillance, impact of immunisation safety surveillance, health care provider knowledge, perceptions and practice, immunisation risk communication health service delivery, motivation, partnership, guidelines for service provider and challenges experienced in immunisation safety surveillance.

Chapter 3: Describes the research design and methods. It incorporates; setting, study population, selection criteria, sampling, ethical consideration, data gathering procedure, data analysis, quality control, validity and reliability.

Chapter 4: Details the presentation and explanation of the quantitative and qualitative findings of the study, including the interpretations and discussion of both research designs.

Chapter 5: Presents the triangulation and integration of quantitative and qualitative findings of the study.

Chapter 6: Presents the Ethiopia AEFI guidelines gap analysis in comparison with the global AEFI surveillance and the immunisation safety surveillance pocket manual for health care providers prepared based on the results of the study and expert review.

Chapter 7: Presents the summaries, conclusion, limitation and recommendations of the study.

1.12 SUMMARY

This chapter presented a brief orientation on the basic components of the research. It highlighted the global and Ethiopian immunisation safety surveillance challenges with suggestions of how they could be addressed. The objectives, research questions, foundation and significance of the study were discussed. It briefly explained the research design and methods of the study. In addition, it shows the chapters' division of the whole study.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

The aim of the literature review is to gather relevant information by using different sources on the research topic, in this study, immunisation safety surveillance. This chapter focuses on the history of vaccines and various aspects of immunisation, including the difference between vaccine and drug reaction. Secondly, the chapter examines the available literature on health care providers' immunisation safety surveillance knowledge, perceptions and practices, factors and challenges influencing AEFI surveillance, health system motivation for health care providers and its effect on immunisation safety surveillance. In addition, the chapter reviews the TRA and health care provider (individual) related factors, pointing out the need for partnerships in immunisation safety surveillance and review Ethiopia's AEFI surveillance guidelines in comparison with the WHO standard AEFI surveillance guidelines. It also addresses relevant studies regarding HCPs immunisation safety surveillance and adverse drug reaction (ADR) reporting.

To review references for immunisation safety surveillance, the phrases AEFI surveillance, vaccine post-licensure surveillance, immunisation safety surveillance, vaccine safety surveillance and Phase IV clinical trials have been used as search engines beyond using the entire title. The major mechanisms to gather and review more articles were tracking of references from selected articles which were not traced in the primary literature search engines. From this search, more than 200 references (published and non-published articles and titles) were collected, reviewed and cited to support this study.

The inclusion criteria in addition to topic relevance, language (English) and articles' published time have been applied.

2.2 VACCINES

2.1.1 History of vaccines and vaccination

Although two thousand years ago in China and India vaccination countering smallpox was exercised, a British physician, Edward Jenner, is normally accredited in piloting the contemporary view of immunisation (Paul 2019:1). In 1796, he used substances from cowpox pustules to vaccinate patients effectively countering smallpox, which is instigated by a linked virus (WHO 2013a:11). Therefore, vaccines have a history that started late in the 18th century and could be produced in the laboratory from the late 19th century. Though, in the 20th century, it was practical to produce vaccines based on immunologic markers and in the 21st century, molecular biology allowed vaccine preparation that was impossible earlier (Plotkin 2014:12283).

2.1.2 What is a vaccine and how do vaccines work?

A vaccine is a biological product that increases being insusceptible to a specific VPDs (Mandala 2018:1). Vaccines are usually prepared from either deactivated (dead) or live attenuated types of microorganism, one of its protein surfaces or its toxin and classically comprise disease-causing microbes (WHO 2015a:4). Immunity is a multifaceted biological system gifted with the capability to distinguish and endure whatever belongs to the self, and to distinguish and discard what is foreign (non-self) (BC Centre for Disease Control 2009:2). Active immunity denotes the process of injecting the body with an antigen to generate antigen-specific antibody and cellular immunity. Passive immunity is giving produced antibodies to humans or animals rather than having them produced by their immunity system. Generally, there are four different forms of vaccines which all function in a similar process through making the immune system to defend a specific illness. More or less a vaccine comprises constituents that are the same to the disease-causing microorganism, and hence the immunity substance reacts as it would to an infection with that microorganism (WHO 2015b:3).

2.1.3 Importance of vaccines

Immunisation is among the main fruitful of all public health interventions, accountable for the eradication of smallpox, the nearby eradication of poliomyelitis (El Shazly, Khalil,

Ibrahem & Wahed 2016:1018) and enormous decreases in the incidence of numerous other fatal contagious illnesses namely meningococcal, measles, pneumococcal, diphtheria, rotavirus, and hemophilus influenza type b (Hib) infection (Isaacs 2012:111). Each year, about 3.5 million children in low-income countries still die and many more are disabled from VPDs (Okueso & Oke 2017:24). Annually 2 million additional child deaths could be prevented through immunisation with currently existing antigens (WHO 2013a:10). In spite of the huge contribution of immunisation, globally numerous children do not appreciate its importance. Nearly, 20% of yearly born children are not vaccinated (Kyere 2014:2). Currently, 8.7 million of children's lives were saved due to significant increased distribution of vaccines including introduction of new vaccines and countries were motivated to achieve 90% immunisation achievement (Hardt, Ott, Glismann, Adegbola & Meurice 2013:206).

2.3 ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

An AEFI is defined as "any undesirable medical occurrence following vaccination and which does not essentially have a cause and effect association with the utilisation of the vaccine'' (Sebastian, Gurumurthy, Ravi & Ramesh 2019:1). Adverse events can be any unwanted signs, uncharacteristic laboratory findings, symptoms or diseases (Tozzi, Asturias, Balakrishnan, Halsey, Law & Zuber 2013:2). An AEFI may be local (e.g. redness, swelling, pain) or systemic (e.g. fever, exanthema), and acute (within minutes of vaccination) or chronic (many hours or days following vaccination) (Danova, Kocourkova & Celko 2017:1; Meng, Sun, Shen, Pan, Tang, Wang, Wu & Ye 2017:2).

The population attention has been progressively shifted from the benefit of the vaccine to the safety of the vaccine following the dramatic progresses in immunisation coverage and the considerable drops in VPDs (Gattás, Braga, Koike, Lucchesi, Oliveira, Piorelli, Queiroz & Precioso 2018:2). As compared to the magnitude of the problems, vaccines effectively protect rare AEFIs, obtain unequal public and media focus because of the clear sequential, probably coincidental occurrence of adverse events, but often not due to vaccines (Singh et al 2017:1).

In America, 1.14 cases of AEFI were reported for every 10,000 cases of vaccination (Puliyel 2013:144). In Zhejiang province of China, the total reporting rate of AEFI was 9.2 per 100,000 doses of vaccination (Hu et al 2013:211) and the cumulative reporting rate

for 2016 in Czech the total AEFI reporting rate was 209/100,000 doses (Danova et al 2017:1). In the Republic of Korea, the yearly AEFI reporting rates for all immunisations registered from 2011 to 2016 ranged 0.8-1.2 cases/100,000 doses (Kim, Lee, Kim, Kong, Yang & Suh 2017:151), in Iran the rate was 11.8 per 10,000 doses (Khazaei, Rezaeian, Razani, Zahiri, Saatchi, Khazaei, Hafshjani & Darvishi 2016:1697) and 19.3% in a tertiary hospital in Ilorin, Kwara State, Nigeria, in 2010 (Aderibigbe et al 2010:498).

Mehmeti and Bino (2018:133) note that the variability among countries in their AEFI reporting rates is affected by different issues for example: Socio-demographic characteristics, the study period, severe vents, dispersed dosages or number of vaccinated, vaccine type, number of events with AEFI various definition. Considering the concern that there are no perfectly safe vaccines, it is beneficial to recognise the “normal” rates of vaccine responses pulled from various research in this subject and to approximate the rates of AEFI of a country within this bound.

2.3.1 Impact of adverse events following immunisation on immunisation programme

Low vaccination rates may be because of inadequate resources or substructures, but also from poor confidence on the vaccine. Rationales for poor vaccine confidence incorporate doubts from caretakers and HCPs on antigens, main repeatedly on safety of vaccine (Hardt et al 2013:206).

Fright of vaccine reactions, true or perceived, refrain most populations from undertaking vaccination (Allela 2017:s66; WHO 2013b:1). Moreover, as a majority of the illnesses encountered that vaccines prevent are no longer observable, the dangers associated with the illness are usually lost and the necessity for immunisation programmes to prevent the illness may be under acknowledged (Sato, FerreiraI, TauilI, RodriguesI, BarrosI, Martineli, Costa, Inenami & Waldman 2018:2). When considering vaccination, caretakers may hence be concerned more with the likely adverse reaction than vaccines action on the risks related with exposure to illness (Hardt et al 2013:206).

AEFI reports can be shared using different mechanisms such as reporting paper, fax, email, and or telephone to subnational government and area health leadership (Parrella, Goldb, Marshall, Mayerd, Watsone & Baghurst 2012:662; Sathvik, Chukir, Abo-Aldan &

Soliman 2014:373). Over the past decades, the effects of AEFIs were documented in limited countries mostly in Europe and in some African countries. What is recognised is that the concerns with AEFI (real or apparent) can lead to a drop of population confidence in vaccination, changes in public health policies and, in a few occasions, renaissance of VPDs. The effect can spread from subnational to national and global stages, and vary from short to on-going concerns (UNICEF 2005:4).

Since the late 1990s, concern has increased related to a recovery of the "anti-vaccine movement," a loosely defined group of individuals who spread uncertainty about their effectiveness and vaccine security (Maglione, Das, Raaen, Smith, Chari, Newberry, Shanman, Perry, Goetz & Gidengil 2017:1). In Sweden, DPT achievement reduced abruptly in the late 70s following a powerful medical leader who interrogated the importance for whooping cough immunisation and addressed his opinion recognised to the population. This made numerous paediatricians losing buoyancy in whooping cough vaccine. DPT achievement reduced sharply by 90% in 1974 to 12% in 1979. In 1979 the national policy was altered by the government, stopping the whooping cough antigen. In the following years, whooping cough outbreaks with more than 10,000 cases annually and a number of sad deaths happened in the country (UNICEF 2005:5).

In 1992, UK Department of Health, four years after the Measles, Mumps and Rubella (MMR) antigen introduction, cancelled MMR antigens comprising the Urabe strain of the mumps virus following that relationship with an augmented risk of aseptic meningitis was found. In addition, Brazil, Japan, and Canada halted on a similar scenario the MMR antigens that confirmation emerged of safety risks (Larson, Paterson & Erondu 2012:1055-56).

In Jordan, September 1998, more than 800 school children were exposed to the adverse events of Td toxoid antigen administration during a country wide school-centred operation. More than 100 students were hospitalised. At the beginning, the government, when aware about the first reported events, directed all schools to instantly halt the immunisation operation. Immediately the media transferred the event on TV and radio in country wide coverage, leading to mass fright amongst caretakers. The AEFI investigation then recognised that for the large majority, the symptoms were not due to the antigen but because of mass psychogenic illness ("hysteria"). Only 10 students were recognised to have been real AEFI – this is in the expected span of adverse event to Td. This group of

AEFI happened in response to prior information of the population's doubt to government's management of prior public health concerns, and already wrongly informed media instantly proposed that a "bad vaccine" was utilised. After the investigation, the Jordanian Ministry of Health re-established the Td immunisation operation, expending duration and resources on reinstating population assurance on vaccination programmes. This instance underlines the benefit of constructing long-term partnerships with the population and the media. It also illustrates the effect a small group of AEFI can have on a country wide immunisation operation (Kharabsheh, Al-Otoum, Clements, Abbas, Khuri-Bulos, Belbesi, Gaafar & Dellepiane 2015:768-770; UNICEF 2005).

In 2002, a total of 4,600 children were immunised during a MMR operation in Nahrin district, Afghanistan. Five weeks following the immunisation, vaccination facilitators from a national immunisation day (NID) operation reported in four villages roughly 150 children with abscesses, which were perceived to have relation to the prior measles immunisation. Members of the community accused the vaccinators and health workers. Moreover, routine vaccination achievement reduced from 100 to 8 children a month. The investigation identified the AEFI to a programme mistake that related to poor sanitation safety measures, unskilled vaccinators and utilisation of an unfitting diluent. The major lesson learnt from there was that PHCWs were not capacitated on the danger of adverse events and likely management choice. Afghanistan had no AEFI surveillance guidelines when the events occurred (UNICEF 2005:29).

The community is increasingly becoming uncertain of public health interventions that link disastrous occurrences following vaccination yet, in fact, those are mere speculations that are politicised. These incorporate consistent questions related to the MMR vaccine although plenty evidence disproving supposed relations between autism and the MMR vaccine; the absolute risks as feelings or risks as politics for anti-immunisation campaigns to bring a practice change for (example postponing or rejecting antigens). In most areas of northern Nigeria in five states oral polio vaccine (OPV) immunisation campaign refusal in 2003-2004 was an example totally led by politics. The same worries of OPV leading to infertility were distributed in India and Northern Nigeria refused the OPV. Though, there were other fundamental programmatic issues, in the case of India, they preferred a female and local vaccinator than a male and a far site to vaccinate their children (Larson et al 2012:1054).

Despite robust energies to enhance hepatitis B immunisation coverage in Vietnam, broadcast news of AEFIs have driven to disparities in hepatitis B immunisation achievement. The birth dose immunisation of hepatitis B decreased from 64.3% in the prior year to 26.9% in 2007, partly due to media reports of AEFIs (Li, McNeil, Pickering, Pemberton, Duran, Collins, Nelson & Engler 2016:870).

In a USA, survey conducted in 2010 on 376 caretakers of children six or less years of age, 26% felt that vaccines constituents are insecure and 17% perceived that vaccines safety were not verified sufficiently, only 23% had no issues with children's vaccines. This was evident that several people lacked knowledge about the strict controlling processes involved for quality and safety in vaccine experiment, development and production stages and post-market in order to follow-up and adhere to safety indicators that may occur during vaccine utilisation on people (Hardt et al 2013:207).

Vaccine boycotts may be driven by a shortage of faith in the scientific research community or by public and suspicion of the information delivered by the pharmaceutical manufacturer. This has raised misunderstandings about immunisation, such as the attitude that before vaccines were functional, diseases had started to recede due to improved hygiene and sanitation (Jit, Huyen, Friberg, Minh, Kiet, Walke, Cuong, Duong, Tod, Hutubessy, Fox & Hien 2015:A234) or providing simultaneously several vaccines for a child for various diseases increased the danger of hurtful adverse events and can burden the immune system. The current electronic media such as internet and social media supported the broad and prompt dissemination of information. Currently, electronic media which have conflicting ideas on immunisation, negatively influence the attitude of people worldwide about using vaccines (Hardt et al 2013:206).

Measles epidemic happened in 2012 because of under immunisation in Ukraine and UK and also in Australia, India, USA, New Zealand, Canada, Kenya, Mozambique, and Somalia, where there were excess cases. In many of these countries' infrastructure was not the principal obstacle to the low coverage of vaccines even if there were different explanations. Rather, a mix of low-risk perceptions of measles disease and high risk of the vaccine adverse reaction combined to generate barriers in vaccine achievement, herd immunity gaps, and occurrence of disease outbreaks (Yaqub, Clarke, Sevdalis & Chataway 2014:1-2). In few scenarios, adverse events have provided honest cause for worry, for example the 1990s Urabe mumps strains used in some of the MMR vaccines

and in others, new research which has heightened population worries and arguments, such as around the suggested relationship between MMR and autism, leading to what Seth Mnookin calls the ‘panic virus’ (Larson et al 2012:1056).

In 2010, there was an instance in India that suspended the human papilloma virus (HPV) vaccine. Protest project demonstrates that there can be risky perceptions at various levels, in various localities, that can have their effect geographically which vary from the point of initiation to augment the dangerous perceptions (Larson et al 2012:1055).

In August 2013, Northern Nigeria's Kano state OPV vaccination was stopped after taboos were distributed by religious priests that "OPV vaccine could cause infertility in girls." Following this, Kano became the base of highly spreading epidemic of polio. The epidemic disseminated into 10 African countries that were polio free. In July 2004, the country prohibition of OPV was removed after 11-months and the supplementary immunisation was restarted. Nevertheless, the effect took a long period of time. The debate on polio vaccine safety spread to entire immunisation programmes mistrust and endangered the acceptability of other public health programmes. The incorrect stories about the polio vaccine were distributed out of Nigeria as far as Afghanistan and Pakistan. This explains how local level events can grow to country wide or global impacts on vaccination programmes (UNICEF 2005:6-7).

Studies reveal that in Nigeria, immunisation achievements dropped (Nnenna, Davidson & Babatunde 2013:1) with declines to reviewing children immunisation status during visits to health institutions, declines in vaccinating simultaneously all the desired antigens, and possibly doubts of adverse events, as is currently observed in developed countries. Weak surveillance of AEFI impacts poorly on immunisation (Mohammed, Aliyu, Maiha & Isa 2018:82).

In 1996 Uganda organised its first Polio national campaigns. The campaign was shifted to August-September 1997 in order to harmonise the operation with other countries, which overlapped with the starting season for malaria. After immunisation in the South-Western area, a number of children who died were reported during NIDs. A number of unnecessary deaths of children due to malaria were incorrectly attributed to OPV. Most considered the coincidental relationship as cause-and-effect relationship. In 1998 together with other variables the routine vaccination achievement dropped. For instance,

DPT3 achievement dropped from 80% in 1997 to 54% in 1998 in Mbarara district (UNICEF 2003:20-39).

Worldwide, communities are confronted with groups of vaccination sceptics named ‘‘A Crisis of Public Confidence in Vaccines’’. The crisis justification differs from protection issues to philosophical and religious beliefs, and from suspicion in governments to theories of political and business intentions behind the delivery of vaccines rather than a genuine purpose to protect from illness, for example around the H1N1 immunisation (Larson et al 2012:1056).

2.3.2 Immunisation risk communication

The WHO’s 2002 yearly report selected the slogan of ‘‘decreasing risks, promoting healthy life’’ and gave the definition on risk as ‘’ a chance of opposing result, or a variable that enhances this chance’’. The objective of communicating about risk was usually to target safety of vaccines and awareness creation on the importance of vaccines and informing about the likely risks of an AEFI (Larson et al 2012:1054).

UNICEF (2005:10-12) indicates that some of the principles of risk communication have to be recognised during production of a strategic communication plan and messages, particularly around AEFI. Behaviour change communication (programme communication) is one of the strategies to respond to AEFI through increasing vaccination awareness and positively affecting beliefs and actions of people and groups towards vaccination. It can be targeted at caretakers as well as health professionals and other decision-making bodies. Behaviour change communication applies a combination of various channels: mass media, mini media and interpersonal communication channels.

2.4 SURVEILLANCE

2.4.1 History of surveillance

Surveillance- originates from a French word and in 1802 became adopted into English. It is a noun simply defined as ‘the act of oversight or watching over’. It has two-word elements, ‘sur’ (over or atop) and ‘veiller’ (*Online Entymology Dictionary* 1802, sv ‘surveillance’; Rojanaworarit 2015:30). Surveillance was incorporated into English in 1793 from surveillance committee organised in all municipalities for follow up of suspected individual’s activities due to terror in France. Firstly, surveillance was considered as the act of close follow up of individuals vulnerable to infectious or transmissible diseases for early identification of signs and symptoms which required major actions, for example quarantine. Until 1950, surveillance perspectives shifted from the action of single monitoring to public-centred surveillance of illness existence. Afterward, during the 1954 field trial of poliomyelitis vaccine, this strategy became noticeable in the USA (Rojanaworarit 2015:30).

2.4.2 Public health surveillance

Public health surveillance has been defined as a system consisting of regular data gathering, data analysis and interpretation, distribution of key information and messages to the responsible structures to appropriately strengthen public health action for control and prevention of a disease or situation (Rojanaworarit 2015:31; Zvanaka, Tsitsi, Chonzi, Shambira, Gombe & Tshimanga 2017:2). Immunisation safety surveillance is among public health surveillances that aim to maintain the safety of all vaccines given to the public through monitoring all issues of vaccination programmes. A robust surveillance system that traces safety conditions as early as they happen and continual vaccines utilisation are essential to the acceptability of public health vaccination interventions and their achievement in eliminating VPDs (Ali et al 2015:61; Parrella 2014:1). The benefits of post-marketing monitoring of vaccine safety cannot be underestimated. Since vaccines have been administered to mostly healthy populations, usually children (Pasquale, Bonanni, Garçon, Stanberry, El-Hodhod & Silva 2016:6672), in order to protect, rather than manage disease, anticipation vaccine safety by the population is paramount (Parrella 2014:1; Waldman, Luhm, Monteiro & Freitas 2011:1).

All WHO's member states are governed by the 2005 International Health Regulations to report to WHO any disease that comprises a public health emergency of global concern. These regulations do not need a special surveillance system or stipulate the utilisation of particular type of surveillance system. However, all member states have dedicated to achieve a core capacity for public health surveillance (including detection, verification and reporting) and act as part of global health security (WHO 2018:7).

2.4.3 Immunisation safety surveillance (ISS)

The published and other reference documents were searched by using the phrases, immunisation safety surveillance or vaccine safety surveillance or post marketing surveillance or AEFI surveillance as search engine, and they were interchangeably used in this study.

2.4.3.1 Definition of immunisation safety surveillance

ISS, the course of safeguarding and watching the entire features of immunisation safety, consists of tracing and dealing with adverse events, storage and handling of vaccines, quality of vaccines, giving vaccine, removal of sharps and waste management. The main purpose of ISS is timely tracing followed by adverse event analysis then proper and fast intervention for reduction of the adverse effect on the well-being of users and the immunisation programme (Waldman et al 2011:25).

2.4.3.2 History of immunisation safety surveillance

Efforts to solve certain vaccine safety difficulties began when the biological standardisation expert committee of WHO suggested that all countries shall have vaccine safety, efficacy, and quality monitoring national regulatory authority (NRA) in 1981. In 1997, of the 190 WHO state members only 37 (19%) had consistent NRA, counting 20 (38%) among the 52 vaccine developing countries. In 1999, WHO targeted country capacity strengthening project on immunisation as a safety priority. This initiative was gaining ground in 2008. Of the 193 member states, 58 (30%) had dependable, completely functioning NRA counting 33 (69%) of 48 vaccine producing countries (Graham, Rodriguez, Huzair & Zinck 2012:4953). In 2010, the number had increased to 60 (31.5%) including the 34 (77%) of 44 vaccine producing countries (WHO 2015b:117). Despite

these substantial enhancements, yet even in developed countries only about one out of four LMIC have a dependable NRA with adequate manpower and logistic assets to review and control antigen safety, and largely covered real-time active surveillance for AEFI continues to be ideal. AEFI tracing, reporting, responding and monitoring continue to be an issue of vaccine producers, regulators, HCPs, and the public (Graham et al 2012:4953).

2.4.3.3 Types of immunisation safety surveillance

Passive surveillance incorporates all voluntarily AEFI reporting to the primary health care surveillance system from vaccinators, health facilities and parents. Reports, starting from there, are transferred to the subsequent reporting system level(s) with until they reach at the responsible federal level unit and global AEFI surveillance organisations. Theoretically, passive surveillance systems allow anybody in a given area to report, and because of their wide coverage, they can deliver the primary signal of an unpredicted AEFI. Active surveillance is mainly for detail analysis of the AEFI features, degrees and risk factors, but logistic and resource shortages restrict its extensive execution. States may conduct AEFI surveillance at identified sites or organisation for only targeted AEFI (sentinel sites). Ad hoc studies are epidemiological studies that can be conducted to increase immunisation safety surveillance duties. These studies are dedicated to nominated issues of the safety of vaccine (WHO 2016:27).

2.4.3.4 Importance of immunisation safety surveillance

Most AEFIs are mild, local and systemic, thus, surveillance activities are dedicated on moderate and severe events. These events are correlated to various types of variables, for example the type of antigen, situations of provision, storage, and features of the vaccines. Events strength, though, may differ from mild and predictable outcomes such as local appearance to moderate and serious events and rare cases, classified as unpredicted. Taking the features of the antigens, children aged under one year comprise the highest AEFI-influenced category. The largest focus of antigens accessible and doses used are in this age category. Research piloted in São Paulo and Teresina revealed that the occurrence of AEFI in this age category denoting roughly 80% in reference to the other population categories. In this relation, it is essential to accomplish screening and monitoring after immunisation so that AEFIs are detected and response actions are

adopted timeously, allowing keeping the quality, safety of the vaccines, and maintenance of the trustworthiness of the vaccination (Santos, Pontes Netto & Andrade 2016:627).

Patel, Shah, Desai, Kalaiselvan and Singh (2018:326) explain in a retrospective qualitative and quantitative analysis of AEFI report submitted to national cadet corps-pharmacovigilence programme of India from 2015-2016, that approximately 13% were serious AEFIs in nature with seven deaths. Most AEFIs were mild, however, severe AEFIs need detailed reporting, investigation, and follow up for causality assessment and to recognise risk factors.

The achievement of immunisation programmes forms an antagonistical condition in developed countries: as the perception of risk associated with immune-preventable diseases declines, there were worries about AEFIs (Salmon, Pan, Omer, Navar, Orenstein, Marcuse, Taylor, DeHart, Stokley, Carter & Halsey 2008:286). This can decrease adherence with immunisation, allowing for the recurrence of controllable diseases (Tozzi et al 2013:2; Waldman et al 2011:1).

Though there are remarkable outcomes gained with immunisation, vaccines have been a sufferer of their own achievement: as the frequency of illnesses avoidable by immunisation, gradually reduce the progresses made occasionally could be under recognised by vaccine safety issues (Alicino, Merlano, Zappettini, Schiaffino, Luna, Accardo, Gasparini, Durando & Icardi 2015:91). Isaacs (2012:111-115) emphasises that the evaluation of the risks and benefits of vaccines is important to guarantee the population's faith in vaccination.

Twene and Yawson (2018:105) found that the anticipations from immunisation are far greater and difficulties related to vaccine or vaccinations are slightly tolerable to the population and other contrasting drugs. There is therefore the need to actively monitor all AEFIs and respond to them appropriately.

Regarding events, what is reportable by law to the vaccine adverse event reporting system (VAERS) is identified by the reportable table (RET) including concerns available in the vaccine producer package insert. The RET mentions that HCPs are expected to share any unforeseen events or clinically relevant for the vaccine whether it is mentioned or not in

the RET. It is also a prerequisite by law that the vaccine producer should share all adverse events of any vaccine to VAERS which are known to them (VAERS 2017:5).

In post-marketing surveillance programmes, all adverse events should be identified and shared in order to enhance goods safety and management (Stefanizzi, Calabrese, Infantino, Matto, Tafuri & Quarto 2017:154). Passive surveillance is the primary technique of post-marketing VSS in Ethiopia. Vaccine receivers themselves and or caretakers of vaccinated children/infants and health care providers at immunisation centres are expected to identify or trace AEFIs when they first happen (WHO 2016:26). Health workers who conduct immunisation services in the district have the responsibility of identifying and reporting AEFIs to the district EPI focal person for onward submission to the region (Twene & Yawson 2018:106). The district office should actually be made aware of any severe AEFI cases telephonically and this must be supported by the filled reporting form (EFMHACA 2016:29).

Passive surveillances are commonly implemented and are grounded on spontaneous announcement of adverse events by health workers or by the patient or caregiver. This kind of surveillance is the easiest and cheapest substitute and their widespread population base allows for the detection of occasional events and of the safety history of vaccines in the post-marketing period. On the other hand, this strategy has poor sensitivity and delivers vague risk approximates when used as a denominator, the number of dosages of vaccine dispatched or given, which is an inexact delineation of the unprotected people (Bok 2014:3).

Post-licensure immunisation safety surveillance includes applying particular pharmacovigilance plans that are “well-timed, resourceful and adequately large and practical for the life of the vaccine” (Griffin, Braun & Bart 2009:s346). Furthermore, such systems should provide beneficiaries with updated information on adverse impacts and precautions, as well as support to the advancement of procedures directed at guaranteeing the safety of immunisation programmes. The first goal of VAERS is to identify safety indications that might be connected to immunisation.

The major purposes of VAERS are to:

- Trace new, infrequent, or unusual adverse events (Hawken 2014:1).

- Monitor reporting patterns that could reveal real increments in common adverse events.
- Detect possible risk factors for special kinds of adverse events.
- Evaluate the safety of recently approved vaccines and new recommendations for existing vaccines.
- Identify and cover likely reporting clusters.
- Identify consistent safe-use problems and administration mistakes.
- Deliver a national safety monitoring system that ranges to all general population for response to public health emergencies (Griffin et al 2009:s346; Shimabukuro, Nguyen, Martin & DeStefano 2015:4401). VAERS admits all reports without rendering judgment on medical benefit or whether vaccine(s) might have caused the adverse event (Shimabukuro et al 2015:4401).

2.4.3.5 Impact of vaccine post licensure (marketing) surveillance

There are different instances of how passive post marketing surveillance has confirmed its capability to identify infrequent adverse events that were either not identified or partly known during pre-market clinical trials. One instance of the benefit of voluntarily reporting of a newly clarified AEFI was verified in 1999 in the USA by the identification of the relationship between intussusception and Rota Shield, which consequently drove to the removal of the Rota Shield vaccine. The first rotavirus vaccine/Rota Shield (Rota virus, Live, Oral, Tetravalent – Wyeth) was approved and suggested for routine use in the USA (Cashman, Macartney, Khandaker, King, Gold & Durrheim 2017:165; WHO 2009:3) by the Advisory Committee on Immunisation Practices (ACIP) in 1998. On July 16, 1999, the VAERS reported 15 cases of intussusception among receivers. The CDC positioned a provisional interruption on routine administration until a case control investigation could evaluate these cases (Schwartz 2012:288). This investigation demonstrated a strong relationship between Rota Shield and intussusceptions, prompting the ACIP to be removed of its suggestion for routine use in October 1999. The manufacturer spontaneously removed this item from the market shortly afterward (Larson et al 2012:4-5).

2.4.3.6 Trends of vaccine safety surveillance

Lei et al (2018:1577) indicate the use of new global indicators for ISS and reporting patterns of AEFI which aimed to establish patterns in the AEFI reporting ratio worldwide and among the six WHO regions in a study done from 2000-2015. The number of AEFI reports communicated every year from 2000-2015 was shown in the WHO/UNICEF joint reporting form on immunisation. The AEFI reporting ratios were calculated to detect WHO countries that fulfil the minimum reporting ratio of 10, a proxy indicator for a well-functioning system for AEFI reporting. Countries reporting any AEFI varied from time to time but scaled up from 32 (17%) in 2000 to 124 (64%) in 2015. Worldwide, the mean AEFI reporting ratio was 549 AEFI reports per 100,000 living infants in 2015. Countries with AEFI reporting ratios greater than 10, increased from 8 (4%) in 2000 to 81 (42%) in 2015. Sixty percent of countries in the WHO Americas Region reported at least 10 AEFI per 100,000 living infants, followed by 55% in European Region, 43% in Eastern Mediterranean Region, 33% in Western Pacific Region, 27% in South-East Asia Region and 21% in African Region in 2015.

2.5 HEALTH CARE PROVIDER KNOWLEDGE, PERCEPTIONS AND PRACTICE ON VACCINE SAFETY SURVEILLANCE

Spontaneous surveillance is the means of getting information passively from those who are willing to share their experiences without exerting active effort to detect and gather information. Therefore, VAERS particularly relies on health workers' perceptions and practices but also care givers', parents' and patients' support in distinguishing and reporting rare AEFI or suspected vaccine safety problems (Shimabukuro et al 2015:2).

Globally surveillance system of most AEFI and ADR reports are sent from health care providers (Amarasinghe 2012:86-89). In their view, Mehmeti et al (2017:2) acknowledge that the KAP of health professional AEFI reporting is an insufficiently studied concern and little is known related to variables which support or impede health professionals' AEFI reporting. Only few studies that concentrate on health care providers AEFI reporting, have been conducted to date and those studies are reviewed and presented below based on knowledge, perceptions and practice categories.

2.5.1 Health care provider knowledge

2.5.1.1 Health care provider vaccine safety surveillance knowledge

Knowledge is a more complex concept to define. Among the major repeatedly referred functioning definitions of knowledge, Thomas Davenport and Laurence Prusak has framed it: “Knowledge is a fluid mix of values, contextual information, framed experience, and expert view that gives a framework for evaluating and including new practices and information (Bolisani & Bratianu 2018:13). One of the key indicators for institutional knowledge depends on the capability of institutions and individuals within them to share knowledge among each other, especially institutional knowledge (Funmilola 2015:2).

Job-related knowledge or job knowledge is the knowledge that individuals have in connection with the jobs they are doing. Knowledge related to a job encompasses job connected units which are beneficial to the existing job, such as operational thoughts, behaviours, standard operation procedures, institutional routines, context and client knowledge, as well as individuals’ views and their previous work experience (Pangil & Nassrudin 2012:351).

The population receives contradicting information about the relevance and safety of immunisations from a variety of sources including HCPs and the media (Buxton, McIntyre, Tu, Eadie, Valencia, Remple, Halperin & Pielak 2013:e516). It is relevant to enhance awareness of vaccine safety, to decrease the frequency of vaccine adverse events and sustain population trust in vaccines and thus ensure the production and utilisation of safer vaccines. In order to obtain and sustain population trust in the safety of vaccines through proper AEFI surveillance, HCPs have important and crucial roles to play. These roles encompass delivering evidence supported information on the relevance and adverse effects of vaccines: detecting and reporting of AEFI (Mohammed et al 2018:82). According to Brown, Oluwatosin and Ogunde (2017:2) in Nigeria inadequate knowledge levels regarding vaccinations and their incapability to talk clearly with care takers about immunisation have been detected as some of the reasons children are under immunised.

In a survey done in Sri-Lanka on AEFI surveillance, the knowledge of nurses on AEFI was examined. The findings indicate that the knowledge levels differed on various issues

of AEFI surveillance under investigation by the MOH, Sri-Lanka in 2012 (Masika et al 2016:15-16).

Human capacity development in low- and medium-income countries is an essential priority in order to cover numerous vaccine safety concerns that can alter the achievement of immunisation programmes. Enhanced capability in relation to expertise should also be supported by the advancement of an infrastructure that assists continuous monitoring of the safe utilisation of vaccines (Masika et al 2016:16; Zuber 2009:705). A descriptive study carried out on KAP of staff on AEFI at Shadong province in China indicates that most staff had general but not detailed knowledge about AEFI (Masika et al 2016:16). A study in the USA on vaccine safety among 293 recruited HCPs found that sixty percent of them knew how to report a suspected AEFI using the reporting system (Masika et al 2016:4). However, in another study in the USA among physicians, pharmacists and nurses that reviewed reporting systems, the frequency of reporting of vaccine adverse events, beliefs and awareness of AEFI found that 17% were not aware of how to report. In addition, research examining Canadian family physician's awareness of vaccine related adverse reactions, assert that less than half of the research participants were aware of a monitoring system for AEFI, one-third knew of the reporting indicator and one quarter gained training on vaccine adverse events during medical education. Another study from the United Kingdom on AEFI reporting of meningococcal sero group C conjugate vaccine found that nurses reported AEFIs more frequently than general practitioners and hospital doctors (Ogunyemi & Odusanya 2016:80; Parrella, Mayer, Gold, Marshall & Baghurst 2013:2).

Health professionals' awareness on AEFI and their reporting knowledge, practice, and approaches in Albania found that only 12.7% had good knowledge level on AEFI. Most of them 52.9% had fair knowledge level and a considerable proportion 34.3% had poor knowledge level (Mehmeti et al 2017:7).

According to Ogunyemi and Odusanya's (2016:81) study on primary HCP's knowledge and reporting practices on AEFI survey in Alimosho, Lagos, the most repeated AEFI symptoms identified by the participants were fever (84.8%), redness (82.9%), swelling at injection site (89.6%) and pain (83.5%). Less than half the number of the respondents was familiar with encephalopathy/encephalitis, hypotonic or hypertonic response episodes and convulsion/seizure as symptoms of AEFI. More than two-thirds of the

respondents knew correctly that all cases of immunisation-related hospitalisations (69.5%), immunisation-related unusual medical incidents (69.5%) and immunisation-related deaths (67.1%) were reportable AEFIs. Over half (57.9%) of the participants were also aware that low-grade fever (<38°C) was not a reportable AEFI. Two-thirds (68.9%) of the participants, however, incorrectly acknowledged that redness around injection site was a reportable AEFI. Most of the respondents (92.7%) knew about filling an adverse event form as a method of reporting AEFI, as well as reporting through telephone calls (65.2%). Over half of the respondents (56.1%), however, knew talking about AEFI with colleagues was not a method of reporting AEFI. One hundred and thirty-one (79.90%) health care workers gained greater than 50% of the scores on knowledge of AEFIs and were categorised as having either fair (55.5%) or good (24.3%) knowledge.

Yamoah, Bangalee and Oosthuizen's (2019:1) case study from Ghana on knowledge and perception of AEFI among HCPs in Africa reveals that knowledge of AEFIs was high in (10.8%) respondents, moderate in (47.0%) respondents, and low in (42.2%) respondents.

AEFI surveillance from 2009-2010 in Kwekwe District, Zimbabwe, found that none of the health care providers could perfectly describe an AEFI. Among all the respondents, 80% knew the number of forms filled on notification and reporting AEFIs though only (60.7%) knew the correct notification time for a severe AEFI case. In addition, 45.7% knew minimum of two possible manifesting signs of AEFIs (Muchekeza et al 2014:2).

Zvanaka et al (2017:3) confirm that on AEFI surveillance system evaluation in 2016, in Harare City, Zimbabwe, 98% knew the aim of AEFI system and were conscious of who handles which form, 94% knew a minimum of two manifesting signs of AEFIs, 77% knew the right schedule of submitting the form to the next level. The degree of knowledge among nurses was considered excellent (76%).

Masika et al's (2016:81) study on Knowledge, Perception and Practice (KPP) of nurses on surveillance of AEFI in Nairobi, Kenya states that some participants (37.4%) distinguished the causes of AEFI, 10.3% of the participants distinguished reportable AEFI cases, 25.5% mentioned that AEFI investigation should be initiated within 24 hours and less than 40% of the participants knew how to handle a child with post-immunisation

anaphylaxis. Generally, 194 (70.8%) of the participants had poor knowledge whereas 80 (29.2%) had good knowledge on AEFI surveillance.

2.5.1.2 Health care provider perceptions for immunisation safety surveillance

There are several descriptions and philosophies of perceptions. In a simple definition it is the process by which we interpret the world around us, creating a mental demonstration of the environment (Christopher [s.a.]:73-74). Individuals vary in their risk perception reliant on their life experience and knowledge, and their view that some risks may be more normal than others (UNICEF 2005:11). Enhancing the immunisation knowledge of care providers and their patients might change attitudes and subjective norms and thus scale up the utilisation of immunisation by both care providers and their patients (Buxton et al 2013: e516). Owino et al (2009) identified fear of AEFIs as having a role in contributing to the high vaccination dropout rates (Masika et al 2016:18-19).

As described by UNICEF (2005:14), from experience it is known that due to fright of guilt or fear sanction, several health workers do not report an AEFI. It is important to inspire and assist health workers particularly in cases of programme mistakes to report AEFI. Furthermore, the safety of the native health worker and vaccinator has to be guaranteed, if a real or perceived AEFI happens, as they might become target of aggression or be confronted of after by members of the affected community.

The effect of nurses' perceptions in relation to AEFI surveillance is not properly dealt with and documented (Mohammed et al 2018:82). According to MoH, Ethiopia (2011), poor inspiration and staff worries on the consequences of programmatic mistakes adversely affected AEFI surveillance, particularly on adverse events reporting (Ogunyemi & Odusanya 2016:3).

Garg, Sharma and Bajaj's (2017:1499) assessment of KAP of pharmacovigilance in a tertiary care hospital in India found that respondents were of the view that ADR monitoring was important (33%), and that it should be compulsory as was agreed upon by 67% of the respondents. Respondents acknowledged that 59% and 67% medical students and nurses respectively have a role to act in pharmacovigilance and 50% of respondents reported that monitoring of ADR station should be available in each hospital.

Mehmeti et al's (2017:13) study on knowledge, practice and approaches of HCPs to AEFI and their reporting in Albania explains that most of the participants (88.2%) perceived that increasing AEFI surveillance could enhance vaccine safety. A large number of participants (82.3%) replied that they considered the event was not connected to the vaccine and because of this, respondents did not report.

Ogunyemi and Odusanya (2016:82) PHCW knowledge and reporting practices on AEFI in Alimosho, Lagos survey result clarifies the major common perceived challenges of not reporting AEFIs are not taking the event as connected to immunisation (56.1%) and inability to find AEFI reporting forms (50.6%), whereas the least perceived barrier to reporting AEFIs was lack of time (48.2%).

Evaluation of the AEFI surveillance system in Harare City, Zimbabwe, 2016 found that the majority (98%) of the nurses affirmed that filling of AEFI announcement form was their responsibility. Eighty three percent of nurses and all the 9 key informants volunteered to proceed be involved in the system (Zvanaka et al 2017:3).

A study on KAP of AEFI surveillance among nurses in Nairobi, Kenya indicates that 42% of the participants perceived that an AEFI reporting cannot lead to personal consequences. Of the total participants, 42.3% held the view that reporting an AEFI could make them feel guilty about having caused harm and be held responsible for the event. Some participants (25.2%) sensed that the procedure of reporting an AEFI was long and exhaustive although, 77.4% of them recognised that nurses play a key role in diagnosing, reporting, investigating, and treating AEFI. Remarkably, 93.8% of the participants needed to learn more about AEFI surveillance even if 9.9% of the respondents were not happy in investigating an AEFI. Generally, 150 (54.7%) of respondents had poor perceptions, while 124 (45.3%) of the participants had good perceptions (Masika et al 2016:2-3).

2.5.1.3 Practice of health care providers on vaccine safety surveillance

Health behaviours are any activities carried out for preventing or identifying disease or for improving health and wellbeing (Conner 2002:1). Behaviours have been affected by personality factors. Cognitive factors also determine whether a person practices health behaviour and may determine how other factors influence behaviour (Holdershaw & Gendall 2014:1). Different cognitive factors have been studied including perception of

health risk, efficacy of behaviours in influencing this risk, social pressures to practice the behaviour, and control over practice of the behaviour (Conner 2002:5).

VAERS inspires the reporting of entire AEFI of any vaccine approved in the USA. Reports can be sent by fax, online or by mail (*Understanding the vaccine* 2013:2).

Knowledge, attitudes and belief towards reporting of AEFI amongst the military health system study conducted in the USA, affirm that 54% of the respondents reported familiarity with the VAERS. The proportion of respondents who acknowledged reporting an AEFI was 71% and 90% of the respondents identified three factors deemed to facilitate AEFI reporting: training in detecting AEFI, information on when to report AEFI and information on how to report to the surveillance system (Li, McNeil, Pickering, Pemberton, Duran, Collins, Nelson & Engler, 2014:435). Another study on knowledge, attitude and beliefs of HCPs towards AEFI was conducted in Atlanta (USA). Results reveal that 40% of HCPs diagnosed at least one AEFI and the proportion of health care providers who had ever reported an AEFI to VAERS was 19% (Masika et al 2017:19-20). Another separate survey planned to explore demographics and professional factors, knowledge and attitudes of detecting and reporting an AEFI to VAERS, HCPs basis of information about VAERS and how to enhance conscientiousness of reporting, indicates that though 71 % were acquainted with VAERS, only 14% were tremendously accustomed with the paper reporting process, and an estimate of one third were not acquainted with when it was needed to report an AEFI. Roughly 40% of all study respondents had detected a minimum of one AEFI, with only 18% specifying they had reported to VAERS (Miller, Suragh, Hibbs & Cano 2018:8). McNeil, Li, Pickeringa, Real, Smith and Pembertonc's (2013:2673) study on who is unlikely to report adverse events after vaccinations to the VAERS found that of the participants, 73% reported that they would report a severe form of AEFI when they know it and 62% reported even if the event was unknown about its association with immunisation. Respondents who specified that they were not accustomed with submitting a paper report to VAERS were more likely (OR: 12.84; $p < 0.001$) not to report an AEFI than respondents who were well accustomed with that procedure. Participants who were not totally accustomed with reporting standards to VAERS tended not to report, compared to participants who were very or extremely accustomed with the necessities (OR: 5.52; p: 0.013).

Knowledge, practice and approaches of health care providers to AEFI and their reporting

in Albania affirms that although most (70.5%) of health care providers had faced an AEFI during their practice, (36.2%) of them had never reported an AEFI and only 31.4% specified that they ever filled an AEFI reporting form. Although most (63.7%) of the respondents responded that they knew how to complete an AEFI reporting form but 31.4% of them had never filled an AEFI reporting form. Though 70.6% of respondents knew from where to obtain an AEFI reporting form, only 63.7% of them really had the AEFI reporting form in their work setting (Mehmeti et al 2017:11).

According to Garg et al (2017:1500), tertiary care hospital assessment Pharmacovigilance KAP among interns in India found that 50% of them had seen an ADR and 42% knew how and where to report it.

Despite good reporting rates, investigation of AEFI was still a main problem with most of the cases not being investigated (MOH Sri-Lanka, 2012). The WHO (2011) emphasises that if AEFI cases are not reported for a long period of time, health workers lose the desire or forget suitable processes to treat AEFI cases (Masika et al 2016:18).

In a qualitative study amongst health care providers in Australia, some respondents cited either being busy to fill reporting forms or the reporting system being too difficult as an obstacle to their participation in AEFI surveillance (Parella et al 2013:8).

A survey of knowledge and reporting practices of PHCWs on AEFI in Alimosho, Lagos confirms all health care workers who had encountered AEFI in their practice reported (51.5%) or treated/reassured the patient (47%). Of the 34 respondents who had encountered the AEFI, more than half used a reporting form, 20% made telephone calls and 5% reported using electronic mails. About 56% of respondents reported AEFI encountered either immediately or within 24 hours. Of 55 health care workers, 31 who had encountered an AEFI, reported within 24 hours of seeing such (Ogunyemi & Odusanya 2016:82).

Surveillance of AEFI in Kwekwe District, Zimbabwe, 2009-2010 illustrates that among 61 HCPs interviewed, 54 (88.5%) responded that filling AEFI surveillance forms was part of their responsibility (Muchekeza et al 2014:2).

Zvanaka et al (2017:3) express that AEFI surveillance system evaluation in Harare City,

Zimbabwe in 2016 within 24 hours all adverse events were reported to the districts. The three meetings' minutes were organised and two inspections held in 2016 found reflecting the system was considered adequate.

Nurses' KPP on AEFI surveillance in Nairobi, Kenya affirms that a majority of nurses (85.8%) had no anaphylactic packet with adrenaline in their immunisation rooms. Some nurses (32.1%) ever had identified a child with BCG lymphadenitis, abscesses, shock, injection site swelling and redness, convulsion, fever >40^{O}C or acute flaccid paralysis. Even if 44.5% of the nurses had ever observed an AEFI reporting and investigation form but only 2.3% of them had ever been involved in AEFI investigation. Few (2.3%) of the participants had ever reported an AEFI. Generally, regarding AEFI surveillance, 88 (32.1%) of the participants had good practice and 186 (67.9%) of them had poor practice (Masika et al 2016:2).

2.6 HEALTH CARE PROVIDER ADVERSE DRUG REPORTING

Adverse drug reactions (ADRs) are described as any response to a drug which is harmful and accidental and happens at dosages usually used in man for prophylaxis, investigation or treatment of disease or the adjustment of physiological function (Reumerman, Tichelaar, Piersma, Richir & Agtmael 2012:307). Worldwide, the patterns of ADRs have been enhanced in numerous countries, such as Norway (11.5%), Sweden (12%), New Zealand (12.9%), and Australia (16.6%) leading to improvements both in the hospital and community settings patient-related illness and death (Almandil 2016:1359-60; Miller, Valenti, Britt & Bayram 2013:1).

As there are few studies relating to health care professional AEFI reporting, studies assessing rationales why ADRs are not reported, may provide to some degree, recognition of variables valid to rationales related with AEFI poor reporting rate (Parrela 2014:28).

Pharmacovigilance (PV) is the discipline and the actions with regard to the collection, identification, reviewing, knowing and the counteraction of adverse effects or any other drug-related problems (Farha, Hammour, Rizik, Aljanabi & Alsakran 2018:611; Hardeep, Bajaj & Kumar 2013:97). The international pharmacovigilance system requires the presence of information conversation and communication about vaccine safety using

usual terminology that is easy and not very complex, nevertheless yet has the necessary consistency. For this aim, Council for International Organisations of Medical Sciences (CIOMS) have already (1999) published defined terminologies and indicators for reporting ADRs, covering those for vaccines (WHO 2012b:11).

The reporting flow of an AEFI is similar to ADR in many PV systems. ADRs are worldwide difficulties of most concern (Tew, Teoh, Baidi & Saw 2016:1). In pharmacology, a drug is a known chemical substance other than a nutrient of a necessary dietary element, which, when given to a living organism, yields a biological outcome (Definition of drug 2019).

Many countries do not yet have systems for direct patient reporting of ADRs (Hunsel, Harmark, Pal, Olsson & Grootheest 2012:46). The Uppsala Monitoring Centre (UMC) in Sweden, remains the adverse drug reaction reports international database which was established in 1971. The system began with 10 countries that had previously founded national systems for voluntary adverse events reporting and was approved to contribute data (WHO 2013a).

One of the crucial roles of all health workers are spontaneous or voluntary reporting of suspected ADRs (Bhagavathula, Elnour & Jamshed 2016:1). However, approximately of all ADRs less than 10% are reported and that only 5% of medical professionals report to ADR systems (Goyal, Bansal, Yadav, Grover & Preetkanwal 2013:281). Both hospital based and general practices arrangements systematic review of 37 studies estimated the rate of under-reporting of all ADRs to voluntary reporting systems from 6% to 100%, with a median under-reporting rate of 94% (Hazell & Shakir 2016:385).

A severe and possibly lethal adverse events focused study done in Sweden found that over a period of five years, the total under-reporting rate was 86% (Parrella 2014:2018). Northern India, tertiary care hospital assessment on pharmacovigilance KAP found that 50% of respondents stated the correct meaning of PV and 59% of them agreed that PV incorporates all systems of medicine and had knowledge about drugs forbidden due to their ADRs. Forty-two percent knew where and how to report, and very few (9%) respondents were informed of what happens to the data shared by them (Garg et al 2017:1499-1501).

2.6.1 Findings of reasons for adverse drug reactions under reporting

Research done in the USA on 293 participants, physicians, pharmacists and nurses or nurse practitioners found that gaps to reporting included uncertain definitions of a reportable AEFI; shortage of time due to other priorities than to a report; and misunderstanding of who is responsible for reporting. Reporting was associated with being warned to see for exact events (87%); disregarding other clarifications for the event (81%); if the event was observed recurrently (71%) and if the events happened in susceptible patient groups such as infants, pregnant women or patients ≥ 65 years of age (44%) (Parrella 2014:26).

Forty-five studies done in Asia, Europe, UK, and the USA were systematically reviewed that assessed the personal and professional variables effect on ADR reporting and summarised the main contributors related with under-reporting. The most repeated attitudes that related to health care workers not reporting ADRs, were: negligence of what to report or absence of a reporting system in 95% studies; fatigue in 77% studies; hesitancy in 72% studies; indifference and insecurity regarding causation (impossible to confirm that the drug results in the event) in 67% studies; a perception that harmless drugs are out in the market in 47% studies; and fear of involvement likely participation in lawsuit or examination 24% (Agarwal, Daher & Ismail 2013:58).

A qualitative study on 16 community pharmacists reported misunderstanding of ADR and little knowledge of the presence of the pharmacovigilance system in Malaysia. The gaps identified in this study for reporting were the same as the findings obtained in the quantitative studies of ADR reporting: not able to identify an ADR, poor understanding of flow of reporting, reporting procedure difficulty and absence of feedback from leadership were distinguished (Parrela 2014:29).

As Tew et al (2016:1) point out, that under-reporting of AEFI may happen because of shortage in identifying an ADR, it was concluded that doctors were not reporting AEFI even when they encountered and identified it. A study in Kuala Lumpur, Malaysia indicates that of all 350 participants, 81.4% expressed that even if they did not report ADR, they had suspected it, however around 40% of the participants were unclear about the presence of the countrywide reporting system in Malaysia.

Among health care providers' survey on the KAP of PV at a teaching hospital in South India, underreporting contributing to variables for PV was identified. From this study, the contributing factors for underreporting included no payment, time shortage to report ADR, perceptions that ADR database will not be affected because of one unreported case, and a challenge to define if ADR happened or not. Additional rationales were shortage of training, unfamiliarity related the ADR reporting form, unawareness of the rules, and process for reporting (Gupta, Nayak, Shivaranjani & Vidyarthi 2015:47).

A total of 306 health care workers from 169 health institutions were involved in a study on barriers to reporting AEFI through HCPs in four regions of Ghana. One hundred and twenty health care workers mentioned numerous shortcomings to report AEFI; the major usual shortcomings were fear of individual consequences (44.1%), lack of knowledge or training (25.2%), and not perceiving an AEFI was severe or sufficient to report (22.2%) (Gidudu, Shaum, Dodoo, Bosomprah, Bonsu, Amponsa-Achiano, Darko, Sabblah, Opare, Nyaku, Owusu-Boakye, Oduro, Aborigo, Conklin, Welaga, & Ampadu 2020:1).

AEFI surveillance system evaluation in Guruve district, Zimbabwe found that 45% of the HCPs had encountered AEFIs, but none had been reported. The major rationale for defaulting to notify AEFIs incorporated HCP's fright of personal consequences and an assumption that an adverse event was not severe enough to notify (Constantine, Cremance, Juru, Gerald, Notion, Peter & Mufuta 2018:1).

2.7 DIFFERENCE BETWEEN VACCINE REACTION AND DRUG REACTION

A drug level of risk is much tolerable than a vaccine level of risk. An instinctive hazard is perceived as higher than a willingly taken hazard (Glassman & Weber 2016:157-158). This reality further decreases acceptability for AEFI if there is any element of coercion in the immunisation programme. In addition, contrasting with drugs, vaccines are given not merely for the advantage of the single person, but also for the advantage of the population. Therefore, AEFI can be taken that the concern of the population, contrasts with drug reactions. A surveillance system for ADR being used to monitor AEFI does not impede through these variances, but the surveillance has to be very specific to the definite properties of vaccines. In several countries the AEFI surveillances with a single follow up system is likely to be unnoticed. AEFI reporting and response requires various mechanisms to be incorporated into the available ADR surveillance system. The

immunisation programme reporting mechanism may not be part of the common drugs reporting system and also the greatest efficient means of adverse events data gathering and reports may vary for vaccines and drugs. Vaccines and drugs adverse events causation, examination and exploration are conducted in different ways; AEFI examination needs various kinds of capabilities and knowledge of immunisation programmes. The primary aim for immunisation safety surveillance is to detect and take action for immunisation errors and to lessen additional likely AEFI. An AEFI degree of consequences completely vary, since a batch is administered to a significant portion of the population, compared to adverse events related to a drug that it is only taken by comparatively few targets of users. Hence, AEFI intervention and communication are both more essential to the wellbeing of the masses, who have an interest, and which may be difficult to convince otherwise. Vaccines are used on larger scales and exposes them to more coincidental events, but these are related to immunisation in a short period of time (Bisetto & Ciosak 2017:82; WHO 2015a:35).

2.8 HEALTH SERVICE DELIVERY SYSTEM

2.8.1 Delivery of service

Delivery of service is the health system efforts of an instant desirable outcome through the health workforce. Assuring health services availability that fit a highest quality indicator and getting access to health services are core components of the health system. Both service providers and receivers' successful implementations depend on the acceptability of the services (Sekhon, Cartwright & Franc 2017:1).

The discourse on Human Resource for Health is developing from a special emphasis on obtainability of health workers, which means that numbers are equally important to accessibility, acceptability, quality and performance. Availability– fitting the health requirements of the public through a combination of abilities and skills, with adequate provision and proper variety of health workers; Accessibility – the reasonable distribution of workforce taking into account the socio-demographic structure, combination of urban-rural and disadvantaged places or populations; Acceptability – features and capability of health personnel (for example age, sex, language, culture, etc.) to manage patients with self-respect, creating trust and encourage increased demand for services; Quality – knowledge, behaviour, capabilities and skills of health personnel that are measured

acceptable norms and as perceived by beneficiaries. Accessibility cannot be ensured in the absence of adequate availability; if the health workforce is available and accessible, in the absence of acceptability, the health services may not be utilised, when the quality of the health workforce is insufficient, there will not be reasonable progress in health outcomes (Global Health Work Force Alliance 2018:1).

As MacDonald and Law (2017:1) in Canada point out, the current practice of eight components of vaccine safety system are strong regulations for manufactures, evidence based pre-marketing review and approval process, Pharmacovigilence programmes to detect causality of adverse events, independent evidence based vaccine use recommendation, a programme for vaccine safety and efficacy signal detection, immunisation competency training and standards for HCPs, determine causality of AEFI, specific vaccination clinics for children who have experienced severe AEFIs with immunisation.

Services' physical presence can function as a base for deciding strategy to improve service provision (Ware 2013:4). One of the most significant noncash obstacles, which hinder access to health service, is known to be distance, specifically in rural settings. Lengthy topographical distances to a health care worker combined with a shortage of transportation services can negatively impact the use of health care and health benefits (Kumar, Dansereau & Murray 2014:4092).

The effect of distance and level of service delivery on Antenatal Care (ANC) utilisation in rural Zambia, shows a robust effect of both distance to a facility, and level of delivery at the nearest ANC facility on the quality of ANC received; for every 10 km increment in distance, the odds of women getting good quality ANC were reduced by a quarter, while every increase in the level of provision category of the nearest facility was associated with a 54% increment in the odds of getting good quality ANC (Kyei, Campbell & Gabrysch 2015:1).

2.8.2 Service delivery monitoring system

It is essential to decide the proportions along which progress would be measured in order to follow developments in improving health service provision. The amount of health services and type of organisation may vary from one country to another, while in any

health system the pattern of service provision should have the following vital features: accessibility, continuity, comprehensiveness, coverage, quality, person-centeredness, efficiency and accountability (WHO 2010:2-3).

Service provision controlling has an instant relevance for health services management that identifies this section from other health systems building blocks. Unequal flow of health services, lack of drugs and the presence of supplies or guidelines all must be considered as part of fundamental management of health service (*Service delivery* … 2018:1-12).

Irrespective of the setting, information should advisably be gathered and available at the district level. Principally the base for controlling health system properties are designed at the district level because information important for decision making is available there. Therefore, the key goal is forming a district-based system with the support of the national or regional or provincial levels (Frontline Service Delivery Monitoring … 2017:10; WHO 2010:7).

2.8.3 Health care provider training in vaccine safety surveillance

Vaccination programmes need special training methods (Ildarabadi, Moonaghi, Heydari, Taghipour & Abdollahimohammad 2015:1). Importantly, HCPs central role is preserving population trust related to vaccines, thus it is important to be ready with current information and have confidence in delivering advice when fears are expressed (eHealth Ontario 2014:4). Hardt et al (2013:216-217) highlight that community engagement is further supported through better designed communication materials when shared through proper channels.

UNICEF (2005:11-14) points out that having a communication plan, good preparation, training of staff and partners usually protected an AEFI caused crisis. Training and development of health care providers will be reflected in their perception and practice. Health professionals and vaccinators should be trained for the skills of interpersonal communication (IPC) with families and communities.

Parents seek foremost from health workers instructions related for the safety of vaccines. Therefore, it is vital that health workers should be prepared to react definitely to a broad

spectrum of caretakers' issues. Occasions where there has been reduction of health professional confidence in immunisation safety have been followed by major decrease in immunisation rates (Leask, Quinn, Macartney, Trent, Massey, Carr & Turahui 2008:224).

Courtot, Brinkman and Ruttenberg (2014:2) stress that clear knowledge on the relevance of immunisation and potential adverse events is required by health workers and vaccinators and they need to be able to communicate these openly to parents. Furthermore, Okueso and Oke (2017:59) note that an operative surveillance system should confirm HCP training and understanding of surveillance processes of vaccines since it is a central constituent of the system. Pre/post service training and practical practice are the means for health care providers to gain vaccine safety knowledge (Doherty, Buchy, Standaert, Giaquinto & Cohrs 2016:6708; Hardt et al 2013:6701).

In order to deliver operative immunisation facilities, PHCWs working at the ground level need to have on-going updated information about immunisation to keep them competent with the basics of immunisation and the fundamental practices relating to immunisation programme. In addition, health workers' perception and behaviour will reveal their training and development, regular education can enhance their knowledge base and skill level, it can alter their actions and perception, and improve health outcomes (Jelleyman & Ure 2015:1; Leask, Willaby & Kaufman 2014:2601).

Masika et al (2016:15) explain that health professionals should show capability, current evidence-based knowledge and understanding of AEFI. In trying to establish the familiarity of health workers in the USA with VAERS it was found that such familiarity was dependent on AEFI training. Training was associated among HCPs with greater AEFI reporting rates, particularly among nurses.

Although training is mandatory for health care providers, only few countries have developed the systems to update personnel on AEFI surveillance. Of the studied 26 European Union countries, only 35% had ready knowledge enhancing mechanisms such as a training schedule or manual for nurses on prevention, differentiation and management of AEFI. This is an indication that health professional training programmes are clearly abandoned not only in the European Union countries but also in most parts of the globe (Kurstak 2009:3380; Masika et al 2016:15).

Immunisation safety surveillance should incorporate training that promotes appropriate response in the entire system. The individual accountable for immunisation safety surveillance requires to be updated about the current preparation in safety, controlling, and emerging issues related to immunisation (Mohammed et al 2018:82).

From 2009-2010 AEFI Surveillance in Kwekwe District, Zimbabwe shows below half (43.5%) of respondents had gained prior education on AEFIs (Muchekeza et al 2014:2).

Masika et al (2016:42-43) KPP of AEFI surveillance study in Nairobi, Kenya found that more than half of the number of participants (51.8%) had no previous training in AEFI. Most of the participants (77.3%) with prior AEFI training grasped good knowledge in AEFI surveillance (χ2: 71.79; P < 0.0001). Additional binary logistic regression analysis found that participants with previous AEFI training were 9.7 times more likely to have good knowledge towards AEFI surveillance (OR: 9.65, 95% CI: 5.55–16.78; P < 0.0001). Respondents with previous AEFI training were 2.7 times more likely to have good perceptions related AEFI surveillance (OR: 2.67, 95% CI: 1.64–4.35; P < 0.0001). Those with previous AEFI training were 1.8 times more likely to have good practices in AEFI surveillance (OR: 1.78, 95% CI: 1.09–2.89; P=0.021).

2.8.4 Guidelines for service providers

Guidelines are commendations planned to support providers and receivers of health care and other stakeholders to make informed decisions (WHO 2012a:1). The WHO has readily available generic guidelines for AEFI surveillance that can be modified to local situations and structures since 1999 (Zvanaka et al 2016), and 70% of countries reported having a national AEFI surveillance system in 2003 compared with 53% in 2001. Functionality of some populated countries surveillance system casts doubt due to the absence or small number of AEFI reports (WHO/UNICEF 2005:146-147).

LMIC are low utilisers (Burton, Bigogo, Audi, Williamson, Munge & Wafula 2015:2) of standardised safety protocols and practices (for example International Classification of Diseases, Uppsala Monitoring Centre, Brighton Collaboration) and have uncertain capability for the identification of AEFI that remains under-reported and under-investigated (Graham et al 2012:4953). Yamoah and Oosthuizen (2018:46) acknowledge that globally, AEFI reporting remains to be a difficulty. It is approximated that about 95%

of AEFIs do not ever get reported following immunisation demanding means to advance it.

Guidelines of the WHO refer to any paper consisting of endorsement about health activities, whether these are clinical, public health or policy recommendations. A recommendation provides information about what policy-makers, HCPs or patients should practise or do (WHO 2012a:1).

According to Brown et al (2017:2), the 2009 national immunisation policy of Nigeria outlines that, to increase immunisation providers' knowledge and practice, guidelines are important for constant on-the-job training for health professionals on immunisation biannually. It is not clear if entire levels of the health care system successfully practised this part of the policy.

Ethiopia has developed AEFI surveillance guidelines based on WHO Immunisation safety surveillance guidelines through EFMHACA (EFMHACA 2016:1-87). However, EFMHACA has no official structure below the regional level. Similarly, the AEFI guidelines do not mention a report channel, but simply state that AEFI cases should be reported to a higher level and also lack clarity on the type of AEFI to be reported (EFMHACA 2016:43-44). In addition, there was no properly documented reported AEFI case in the country (FMOH Ethiopia 2015:1-187).

On the other hand, the WHO has developed different immunisation safety surveillance related- guidelines like global manual on surveillance of AEFI (WHO 2016:1-124), vaccine safety basics learning manual (WHO 2013a:1-207), ISS guidelines for immunisation programme managers on surveillance of AEFI (WHO 2015b:1-120), vaccine safety and the management of AEFI (Green Book 2012:1-15), causality assessment of an AEFI (WHO 2013b:1-56), AEFI surveillance and response guidelines (WHO 2010:1-156). The Global manual on surveillance of AEFI clearly has a chapter on reporting AEFI, but this is not clear in the Ethiopia AEFI surveillance guidelines (EFMHACA 2016:1-87; WHO 2016:43-48).

In this study, the guidelines are reviewed compared to the study findings and the global AEFI surveillance guidelines, so that the AEFI guidelines would be comprehensive, which is one of the objectives of this study.

2.9 THE THEORY OF REASONED ACTION (TRA)

Martin Fishbein first introduced the TRA in 1967 in an effort to know the association concerning attitude and behaviour. Tlou and Dyk (2009:26) explain, by referring to Ajzen and Fishbein (1980), the TRA is grounded on the assumption that human beings are reasonable and act according to systematic use of existing information. Before people decide whether to engage in a given behaviour, they take into consideration the consequences of their actions. The TRA describes the association among *beliefs, attitudes, intentions* and *behaviour.* According to TRA, the primary cause of behaviour is behavioural *intention*. In turn, behavioural intention is a combination of an individual's attitude toward acting the behaviour and subjective norms (Holdershaw & Gendall 2014:2-6). Nevertheless, these theories are specifically used to assist describe patient behaviour, however, Millstein (1996) argues that they should also be applicable to physician behaviour. For example, Perkins et al in their literature review, they identified nine studies that implemented one or both of these theories to physician populations on various topics, detailing mammography screening Taylor's 1994, intention to prescribe antibiotics and provision of STI education services to adolescents, Millstein 1996 (Roberto, Krieger, Katz, Goei & Jain 2014:305).

The theory of planned behaviour (TPB): Ajzen, extends the TRA by making a direct connection from perceived behavioural control to both behavioural intention and behaviour. Different meta-analyses offer consistent support for the ability of both theories to predict intentions and behaviour (Ajzen 1991:179; Roberto et al 2014:305).

The TPB, has been used to isolate variables associated with the intention to exercise behaviour, including being immunised (Wiemken, Carrico, Kelley, Binford, Peyrani, Ford, Welch & Ramirez 2015:2). According to the TPB, human action is directed by three types of thoughts: behavioural beliefs; normative beliefs; and control beliefs. For example, to encourage utilisation of HPV vaccine, one barrier can be HCP lack of time. Another barrier is perception of risk; if users do not sense that they are at risk of being infected by HPV and interrelated diseases, they are less likely to be immunised. In addition, the price of the antigen tends to be exclusive for some patients (Britta, Hatten & Chappuisa 2014:53).

2.9.1 Determinants of behavioural intentions

Behavioural intentions have two causative factors, namely the personal or attitudinal component and the social or normative component. These determinants are discussed (Tlou & Dyk 2009:29).

2.9.2 Attitude towards behaviour

It makes sense that attitudes should guide behaviour and it has been a central focus of persuasion (Frymier & Nadler 2017). The attitudinal component refers to a person's attitude towards exercising the behaviour under consideration (Holdershaw & Gendall 2014:2). People's likelihood of accomplishing a specific behaviour will be robust if they hold a positive attitude related to the accomplishment of that behaviour. Fishbein (1993) refers to a difference between attitude towards an *object* (for example, attitude towards AIDS) and attitude towards a *behaviour* (for example, attitude towards seeking an HIV test) in relation to an object (*Behavioural beliefs and attitudes* 2017:8; Tlou & Dyk 2009:29). In this study, it could be likened to attitudes towards vaccine/s, attitudes towards immunisation/vaccination and attitude towards AEFI surveillance.

2.9.3 Subjective norm

Subjective norm denotes a person's perception of the social pressures to act or not to act on a given behaviour. The subjective norm is decided by whether relevant referents accept or reject the accomplishment of behaviour, influenced by his/her motivation to comply with those referents. These beliefs, which underlie a person's subjective norm, are called *normative beliefs*. This means that individuals are likely to perform behaviour when they evaluate it positively and believe that significant others think they should accomplish it (*Behavioural beliefs and attitudes* 2017:9).

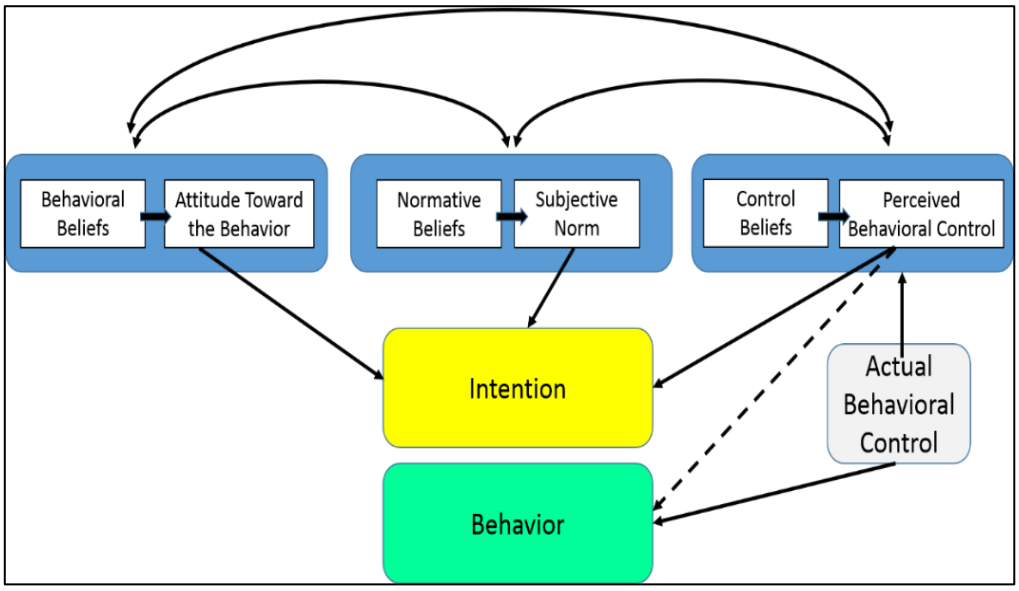

Figure 2.1 Determinants of behaviour

(UK essays 2017:9)

2.10 HEALTH CARE PROVIDER MOTIVATION

2.10.1 Motivation

Motivation in a work setting can be framed as an individual's degree of readiness to apply and conserve a resource towards organisational goals (Weldegebriel, Ejigu, Weldegebreal & Woldie 2016:159). Motivation is not a trait of the individual or the organisation: rather, it comes from the deal between individuals and their work environment (Sonnentag, Volmer & Spychala 2012:437).

Work motivation exists in the presence of an agreement between an individual and institutional objective: when accomplishment of organisational goals is associated with personally wanted results, such as a feeling of accomplishment or gaining of monetary incentives. Though it is not possible to quantify motivation directly, it is possible to measure the contributions (or elements) and the results of the motivational process. The process of work motivation functions in two interconnected psychological foundations:

A. The "will do" part: the extent workers adopt organisational goals.
B. The "can do" part: the extent workers mobilise effectively their personal resources to accomplish common goals (Franco, Bennett, Kanfer & Stubblebine 2000:1).

2.10.2 Health worker motivation

Health sector accomplishment is highly dependent on worker motivation (Borghi, Lohmann, Dale, Meheus, Goudge, Oboirien & Kuwawenaruwa 2017:193). While guaranteed resource availability and worker capabilities are vital to worthy service delivery, they are inadequate in themselves to guarantee anticipated worker performance. In addition, worker accomplishment relies on the servant's readiness to attend to work continuously, perform attentively, be resilient, and perform the required duties (Sonnentag et al 2012:428).

Service delivery in health care is extremely labour-intensive, and thus, service excellence, effectiveness, and fairness are all directly facilitated by workers' readiness to engage themselves in their duties (McPake, Maeda, Araújo, Lemiere, El Maghraby & Cometto 2013:841). Service providers' work satisfaction is mandatory in providing quality services. HCPs recognised nine organisational issues they thought affect their inspiration and accordingly work satisfaction. Participants outlined factors that influence their satisfaction with the job they were doing (Bonenberge, Aikins, Akweongo & Wyss 2014:4).

There are personal, institutional and environmental variables that affect a caretaker's job gratification and subsequently dedication in delivering quality services. Individual factors include age, personality, schooling, competences, and years of service (**Mosadeghrad** 2014:85; Weldegebriel et al 2016:163-65). Organisational variables incorporate management type, working situations, and contacts with staff working together (Bonenberger et al 2014:9; Mosadeghrad 2014:85). The provider's subjective characteristics, together with the attention they give to care, would have a regulating effect on the provision of care (Mosadeghrad 2014:85).

According to Mohammed et al (2018:82), AEFI surveillance, particularly adverse events reporting is negatively affected by lack of motivation and staff worries about consequences of programmatic mistakes. These comprise unconscientiousness, reporting system unawareness, fear of lawsuits, and inadequate time are some of the reasons. However, motivation together with training and supervision supported meaningful enhancement to reporting rates of AEFI in Ghana.

Availability of reporting forms for AEFI at the immunisation centres meaningfully affected the reporting. In Ghana's 10 months prospective study, Dodoo et al found a six hundred percent increment in AEFI reporting rate after training, supervision and AEFI reporting forms supply (Masika et al 2016:19-20).

Weldegebriel et al's (2016:166) study on health worker motivation and associated factors in Amhara public hospitals, Ethiopia, explain that health worker motivation was positively predicted by the management of performance (job descriptions, supervisions, on-going education, and performance appraisal). In their study, nearly 91% of participants replied that there was observable of progress with action nearly 57% of participants stating that their evaluation was used for improving performance.

2.11 INDIVIDUAL FACTORS

Different characteristics have been shown to contribute with to individual improvement in health practices (Conner 2002:4). Demographic characteristics show consistent relations with the improvement of health practices (Becker & Newsom 2003:742). According to Mosadeghrad (2014:81) the attributes and personality of HCPs change the quality of health care services.

A survey on KAP of nurses towards ADRs reporting was done in United Arab Emirates. Results reports that higher knowledge levels among nurses with degree education and those less than thirty years of age (John, Arifulla, Cheriathu & Sreedharan 2012:3).

Ogunyemi and Odusanya (2016:81) note that in a survey of knowledge and reporting practices of PHCWs on AEFI in Alimosho, Lagos younger age of health care workers was found to have a significant relationship (P=0.029) with knowledge.

Masika et al (2016:4) in AEFI surveillance of nurses KPP in Nairobi, Kenya explain that 56.6% of nurses with diploma or degree nursing education level, had good knowledge on AEFI surveillance (χ2: 5.23; P=0.022) and participants having diploma or degree training in nursing were 2.5 times more likely to have good perception towards AEFI surveillance (OR: 2.54, 95% CI: 1.55–4.17; $P < 0.0001$). Nurses having either diploma or degree nursing training (58.5%) and those with prior AEFI training (61.4%) had good perception

towards AEFI surveillance (χ2 13.93, P < 0.0001 and χ2 15.82, P < 0.0001), respectively. Likewise, those with diploma or degree level of nursing education were 1.8 times more likely to have good knowledge towards AEFI surveillance [OR: 1.76, 95% CI: 1.08–2.85; P=0.023]. Nurses practising in their thirties were five times more likely to have good practices towards AEFI surveillance (OR: 5.01, 95% CI: 1.88–13.30; 0.001). Additionally, the practice level towards AEFI surveillance also enhanced with years of experience since participants with minimum 30 years of work (75.9%) had good practice (χ2 31.47; P < 0.0001) and respondents aged 30–39 years were 3 times more likely to have good perception towards AEFI surveillance (OR: 3.28, 95% CI: 1.51–7.12; P=0.003).

2.12 PARTNERSHIPS IN IMMUNISATION SAFETY SURVEILLANCE

2.12.1 Definition of partnership

A partnership is formation of any number of stakeholders, known as business partners, who reach a consensus to collaborate to progress their shared welfare. The partnership parties can be individuals, businesses, need-based institutions, schools, public-private or joint (*Partnership* 2020).

2.12.2 Importance of partnership

It is important that all partners such as NIP, EFMHACA, vaccine developers, laboratories, HCPs and development partners expend intense energies to deliver documented evidence through a successful AEFI surveillance system. This will ensure the provision of up-to-date immunisation facilities to the population that incorporate successful controls and reaction to AEFIs. It is envisaged that stakeholders at all levels be part of the consortium of the AEFI surveillance system in Ethiopia (EFMHACA 2016:4).

2.12.3 Why partnership is important

Private sector health care provision in LMICs is occasionally described to be more efficient, responsible, and long standing than public sector delivery. Inversely, the government facilities are usually considered as giving more unbiased and empirical care (Basu, Andrews, Kishore, Panjabi & Stuckler 2012:2). The private sector indicates that as it has substantial role in the global health care provision based on the standardised

country target information based on its contribution to the total health expenditure. For instance, in 2014, the percentage of private sector share of total spending on health care surpassed 20% in 82% of 192 countries internationally and surpassed 50% in 30% of countries (WHO 2017:149), with great differences by the WHO region and country income status.

Contribution of the private sector in preventive services is often more restricted. For instance, in Africa, private sector contribution in preventive services was 45% in Nigeria, 30% in Uganda, but less than 20% in others. Faith Based organisations and NGOs are the major deliverers of private preventive care, usually in collaboration with the public sector (WHO 2017:6).

In Europe a project was developed to hasten progress of vaccine benefit-risk partnership on the principle that a harmonised, maintainable, on-going antigen controlling system is of utmost relevance for gaining updated, reachable information on the achievement, importance, hazards and effect of antigens. In order to develop and sustain population trust in vaccines and make informed decisions based on freely accessible information might be helpful and this in turn can be used for regulating vaccines, vaccination policies and individual vaccination. Hastened progress of vaccine benefit-risk partnership in Europe emphasises the use of obtainable, accessible, secondary European Union health care data, which could give global confirmation on vaccine benefit-risk an update on the utilisation of vaccines (Sturkenbooma, Bahrid, Chiucchiuinie, Krausef, Hahnég, Khromavah, Kokkii, Kramarzi, Kurzd, Larsonj, Lusignank, Mahym, Pagnonn, Titievskyo & Bauchaup 2019:3).

2.12.4 Who should be involved in the partnership of vaccine safety?

There is no completely safe and free of adverse events medical intervention involving vaccines. The commonest AEFIs are self-limited and minor and controlling officials are able to detect safety issues, perform continuous benefit-risk evaluations using the existing vaccine safety controlling and evaluation systems. The relevance of vaccination against severe adverse reactions and the associated risks are explored and triangulated. Furthermore, societal and behavioural studies are required in order to decide how to cover beliefs properly through appropriate advantage- disadvantage communication messages (Hardt et al 2013:216; Rath 2018:1038-41).

In order to make decisions on vaccines in an open and responsible way and to implement the plans of vaccine communication, health leaders are required to play a vital role. For industries to be reliable, they need to be dedicated to producing quality and effective vaccines for all countries and mechanisms should be transparent for vaccines safety during developing, production, and controlling (Hardt et al 2013:216).

According to Hardt et al (2013:217) it is paramount that to maintain confidence in vaccines, partnerships among all actors in the government health institutions be taken seriously such as, HCPs, policy developers, health authorities, central and sub-central institutions. Vaccine producers and others, are required to safeguard vaccine utilisation coverage, detect and consent to the introduction of new vaccines and keep population and others aware of the importance of vaccines and how regularly vaccines are explored, confirmed and to checked for safety.

2.13 SUMMARY

This chapter began with explaining the history of vaccines and vaccination and defined Adverse Events Following Immunisation (AEFI). It also presented reviewed literature related to the impact on adverse events following immunisation, health care provider knowledge, perception and practice towards immunisation safety surveillance. The chapter addressed TRA as it is the theoretical framework for this study and reviewed literature on health care provider motivation and individual factors. It also shows importance of partnership for concerted effort of immunisation safety surveillance implementation.

CHAPTER 3

RESEARCH DESIGN AND METHODS

3.1 INTRODUCTION

In this chapter, a detailed explanation of the research design and methods is presented. The research philosophy, mixed research design and rationale for why mixed methods are preferred for the study, research methods, sampling procedure, ethical considerations, methods of data collection, strategies to employee for ensuring research quality (reliability, validity and other quality control mechanisms) and data analysis are described and discussed.

3.2 PHILOSOPHICAL WORLD VIEW

Research philosophy is concerned with the means by which data about a phenomenon should be gathered. The knowledge development and understanding are influenced by a few assumptions centred on viewpoints of the world which are the practical thoughts while choosing a study title. A philosophical method allows the investigator to select which method should be adopted and why (Chetty 2016:1-2). According to Creswell (2018), while philosophical ideas continue mostly unseen in research, they still affect the practice of research and require to be recognised.

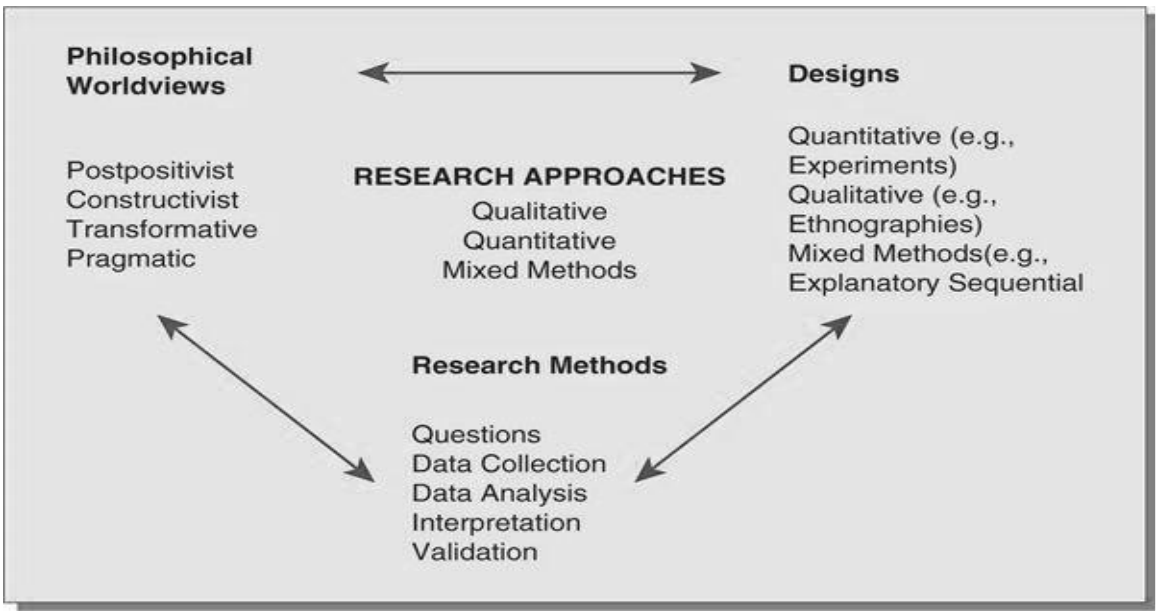

Figure 3.1 Framework of research − the interconnection of worldviews, design and research methods
(Creswell 2018:39)

3.2.1 The pragmatic worldview

Pragmatism developed from James, Mead and Dewey's work (Cherryholme 1992). As a worldview, pragmatism develops out of actions, conditions and consequences instead of antecedent situations. Researchers focus on the research difficulty and utilise all existing methods to clearly understand the challenge instead of concentrating on approaches. Pragmatism provides a philosophical basis for research and is not dedicated to one philosophy and reality. The pragmatic worldview applies to mixed methods research in which questionnaires are extracted freely from quantitative and qualitative assumptions.

- Principal investigators have a liberty of options in selecting research procedures, methods, and techniques that best fit their requirements and aims.
- Pragmatists do not consider the world as a single entity. In the same way, mixed methods investigators search for several strategies for gathering and analysing data rather than focusing solely on one way (quantitative or qualitative research designs).
- Reality is what exists at a time, as such it is not based on duality between realities independent of the mind. Hence in mixed methods research investigators apply both quantitative and qualitative data since they help to produce the best knowledge of a research problem.
- A pragmatic investigator searches for what and how to research depending on the planned outcomes-where they need to create a purpose for the mixing, a reason for justifying why quantitative and qualitative data are required to be combined.
- Pragmatists agree that research at all times happens in social, historical and other settings.
- Therefore, for the mixed method investigator, pragmatism unlocks the door to various methods, various worldviews and various assumptions comprising various types of data gathering and analysis (Cherryholmes 1992) and (Morgan 2007) cited in Creswell 2018:5).

This study is based on a pragmatic philosophical worldview, since it plans to address issues following consequences of actions that are problem-based. A pluralistic approach is used to explore problems that are real-world and practice oriented.

3.3 RESEARCH DESIGN

Research designs represent the overall means selected to be combined in a coherent and logical way to integrate the various components of the study. Others have named them strategies of inquiry (Creswell 2018:47). Several research methods texts confuse research designs with methods. It is common to look at research design managed as a mode of data gathering instead of as a logical order of the inquiry (Haradhan 2017:7).

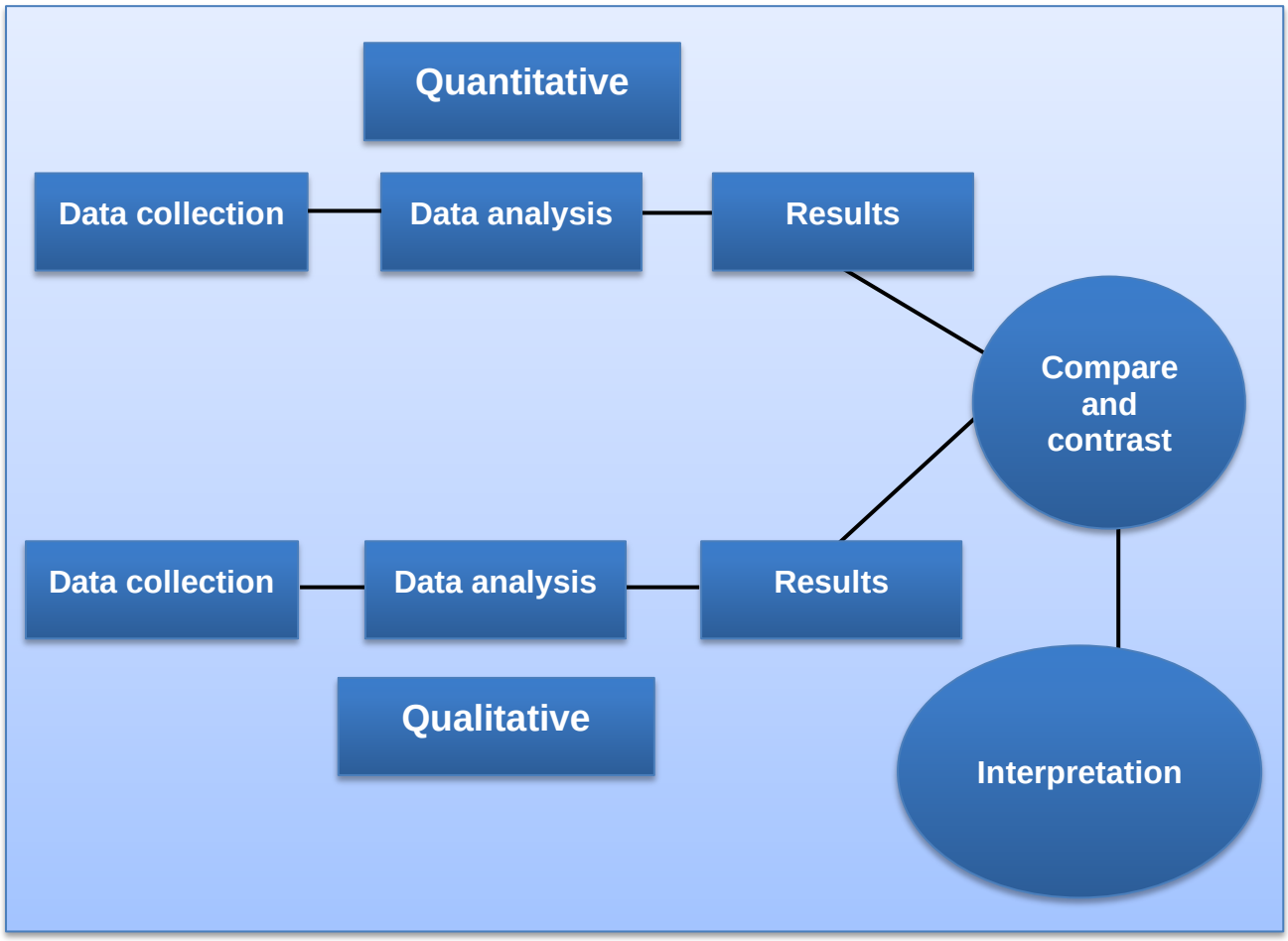

Figure 3.2 Mixed methods research design

(Wisdom & Creswell 2013)

3.3.1 Mixed methods research design

The term “mixed methods” denotes a developing methodology of research that involves the systematic integration, or “mixing”, of quantitative and qualitative data within a specific investigation or sustained programme of inquiry (Wisdom & Creswell 2013:1). According to Creswell (2018:47), quantitative data often comprises prearranged answers such as

available on questionnaires while qualitative data inclines to be open-ended without prearranged options. The area of mixed methods research is comparatively recent with most tasks in formulating it arising from the middle to late 1980s. Triangulating data sources, a way for looking at convergence across qualitative and a quantitative method was born. By the early 1990s, mixed method research research focused on the systematic merging of quantitative and qualitative databases, and the notion of integration in various forms of research designs developed.

3.3.1.1 Advantages of mixed methods research design

Using a mixed method design has various advantages as mentioned in Wisdom and Croswell (2013:3):

- Mixed methods are particularly helpful in exposing paradoxes between quantitative results and qualitative findings.
- Mixed methods provide a chance to research participants and guarantee that research findings are based in participants' practices.
- Mixed studies range to multidisciplinary research groups by inspiring the collaboration of quantitative, qualitative, and mixed method scholars.
- Have more adaptability and are adjustable to several research designs.
- Mirror the way persons indeed gather data − by integrating quantitative and qualitative data.

3.3.1.2 Limitations of mixed methods research design

Mixed methods research designs are difficult to apply particularly when used to evaluate complex activities. Some of the several challenges according to Wisdom and Croswell (2013:3-4) are:

- Mixed methods studies are multifaceted to design and conduct.
- Integrating qualitative and quantitative data during analysis is usually a difficult stage for numerous investigators.
- Conducting high-quality mixed methods studies needs a multidisciplinary team of researchers.

- Finally, mixed methods research is more resource demanding than those required to manage single design research.

3.3.1.3 Mixed methods research design procedures

Mixed methods research includes the gathering and “mixing” or integration of both qualitative and quantitative data in a research. The three basic designs in mixed methods research are:

(a) Convergent, (b) Explanatory sequential, and (c) Exploratory sequential. According to Creswell (2018:176-177), their features, information gathering and analysis, characteristics, and approaches to interpreting and validating the research are as follows:

(a) Convergent parallel mixed method is a type of mixed methods design in which the investigator merges quantitative and qualitative data in order to give a detailed analysis of the study problem. The researcher classically gathers both types of data at approximately similar times and then merges the data in the interpretation of findings obtained in the study.
(b) Explanatory sequential mixed method is one in which the investigator first conducts a quantitative study, analyses the results and then enriches the results to describe them more comprehensively with a qualitative study. It is taken as explanatory because the first quantitative data results are further explained with the qualitative data.
(c) Exploratory sequential mixed method is the opposite order from the explanatory sequential design. In the exploratory sequential method, the investigator first starts with a qualitative study phase and explores the insights of participants. The information is then analysed, and the data utilised to construct the second quantitative phase.

In this study, a convergent parallel mixed method design was followed where both quantitative and qualitative data were gathered simultaneously, merged both quantitative and qualitative data in the interpretation of findings in order to give a detailed analysis of the study problem.

3.3.1.4 Rationale for mixed methods design

Creswell, Fetters and Ivankova (2004) debate that a mixed methods study goes beyond easily gathering both qualitative and quantitative data: it suggests that data are mixed at some stage of the study course. They further explain that the grounding logic to integrating is that neither qualitative nor quantitative methods are adequate in themselves to seize the patterns and comprehensiveness of the condition, however, when utilised together, both qualitative and quantitative data produce a more comprehensive analysis, and they reinforce one another. The elementary principle of this methodology is that such integration allows a more comprehensive and complementing use of data than either quantitative or qualitative data gathering and analysis (Wisdom & Croswell 2013:1).

This study applied a mixed method of quantitative and qualitative research design to determine knowledge, perceptions, practice and challenges of immunisation safety surveillance. The quantitative tool was applied to explore the socio-demographic, knowledge, perceptions and practice of health care providers who were working at hospitals, HCs and HPs level and to assess health service access, organisational and motivational factors of health facilities. The qualitative tool was employed for those participants working at zonal and district health office level who were responsible to train, supervise, follow up, provide feedback, solve problems, make decisions, design job aid materials, allocate logistics and budget for surveillance and immunisation for the respective health facilities. The reason for applying a mixed method design for this research was based on the premise that neither qualitative nor quantitative methods individually were adequate to satisfy the study inquiries. In addition, the mixed designs assist to countercheck data sources as a strategy for looking at convergence between qualitative and quantitative methods (Creswell 2018:47). While both of these two research methods may be grounded on different epistemological premises, the strengths and shortcomings of both provided a sound justification for their integration. When used jointly for the purposes of this thesis, the two approaches would synergise instead of being competitive (Parrella 2014:39). Bentahar and Cameron (2015:6-12) propose that the integration should be coherent with the research design. Results from the quantitative research design are supported by the qualitative findings.

3.4 RESEARCH METHODS

Research methods are the various procedures, schemes, algorithms applied in research and they are basically planned, scientific and value-neutral. They incorporate experimental studies, theoretical procedures, statistical approaches, and numerical schemes (Ground 2012:9). They encompass the unique types of information gathering, analysis, and interpretation that investigators recommend for their research, Creswell (2018:314) and comprise all the techniques and methods, which will be taken for conducting research. Quantitative research is an approach for confirming objective theories by assessing the interrelationship among factors (Creswell 2018:38). Qualitative research is a query procedure of knowing, centred on a methodological convention of inquiry that explores a problem (Shone 2015:40).

3.4.1 Research setting

Benichangul-Gumuz region is one of the ten regional states in Ethiopia. It is located to the south-western part of Ethiopia along the border of South Sudan and Sudan. The study was conducted in Asosa Zone the sub part of Benishangul -Gumuz region. It is more than 600 km away from the capital city of Ethiopia. The zone has seven woredas, namely Asosa, Bambasi, Homosha, Kurmuk, Menge, Odda, and Sherkole. In all these woredas there were two hospitals, 16 health centres, and 210 health posts (Asosa Zone Health Department 2018). The data were collected from HCPs' working at zone, woreda, hospital, health centre and health post levels.

Figure 3.3 Map of Ethiopia (left) and the study area (Benishangul Gumuz Region-Asosa Zone)

(Benishangul Gumuz Region Map [s.a.].)

3.4.2 Quantitative research design

Quantitative research method is a recognised, impartial, organised study procedure that measures in order to ensure enquiry and its data analysis is conducted numerically (Gray et al 2017:116). A quantitative approach was applied to identify health care providers' knowledge, perceptions and practice as well as challenges of immunisation safety surveillance in Asosa Zone.

3.4.2.1 Characteristics of quantitative research design

The following are characteristics of a quantitative research design that the investigator took into account during the course of data gathering as adopted from Brink, Van Der Walt and Van Rensburg (2012:103):

- Quantitative design focuses on a limited number of ideas.
- Well organised procedures and tools are employed to gather data.
- It starts with defined thoughts about how the ideas are interconnected.
- Gathers data under controlled situations.

- Statistical procedures are applied to analyse numeric data.
- The researcher does not manipulate in the situation under study and is most probably likely to gather information from the specific environment.
- The methodology includes logistic, deductive reasoning.

3.4.3 Population

A population is a whole set of persons with a special set of features and a sample is a subdivision of the population. However, there are three strictly connected forms of population in a research, and these are target, study and sample population (Asiamah, Mensah & Oteng-Abayie 2017:1607-1608 ; Majid 2018:3).

3.4.3.1 Target population

In this research the target population, the group to whom generalisation is envisioned, were all the HCPs working in Asosa Zone. Any generalisation extracted from the sample population refers only to that population where the sample was selected.

3.4.3.2 Accessible population

Accessible population is part of the population to whom the investigator has access; it may be a subsection of the target population. It could be contended to be similar for both qualitative and quantitative studies. For both designs, members of the accessible population are appropriate to take part in the research (Asiamah, Mensah & Oteng-Abayie 2017:1613-14).

3.4.4 Sample

A sample means a subset of the of population chosen to participate in the research (Surbhi 2017:1) as it may not be possible to study all the health care providers in the Zone due to practical resources and data management.

The samples for the quantitative paradigm were HCPs working in hospitals and health centres as disease surveillance, immunisation, paediatric nurses and heads of facilities.

In addition, randomly selected HEWs and out-patient department (OPD) nurses working in the health posts were included in the sample.

3.4.4.1 Inclusion criteria of respondents

An inclusion criterion reflects features that possible respondents must have in order to take part in the study (David 2017:1). Reasons for inclusion and exclusion criteria are that variables selected as inclusion criteria should be related to answering the research question and that key variables should be described in the inclusion criteria to make a statement about the external validity of the study.

Inclusion criteria of respondents were:

- Government employees at selected health care facilities.
- Health care providers (HCPs) assigned and working for more than three months in hospital, health centres (HCs) and health posts (HPs) in the immunisation, surveillance and paediatric treatment department.
- HCPs delegated as heads of hospital and health centres.
- HCPs assigned as OPD nurses and as HEWs in HPs.

3.4.4.2 Exclusion criteria of respondents

Exclusion principles are any features that possible respondents might have that would prohibit them from taking part in the research (David 2017:1).

Excluded were:

- Employees working at private health care facilities.
- HCPs who were not serving in either immunisation, surveillance, paediatric treatment department or as head of hospital and health centres.
- HCPs who served in the above-mentioned departments for less than three months.

3.4.5 Sampling

Sampling is the procedure of choosing a cluster of individuals, events, practices or other substances with which to do the research (Burns & Grove 2011:535). The number of objects in the sample is the sample size (Singh et al 2018:1). The aim of approximating the proper sample size is to yield studies capable of detecting important variations (Faber & Fonseca 2014:27). For this study, two sample sizes were employed for quantitative and qualitative research designs, respectively. According to the Ethiopian government health system structure, in each health centre and hospital, disease surveillance, immunisation, paediatric treatment department and medical director have contact with immunisation safety surveillance in one or another way. Therefore, health workers who have been working in these four departments comprised the study population. In the health post, outpatient department nurses and HEWs have the mandate to be contacted for any AEFI related cases. Four respondents were selected from each hospital and health centre, and in each health post two respondents (one health extension worker and one OPD nurse) were incorporated in the study.

Since the target population was small, the sample size calculation used Yamane (1967) formula (Israel 2013:4), n=N/1+N (e) ^{2} where n is the sample size, N the population size, e level of precision. According to the 2018 Asosa Zone health facilities profile, there were 2 hospitals, 16 health centres and 210 health posts. The distribution of total study population (N) in each facility was:

For hospitals, N=8, for HCs, N=64, for HPs, N=541. The total number of HPs found from Asosa Zone health profile.

Therefore, the expected sample size (n) considering the level of precision 5% were:

- Hospital, n=8/1+8*0.0025=8
- HCs, n=64/1+64*0.0025=64
- HPs, n=541/1+541*0.0025=230
- The total sample size for the quantitative approach was 8+64+230=302

In order to get 302 respondents all hospitals, all health centres and randomly selected health posts were included as sampling units. In HPs, where more than one HEW were available, one HEW was selected randomly by using lottery method.

The number of facilities required for the study unit or sample size was:

- All hospitals were included to get 8 respondents.
- Required HCs for 64 respondents were 64/4=16.
- Required HPs were, 230/2=115, where 230 is the total sample size in all HPs found based on sample size formula calculation and 2 is the number of respondents required per health post.
- The 115 HPs were proportionally allocated in all the seven districts (Asosa, Bambasi, Homosha, Kurmuk, Menge, Oda and Sherkole), under Asosa Zone. The numbers of proportionally allocated HPs versus the number of HPs per district after exclusion of some HPs in each district were: Asosa (38/69), Bambasi (23/42), Homosha (8/15), Kurmuk (9/16), Menge (13/24), Oda (14/25), and Sherkole (10/19). There were two respondents per HP. Therefore, 133 (2+16+115) HFs were included in this study.

3.4.6 Ethical considerations

Before and during this research, ethical guidelines were followed in order to protect the rights of the participants. These encompassed the esteem for the human person, who has the right not to be hurt or abused, right to give informed, unforced consent to take part in a special portion of study, the right to privacy, and the right to secrecy and/or anonymity, usually shortened as the ethical principles of autonomy, justice, beneficence and non-maleficence (Saxena 2015:6-9). Some of the ethical related considerations are summarised inter alia:

- *Research approval*

Approval to conduct the research was obtained from UNISA (Annexure A). The UNISA approval was submitted to the Asosa Zone Health Department, for the permission of data collection. Following the Zone Health Department approval, data were collected (Annexure C).

- *Anonymity and confidentiality*

Study subjects require have to be assured that they will not be identifiable through the study and that their information will not be identifiable and continue to be anonymous in a study in order to be protected from unnecessary risks. They were guaranteed that their individuality and individual information would not be revealed and that the data handling and storage processes would maintain anonymity and confidentiality (UNISA 2016:16-18).

- *Respect for the human person*

The study teams are responsible not to expose the research participants to potentially troublesome, irrational, recognised or foreseeable risks (Scott 2013:79). As it is the role of the researcher, the participants were provided with the information on the aim, process and rights, risks, discomforts and withdrawal from taking part in the research (Scott 2013:79). Four study assistants were trained to provide sufficient information to all potential selected respondents. The participant information sheet (Annexure D) and consent forms (Annexure E) having information on the investigator, purpose of the research, importance of participating, assurance to discontinue anytime without prejudice and address of researcher to contact were provided.

- *Voluntary informed consent*

Informed consent refers to the participants being completely informed of the study they are participating in. As autonomous beings, participants have the right to do their own choices and their lives. Taking part in the study was voluntary. The research participants were informed about the properties and the degree of the expected involvement in the research, containing information that their involvement and replays would only be used for the purposes identified in the research (Paez et al 2017:5). In this study, informed and voluntary consent were obtained from all of the research participants.

- *Justice*

The principle of justice consists of two components: (i) Fair management in study work, comprising justice to the disadvantaged who should benefit rather than overlooked, and (ii) Involvement without denial based on susceptibility or susceptible individuals utilised

without benefit or with admission into study which is not responsive to their health needs (Scott 2013:82). All health care providers working in the selected departments and dealt with immunisation safety surveillance were qualified to participate in this research. The danger of selection bias and error was minimised by determining the target population, including all cases fulfilling the fitness standards, not neglecting “hard to reach or possibly non-adherent” health care providers.

- *Beneficence and non-maleficence*

The two principles of beneficence (do good) and non-maleficence (do no harm) require that health practice and research do good, protect from harm, as well as being attentive (Scott 2013:81). While this study did not pose substantial worry, danger and load on the participants, it is crucial that scientific studies benefit the patient directly and/or society as a whole (World Medical Association 2015:2192).

3.4.7 Data collection

Data gathering is the procedure of gathering, measuring and analysing accurately understandings from all the important sources searched for responses to the research questions, test the hypothesis and evaluate the outcomes. There are two main kinds of data gathering methods, namely: primary and secondary data collection methods (Dudovskiy 2019:1). In this study, primary method of collecting quantitative and qualitative data were used using a cross sectional method. The data needed were gathered on a number of factors to assess immunisation safety surveillance using a questionnaire. Questionnaires can be managed by the researcher or answered by the participants themselves (self-administered).

This study employed the face-to-face interview approach which has the following advantages:

- Questions and responses could be explained.
- Allowed asking for extra information.
- Complex and open-ended queries were likely.
- Clarifications of queries by participants were done. Therefore, partaking was possibly improved by personal interaction.

The shortcomings of the one-to-one surveys were:

- It can be time consuming.
- Either the participant or the data collector may require transport.
- Could be more expensive than surveys shared through the post or administered online (*Questionnaire design* 2017).

3.4.7.1 Preparation for data collection

Research assistants were recruited and training was provided on data collection techniques, procedures and questionnaire administration. During the training, the research assistants assisted with pre-testing of the instruments and valuable comments were included. The research assistants confirmed appointment dates for a subsequent trip for data gathering with the respondents. Address numbers of the investigator were provided to the respondents and health facilities management so that the investigator could be contacted in case of changes in the schedules. The data gathering process began at the end of February to the 1st week of April 2020. The tool was translated into Amharic language because it is the official working language of the study area and is recommended by authorities to be used in data collection.

3.4.7.2 Pre-test of data collection tool

Pretesting is an approach of verifying the tools function as planned and are understandable by those people who are likely to respond to them. It is helpful to examine a survey tool prior to utilising it to gather data for the study. Pretesting can assist to differentiate questions that do not make meaning to respondents, or concerns in the survey tool that might lead to biased result (Tlou & Dyk 2015:1). The researcher and research assistants conducted a pre-test at one of the selected health centres in Asosa Zone with 20 health care providers who met the inclusion criteria of the study. The aim was to test the data collection questionnaire, recruitment process and consistency of the tool. The outcome of the pre-test informed the researcher about the questions and the way some were phrased, which needed clarification. The researcher then restructured the questions to address the concerns raised prior to the main study. The respondents who participated in the pre-test did not take part in the main study.

3.4.7.3 The questionnaire

The data collection tool had the following sections:

- Socio-demographic characteristics, which comprised respondents' age, gender, educational status, profession, position, and experience.
- Access questions addressed issues related to service user and provider location of health facility, distance of health facility from the district town, access to communication, electricity and transportation.
- Organisational and motivation factors included facility working hours, availability of surveillance focal persons, job description, activity plan, partners supporting the facility for AEFI surveillance, training, reporting formats, AEFI surveillance implementation guide, performance evaluation, supervision and feedback and reward for best performing health care provider, exposure to AEFI cases and service provider satisfaction.
- Indicators/variables of knowledge, perceptions, practice and challenges related to immunisation safety surveillance.
- An open-ended question for respondents to mention any challenges, which hinder them from conducting immunisation safety surveillance.

3.4.7.4 Administering questionnaire

This research tools were administered to the research respondents during pre-arranged periods at the selected sites. The researcher and research assistants completed the structured questionnaires through direct interviews with the respondents. A total of 300 questionnaires were collected using the hard copy and stored in SPSS version 25.

3.4.8 Data analysis

Data analysis is the procedure of gathering, cleaning, transforming and modelling data in order to extract useful conclusions. The fundamental steps in the analytic process comprise recognising concerns, defining the existence of appropriate data, determining which techniques are proper for answering important questions, using the technique and reviewing, summarising and sharing the findings (Peersman 2014:2-15). Data analysis

was managed based on objectives of the study and the major analysis approaches applied were (*Data analysis, interpretation and presentation* 2016):

- Descriptive
- Multi-collinearity test
- Explanatory analysis
- Principal components and factor analysis
- Interpretation of quantitative research

A 95% Confidence level and p-value of <0.05 was considered as level of statistical significance.

3.4.8.1 Descriptive analysis

Objective one of this study was analysed through descriptive analysis to measure the status of health care provider knowledge, perceptions and practice by applying measures of central tendency and variability processed from a number of data (Creswell 2018:205). For this purpose, the SPSS version 25 software was applied after data entry, re-coding and cleaning were completed. Knowledge, perceptions and practice on immunisation safety surveillance parameters was scaled by using the mean value and the parameters were grouped as good (mean and above value), fair (equal to mean value) and poor (below mean value). In addition, statistics of descriptive analysis such as percentage, frequency, mean, standard deviations, skewness and kurtosis were applied to explain the different socio demographics, health facility accessibility, motivational, organisational and characteristics of the sampled respondents.

3.4.8.2 Multi-collinearity diagnostics

Logistic regression analysis was done for the data collected from the sampled respondents to analyse determinants of immunisation safety surveillance in the study area. Multi-collinearity is when two or more independent factors in a multiple regression model are highly interrelated with a significant extent of accuracy. The existence of such a situation can have a negative effect on the entire analysis and can seriously restrict the conclusions of the research. Prior to running the analysis, both the continuous and categorical predictor variables were verified for the presence of multi-collinearity

shortcomings. The shortcoming comes when a minimum of one of the explanatory factors is a linear mix of the others. The availability of multi-collinearity might lead to the approximated regression coefficients to have incorrect signs and fewer odds ratios, which lead to incorrect conclusions. Usually there are two recommended measures to test the existence of multi-collinearity. Variance inflation factors (VIF) for association among the continuous independent variables and contingency coefficient (CC) for dummy variables. The correlation coefficient for every couple of explanatory factors close to ±1 shows that the two variables are highly correlated. The contingency coefficient is computed as:

$\mathrm{CC} = \sqrt{\frac{X^2}{N+X^2}}$ where, CC=Contingency Coefficient, χ2=Chi-square random variable and N=total sample size. For contingency coefficient the decision rule is that if its value is close 1, there is interrelatedness between the separate variables (Assefa 2016:33-34; Schreiber-Gregory & Jackson 2017:1-12).

3.4.8.3 Explanatory analysis

The second objective analysis was done through explanatory analysis. Analytic tests were used and statistical methods were applied to establish the risk and determinant factors for immunisation safety surveillance. For this study, there are factors that affect health care provider good performance of immunisation safety surveillance in the study area either positively or negatively. Association measures were applied to establish associations between the outcome and one or more independent factors. Chi-square or bivariate logistic regression test was done to measure the association between immunisation safety surveillance and independent variables. Logistic regression modelling (multivariable logistic regression) was used to exclude the third factor impact in an approximate of the association and to establish significant variables. The findings were reported by odds ratio with 95% confidence intervals (CI) (Sperandei 2014:12).

3.4.8.4 Principal components and factor analysis

Principal component analysis (PCA) is a tool for dimensionality for reducing a larger set of factors to a smaller set that still contain most information in the larger set. PCA is a mathematical procedure that shifts a number of linked factors into smaller number of unlinked factors called principal components (Jolliffe & Cadima 2016:1-12). The first principal component accounts for as much of the heterogeneity in the data as likely and

each following component accounts for as much of the remaining heterogeneity as likely (Principal Component Analysis 2016).

Objectives of principal component analysis (PCA)

- PCA decreases the characteristic space from a larger number of factors to a smaller number of variables and as such, are an "independent" procedure (that is, it does not assume an outcome factor is detailed).
- PCA is a data compression method.
- PCA selects a subset of factors from a larger set based on which original factors have the greatest correlations with the principal component.

Factor analysis is a statistical procedure to recognise correlations that occur in greater number of factors that are meant to recognise how sets of factors are correlated. Factor analysis could be applied for exploratory or confirmatory purposes. As an exploratory tool, factor analysis is used to find a likely causal structure in the factors. In a confirmatory study, the investigator assesses how similar is real structure of the data, as mentioned by factor analysis, is to the anticipated structure. The main variation between exploratory and confirmatory factor analysis is that the investigator has developed hypotheses about the causal structure of the factors when applying factor analysis for confirmatory purposes. As an exploratory tool, factor analysis does not have numerous statistical assumptions. The only actual assumption is existence of interrelationship between the factors as denoted by the correlation coefficient. If there are no correlations, then there is no underlying structure (Sara 2019:3).

The knowledge, perceptions and practice components of this study were analysed using the PCA and FA. This analysis gave direction for which indicators of knowledge, perceptions and practice should be included in the pocket immunisation safety surveillance manual development.

3.4.8.5 Interpretation of quantitative data

Numbers do not speak for themselves (*Data analysis, interpretation and presentation* 2016). Interpretation means the course of giving meaning to collected data. This presentation may be displayed in different ways such as bar graphs, line charts, tabular

forms and other forms (Toppr [s.a.]). The interpretation contains different steps. The most comprehensive meaning of the findings originates from reporting a detailed explanation and testing of statistical significance. Testing of statistical significance reports an assessment whether the observed values show a trend other than chance. A statistical test is taken to be significant if the findings are improbable or occurred by chance and the null hypothesis is of “no effect” and cannot be accepted. The investigator sets a rejection level of “no effect,” such as $p \geq 0.05$, and then assesses whether the test statistic lies within this level of not accepting.

One type of practical evidence of the results should also be reported by using the Confidence Interval (CI). A CI is a range of values that describes a level of uncertainty around an estimated observed score. A confidence interval reflects how good an estimated score might be. For instance, a 95% CI explains that 95 out of 100 times, the observed score will lie in the range of values (Creswell 2014:212).

3.4.9 Validity and reliability

In a scientific study, the investigator plans to establish significant and valuable conclusions from the scores of the tool (Creswell 2018:316).

3.4.9.1 Internal validity

Validity controls whether a tool correctly measures the element which it is planned to measure (Creswell 2014:19-20). In this study, face, content and criterion validity were considered. Face validity of the instrument was assured by consulting the expert team comprising the statistical analyst and supervisor to determine whether the questions in the questionnaire covered relevant aspects of the research problem.

Content validity ensures that the areas covered by the research instrument represent the research problem, purpose and content. Research questions, specific objectives and conceptual frameworks were deemed to be in line, and thorough literature review, had been done to address content and criterion validity regarding HCPs immunisation safety surveillance system.

3.4.9.2 External validity

External validity reflects how good the result of a research can be probable to use in other settings. Alternatively, external validity reflects how generalisable the outcomes are. For example, can the results be used in another population, situations, settings, and periods? (Cuncic 2019:1). This study directly took relevant health care providers or randomly selected among relevant HCPs for the assessment of immunisation safety surveillance and the development of the sampling procedure, guaranteed that sample size was more than sufficient to overcome with type 2 statistical error. The research also covered possible limitations to external validity that would probably cause a limitation to generalisation as follows (Haumba 2015:131):

- Sample characteristics: relevant respondents were drawn from appropriate departments of respective health facilities and health posts. Random selection was done among relevant HCPs for immunisation safety surveillance.
- Inclusion and exclusion features were used to choose the appropriate respondents
- Setting characteristics: Hospitals, HCs and HPs as well as both urban and rural settings were considered to reflect the general settings in the Zone.
- Research study awareness and pre-testing effects: a cross sectional survey and immediate real data collection was followed the pretesting of the data collection tool, which reduces the Hawthorne effect, or reactivity of participants being informed that they had participated in a research. In addition, respondents having prior information about this study did not affect most of the variables.
- Response rates- revisiting, prior scheduling was done with the respondents in order to enhance the response rate (Bacon-Shone 2015:202). In this study, selection of a homogenous group through stratification, taking sufficient sample size using the scientific formula, use of random sampling technique and considering all relevant departments were employed. Variables were controlled during the analysis and the quantitative data were triangulated with qualitative data.

3.4.9.3 Reliability

Reliability of a tool assesses if a similar tool applied at various times or used to various participants from similar population, will produce the same findings (Heale & Twycross

2015:66). It easily means the degree to which a tool is replicable and persistent. The various forms of reliability applied in this study are:

- *Test-retest reliability*

It is a kind of reliability attained by applying the tool to similar participants on two or more events where if the score for the various events is more or less similar, then the tool is reliable (Heale & Twycross 2015:67). Reliability is used to check consistency of the research tool. In this study, the pre-test of the tool was conducted with the health care providers from one of the sampled health facility. The findings were almost the same hence the tool was reliable.

- *Internal reliability*

Internal reliability is also denoted to as internal stability. When a tool is designed to measure some construct, factors should have a large degree of homogeneity among them since they are expected to count a single usual construct. If the extent of homogeneity is large, then the tool is reliable (Heale & Twycross 2015:67). In the study the factors used were knowledge, perceptions and practices of health care providers towards immunisation safety surveillance. All the factors are interrelated to the construct under study – a sign that the measuring tool was reliable.

3.4.10 Qualitative research design

Qualitative study reflects inductive, all-inclusive, indigenous, subjective and process directed methods used to understand, interpret, describe and develop a theory on a phenomenon (Brink et al 2012:209). It is related to words, language and experiences instead of measurements, statistics and numerical figures. Qualitative research includes the systematic gathering and analysis of subjective data given by participants about the phenomena, comprising how they interpret the experiences and the meaning attached to the experiences (Brink et al 2012:118; Creswell 2014:628). It helped to triangulate the findings obtained from the quantitative study.

3.4.10.1 Characteristics of qualitative research design

General characteristics of qualitative research according to Polit and Beck (2014:759) include:

- Usually includes a mixing of different data gathering methods (i.e. triangulation).
- Is not rigid or extendable, proficient of correcting what is being learnt during the process of data gathering.
- Inclines to be rounded, focusing on for an understanding of the entire experience.
- Needs the investigator to become intensely involved, usually staying in the field for long periods of time.
- Needs continuous analysis of the data to frame approaches and to decide when data collection can be concluded.

3.4.10.2 Sample

Purposive sampling was applied to select the research participants. The study focused on immunisation and safety surveillance, thus, HCPs working in the Zone and district health office serving as immunisation, safety surveillance and HMIS focal persons were purposely targeted. The sample size was decided based on the data saturation.

3.4.10.2.1 Inclusion criteria

Polit and Beck (2012:259) highlight the necessity for investigators to stipulate the features that demarcate the study population. Similar to this direction, the next feature of research participants was included:

- HCPs assigned and working for more than three months in the zone and district government health office levels as immunisation safety surveillance.
- HMIS focal persons.

3.4.10.2.2 Exclusion criteria

- Zonal and district health office HCPs not working in immunisation, surveillance, HMIS.
- All who had worked for three and less months in these departments.

3.4.10.3 Sample size

In the Zone, all the districts were grouped into two groups (near and distant) determined by their distance from the Zone town. One district was selected in each group. Two districts in the Zone were part of the study. Therefore, the Asosa Zone and two districts were included. Three participants from the Zone and three per (6) selected district health offices' surveillance, immunisation and health management information system (HMIS) focal persons were selected purposively from a total 19 HCPs for the one-on-one interview.

3.4.10.4 Data collection

Data gathering is defined by Grove, Gray and Burns (2015:366) as the process of gathering, measuring, and analysing truthful concepts for study employing confirmed methods. Fundamentally there are four alternatives for data gathering: in-person-interviews, mail, phone, online and in-depth interviews. In this research, semi-structured interviews were applied to gather data.

3.4.10.4.1 Semi-structured interview

A semi-structured interview guide was used for data collection. The technique was selected to get data from participants as their attitudes may differ. An interview guide was used to lead the investigator on the questions to be asked. An interview guide is a tool comprising a set of queries, instructions for questioning those queries and space to record the respondents' responses (Brink et al 2012:118).

3.4.10.4.2 Pros of the semi-structured interview

The investigator selected the semi-structured interview technique for information gathering as it has pros mentioned below:

- The interview is ready before hand, permitting the investigator to familiarise himself/herself with content before the interview.
- The approach gives the participants the liberty to describe their opinions in own languages.
- The technique is able to deliver consistent, equivalent qualitative data.
- Semi-structured interviews allow for two-way idea sharing between the interviewer and the respondents.
- It confirms what is previously recognised but also affords the chance to learn. The information gained will not just allow responses but the rationale for the responses.

3.4.10.4.3 Cons of semi-structured interviews

Few cons which the investigator should guard against were:

- The investigator should have interview abilities to get sufficient information from the respondents.
- Places restrictions on what is asked.
- The technique may not ensure truthfulness by the respondents.
- Length of interview may reduce consistency.
- Time consuming and resource exhaustive.

3.4.10.5 Recruitment of the respondents

Following approval to conduct the research, the investigator made appointments with the leadership of the selected health care facilities and data collection trips were arranged with the study subjects. Possible and willing participants who met the sampling criteria were approached beforehand through the operational manager who in turn arranged the meeting.

3.4.10.6 Data collection procedure

The investigator was provided with quiet rooms for data collection and these were helpful not to divert attentions of both the interviewer and participants. The investigator primarily

described the ethical indications of the study. Participants were guaranteed of their privacy, and well- being, they were informed of the right to decline to participate in the study (Streubert-Speziale & Carpenter 2011:22). The participants who volunteered to involve were asked to give their consent. The interviews lasted for 35 to 45 minutes per participant. The investigator listened to every thoughtfully and disruptions of the respondents during talking were avoided. Symbolic communication for example nodding of the head, facial expressions and keeping eye contacts were utilised to encourage speaking.

- *Audio tape recording*

In order to capture all of the information that had been said by each participant, recording, with audio tape recorder was supportive. Before recording participants were informed that their interview would be recorded following their approval (Brink et al 2012:118). The anonymity of respondents during recording was guaranteed, and respondents were coded. Information gathered was transcribed verbatim.

- *Field notes*

Field notes were taken during data gathering for referral during transcription and translation of the recorded voices. Field notes are registers of what the investigator notices and observes, containing the information from participants at the time of data gathering (De Vos, Strydom, Fouché & Delport 2011:221). Field notes helped in registering symbolic communication as they could not be recorded on an audiotape recorder so that essential information was not omitted. Data was collected till saturation was reached after nine participants were interviewed. Also in a qualitative study, saturation is important during data collection to determine the number of participants that are needed for the study of a particular phenomenon. Saturation is the point at which participants keeps repeating the same information as of previous data collected, hence there is no new information being added, at that point the researcher stops interviewing more participants (Polit & Beck 2014: 465).

3.4.10.7 Data analysis

The data in qualitative research is non-numerical and often in the form of written words, or videotapes, audiotapes, and photographs. The researcher conducted nine one on one or face-to-face interviews that comprised the words of the participants, which were transcribed verbatim before analysis (Lewins, Taylor & Gibbs 2018:224). Data were grouped into thematic areas, and thematic analysis was done using a software ATLAS ti 8. Braun and Clarke's (2006:368) six phases of thematic analysis were identified as suitable qualitative data analysis technique, to deliver a rich thorough explanation of the data collected. Thematic analysis is a process that essentially consists of identifying, analysing, and reporting qualitative data. The phases are as follows:

- *Becoming familiar with the data*

To increase the credibility of the findings, field notes were used and any non-verbal communication cues during the interviews were recorded. Personal reflections were added after each interview, to make sense of the field notes, and highlight any thoughts of subjectivity (the interviewer's) that may have occurred during the interview. After the participants granted permission, all the interviews were audiotape recorded, and subsequently, uploaded and stored onto a computer that was password-protected for safekeeping. This enabled the researcher to listen to the audio-tape recordings, repeatedly, for transcription into verbatim text.

- *Generating codes*

The researcher became familiar with the content of the transcripts, by repeatedly listening to the audio-recordings and reading transcripts. Subsequently, the transcripts were uploaded, and preliminary codes were assigned, using Atlas.ti, version 8.

- *Search for themes*

Atlas.ti version 8 was also used to print a code report, later to identify similarities and patterns among the codes, manually. Additionally, preliminary categories were assigned

manually to these printed codes. Subsequently, the researcher grouped the categories into preliminary themes that could be distinguished from each other.

- *Defining themes*

Themes consisting of categories and codes were printed as a report, which was incorporated into a table format in Microsoft Word, which was reviewed by the supervisor. After the supervisor reviewed the table, the researcher sought to refine and interpret the provisional themes, categories/subthemes, and codes, into more identifiable themes, subthemes and codes.

- *Codes reviewing and refining*

Later, the assigned codes were reviewed and refined again, to identify any further similarities and patterns, to validate the existing categories and themes.

- *Writing up a report*

Once the themes, categories/subthemes, and codes were clear, the researcher began to write up the interpretation of the health care providers' knowledge, perceptions, practices and challenges during immunisation safety surveillance.

3.4.11 Measures to ensure trustworthiness

Trustworthiness is the certainty of the qualitative research to accurately portray the practices of the respondents (Lincoln & Guba 1985:315; LoBiondo-Wood & Haber 2014:166). For this study to be evaluated trustworthy, the researcher adopted Lincoln and Guba's five criteria, which were credibility, transferability, dependability, confirmability and authenticity. This further assisted the researcher to confirm whether the study accurately represented the aspects under study (Holloway & Wheeler 2013:254).

3.4.11.1 Credibility

Credibility is the truth of the data gathered and interpreted, and a criterion for evaluating the quality of qualitative data. Credibility is therefore similar to validity, and the researcher

needs to confirm the truth of data collected by using the same instrument. The researcher engaged in a prolonged interaction with the participants to gain confidence with the results grounded on the research method, respondents and setting. This was achieved by interacting with participants when making appointments, explaining the purpose, objectives and process of data collection and signing the consent forms prior to the interviews. This enabled the researcher to collect useful, accurate and rich descriptive information about human experiences, which would add value to the study. This prolonged engagement and persistent observation made participants free to talk and enhanced the believability of the findings. Probing questions were asked continuously throughout the interviews to verify the responses given by all the participants and to redirect them to the questions asked. Participants were required to clarify some of the statements given, to enable correct interpretation by the researcher.

Triangulation was employed as a data source that encompasses several research methods to gather or interpret data about a phenomenon in order to create a correct image of the truth (Creswell 2014:228). Triangulation of observers means that multiple researchers were used in the research. This was to rationalise the liaison between the investigator and the context and internalise the content. Member checking was conducted to validate the validity of data throughout the study. Participants had the opportunity to work through their experiences and check the effect of the research process. Secondly, a formal session was arranged with participants and a summary interview was provided for participants to respond to (Lincoln & Guba 1985:314). Unexplained inconsistencies between the data collected and its interpretations were avoided.

3.4.11.2 Transferability

Transferability is regarded as the capability to generalise from the research outcomes to the larger population. Other investigators should be able to apply the study findings in other contexts. It also reflects to the extent to which the outcomes from the study could be used in other settings or subjects in project implementation assessment (Lincoln & Guba 1985:316; Polit & Beck 2013:492). The methodology was described in detail. The thick description strategy was used, whereby the researcher collected sufficiently detailed descriptions of data in context and allowed judgements about transferability to be made by readers. Hence, sufficient data were evaluated, easy to be used and could be applied

to other contexts when conducting future research by other researchers (Holloway & Wheeler 2013:255).

3.4.11.3 Dependability

Dependability means that if an inquiry into the same phenomenon is repeated, the results would be replicated. Dependability is the strategy used to achieve consistency. It is also indicated that dependability is data stability through time and through situations that means evidence that is consistent and stable with the same respondents or subjects in a similar context (De Vos et al 2011:346; Holloway & Wheeler 2013:254). Other investigators would be able to track the procedures, which were used in this research logically. It also means that the research would constantly provide similar results if repeated under similar conditions that means the same participants and similar context because it is reliable and valid. The results would be stable if the questions were repeated multiplied with similar conditions or in the same setting. That could be verified by auditing the raw data, findings and interpretations to guarantee internal cohesion of inquiry (Lincoln & Guba 1985:318). They should be consistent and accurate (Holloway & Wheeler 2013:254). An audit trail of the research enhanced the dependability of the study. The supervisor of this study was responsible for examining the data, interpretations and recommendations in order to attest that they are supported by data. The researcher has also done peer debriefing with other research colleagues in the workplace. The transcripts from tape recordings of interviews and field notes were sent to an independent coder, who is a qualitative research expert to ensure confidence in the truth of data and interpretation. In this study, all these activities were done to establish the dependability of the study.

3.4.11.4 Confirmability

Confirmability is the criterion for evaluating quality in qualitative data. The results, recommendations and conclusions organised from the research are assisted by the data. Confirmability also reflects to the impartiality or neutrality of the data (Polit & Beck 2013:492). Confirmability is applied to achieve neutrality. If there is similarity in two or more autonomous person about accurateness, significance and interpretation, it means that there is confirmability, objectivity or reliability of the data collected. Thus, the study would be considered confirmable if its findings could be confirmed by another person

(De Vos et al 2011:347). An audit trail was used to determine whether the conclusions, interpretations and recommendations could be traced to the source. Various discussions with an independent coder, as well as the supervisor, regarding the data collection and analysis, allowed for objective feedback. Actual quotes from the participants also formed part of the confirmability in this study. Reflexivity assisted the researcher to be free of bias in processing the data. The findings of this study were the product of the inquiry and not the researcher's biases. This was done by making sure that information was audio taped and transcribed and, therefore this minimised researcher bias and it also ensured that data can be confirmed. Research process, research design, sampling design and data collection process were carefully planned.

3.4.11.5 Authenticity

Authenticity refers to the degree that investigator evenly and loyally displays a range of various realities (Polit & Beck 2014:489). It arises in a report when it takes the exact tone of participants' lives as they are lived. In this study, the researcher demonstrated realities, which depicted the concerns, issues, underlying knowledge, perceptions, and practices of AEFI surveillance safety, achieved ontological authenticity.

3.4.12 Quality control

For this study additional activities and steps were considered to control the quality, and these include (Haumba 2015:137-8):

- Proper standards in recruitment of personnel.
- Proper training: data collectors were trained on the basics of sampling procedure, basics of research ethics, data collection process, and questionnaires.
- Pretesting of the questionnaire.
- Review of the questionnaire after pre-test.
- Close supervision and daily check-up of filled questionnaires during the data collection process.
- Interviews were randomly checked to ensure whether they actually took place.

3.5 Phase 2: Stage 1 - Identification of gaps in the existing Immunisation safety surveillance guidelines of Ethiopia

3.5.1 Introduction

The WHO has developed global immunisation safety surveillance guidelines which have been revised several times. Ethiopia have also prepared its own AEFI surveillance guidelines in 2016, in line with the global one. However, there was no revision or update done on the guidelines, and it is prepared in English language only, which is difficult to read and understand by some frontline health workers. There is low AEFI surveillance progress in Ethiopia, which is attributed to lack of update on the guidelines in AEFI surveillance performance. Therefore, one of the objectives of this study was to identify gaps in the existing national immunisation safety surveillance guidelines of Ethiopia to be in line with the latest WHO standard guidelines. The gaps are summarised in Table 3.1 by using criteria such as, responsible organisation, AEFI Signs and symptoms to be reported to higher level, investigation, procedure for investigation and reporting, feedback, Involvement of NGOs and private sector in AEFI reporting and investigation, between the WHO global and Ethiopia national guidelines to propose recommendations.

3.5.2. Table 3.1: Identified gabs in the existing immunisation safety surveillance guidelines of Ethiopia

Criteria	Identified gaps in the Ethiopian AEFI surveillance guidelines
Responsible organisation	• The existing system for monitoring drug safety (pharmacovigilance) in Ethiopia is being coordinated by the National Regulatory Authority (NRA), namely, Ethiopian Food, Medicine and Health care Administration and Control Authority (EFMHACA). • Monitoring vaccine safety has been challenging as there exist two safety data systems in the country. • The national NIP, which has been actively engaged in increasing vaccination coverage principally gathering vaccine safety data from the districts and AEFI reports but did not search their way to EFMHACA for further regulatory actions (EFMHACA 2016:4). • The federal guidelines assigned the primary reporting body is the district immunisation officer (DIO) (EFMHACA 2014:29). • At national level, EFMHACA is responsible for vaccine safety regulation, but does not have a structure below the region. In addition, at ground level there is a task shift of AEFI surveillance from DIO to District Surveillance Officer (DSO). This results in confusion of responsible bodies for AEFI surveillance.
AEFI signs and symptoms to be reported to higher level	• Health workers should advise vaccine recipients or their parents/care givers about minor home treatments (e.g. accurate positioning of the child when sleeping, increasing consumption of fluids, sponging, breast-feeding, antipyretics etc.). • If home treatments are not helpful, vaccine receivers and/or parents or caretakers of vaccinated infants/children should be advised to report the event to health care providers at vaccination or other health care facilities, (EFMHACA 2016:33).
Investigation	• All severe AEFI should be inspected and a finalised AEFI investigation form should be directed to the national level (EFMHACA 2016:33). • Thorough investigation is not necessary if it is a simple AEFI, DIO should indicate this on the reporting form and email/fax the same to the state and national levels to the next levels (EFMHACA 2016:33). • This statement undermines the need of assessment for minor cases. • The crude data is important to do the assessment for decision of the need of investigation.
Procedure for investigation and reporting	• Flow of AEFI surveillance data; DIO, Regional Immunisation Officer (RIO), the National Immunisation Program (NIP), EPI focal person and the NRA (EFMHACA 2016:34-35). When the national AEFI focal point of the NIP gets and/or the pharmacovigilance centre in EFMHACA the filled AEFI reporting form, it is important to analyse it, (EFMHACA 2016:36). • Two major challenges are; Fisrtly, there is no clear reporting procedure and accountability between NIP and EFMHACA. • Secondly, Ethiopian Public Health Institute (EPHI) is the national responsible legal structure to do the surveillance in the country. Even if it is surveillance activities, the national guidelines directs the work to the Immunisation and EFMHACA sectors.

Criteria	Identified gaps in the Ethiopian AEFI surveillance guidelines
AEFI case reporting	• Events to be reported, when to report, how to report, does not clearly show in subtopic as the global guideline presented clearly, (WHO 2016:43-45). These are major points to be known and should be shown in narrative form clearly but not presented in this way, (EFMHACA 2016:40).
Feedback	• The statement ''Positive feedback to health workers is essential'' as outlined in the global guidelines. Feedback is also stated in the Ethiopia AEFI surveillance guidelines (EFMHACA 2016:37). • The global statement is suitable to reduce health worker fear of accountability, feelings of guilt for harming the vaccinated in reporting AEFI case (WHO 2016:48).
NGOs involvement in AEFI reporting and investigation	• In the manual, listed key stakeholders are parents/guardians, health workers, DIO, RIO, NIP, EFMHACA (EFMHACA 2016:36-39). • It excludes the contribution by NGOs as partners especially those working in immunisation and surveillance.
Private-sector involvement	• The Global WHO guidelines mention the importance of private sector reporting, (WHO 2016:48). However, the Ethiopia guidelines states the word 'private' in the reporting form in case there may be reports from there. • However, the private sectors have to be part of the surveillance system from the onset, rather than expecting them to provide unconditional case reports.

3.5.3 Conclusion

Ethiopia has developed AEFI surveillance guidelines based on the WHO Immunisation safety surveillance guidelines through EFMHACA (EFMHACA 2016:1-87). However, EFMHACA has no official structure below the regional level. Similarly, the AEFI guidelines do not mention a report channel, but simply states that AEFI cases should be reported to a higher level and also lacks clarity on the type of AEFI to be reported (EFMHACA 2016:43-44). In addition, there was no properly documented reported AEFI case in the country (FMOH Ethiopia 2015:1-187). On the other hand, the WHO has developed different immunisation safety surveillance related-guidelines such as the global manual on surveillance of AEFI (WHO 2016:1-124), vaccine safety basics learning manual (WHO 2013a:1-207), ISS guidelines for immunisation programme managers on surveillance of AEFI (WHO 2015b:1-120), vaccine safety and the management of AEFI (Green Book 2012:1-15), causality assessment of an AEFI (WHO 2013b:1-56), AEFI surveillance and response guidelines (WHO 2010:1-156). The Global manual on surveillance of AEFI clearly has a chapter on reporting AEFI, however, this is not clear in the Ethiopia AEFI surveillance guidelines (EFMHACA 2016:1-87; WHO 2016:43-48).

3.6 Phase 2: Stage 2 - Development of an immunisation safety surveillance pocket manual for health care providers

3.6.1 Introduction

The results that emanated from the analysis and synthesis of both quantitative questionnaires and qualitative face-to-face interviews were the basis for the development of a pocket manual for health care providers' immunisation safety surveillance. Corrective measures from the gaps identified in the national immunisation safety surveillance guidelines, are included in the immunisation safety surveillance pocket manual.

3.6.2 The development process

This section presents the steps followed in the development of the immunisation safety surveillance pocket manual for health care providers. In Step 1, the researcher drew evidence for the formulation of the immunisation safety surveillance pocket manual from the summary and conclusions of the triangulated and integrated findings of this study. In Step 2, the researcher also consulted key stakeholders and experts in the immunisation safety surveillance field through meetings, emails and telephone calls during which findings from the literature review, research findings and gaps identified from the national immunisation guidelines were presented. The process was also influenced by Ajzen' and Fishbein's (1980) TRA model and "A guideline on guideline development" (Ansari & Rashidian 2012). This process is outlined as follows:

- Defining the purpose and scope of the immunisation safety surveillance pocket manual.
- Review of both findings of the study.
- Review of the literature.
- Development of the first draft of the manual.
- Establishment of the expert group.
- Review by the group, discussions, reach consensus on first draft of the pocket manual and provision of inputs.
- Revised pocket manual produced.

- Seek inputs from the reference group.
- Present to stakeholders and expert group.

Defining the purpose and scope of the immunisation pocket manual

The topic of the manual is “Development of the immunisation surveillance safety pocket manual for health care providers”. The purpose was to equip health care providers with a readily available and accessible manual which they could use as reference and guidance when confronted with challenging scenarios during health service delivery.

Forming the immunisation pocket manual development group

The group was constituted by eight experts in immunisation safety surveillance. This group comprised the principal investigator and seven experts in immunisation safety surveillance.

Scoping of the guidelines

To scope the immunisation pocket manual, the objectives for the study were clearly defined, the participants in the development group were experts in nursing practice and immunisation safety surveillance. The timeline for the process was over a period of four months. After the results and findings of the study were analysed, they were shared amongst the immunisation pocket manual development group. The group communicated frequently and a session to consolidate the process and findings was held. Communication was mainly through meetings, phones and emails. The group members declared that there was no conflict of interest in participating in the study. Ideas, procedures, and strategies which are important to enhance immunisation safety surveillance and the barriers of health care providers in relation to knowledge, perceptions and practice were addressed.

Development of first draft of the pocket manual

The first draft of the immunisation safety surveillance pocket manual was developed and shared with the development group for inputs. The group made commendable contributions which were included in the final draft.

Identifying the evidence

Systematic literature search was done ahead of the research to support and identify the already existing literature. The integrated research findings of the study formed the basis of the pocket manual development. The gaps from the national immunisation safety surveillance guideline were identified and corrective actions were suggested to enhance the pocket manual.

The review identified the following aspects of immunisation safety surveillance:

- Adverse Events Following Immunisation
- Health care provider knowledge regarding immunisation safety surveillance
- Motivation and perceptions of health care providers
- Detection and reporting of AEFI
- Health care access and infrastructure
- Parents/caretaker treatment seeking behaviour
- Support of immunisation safety surveillance
- Challenges experienced by health care providers and senior officials

Evaluating and synthesising the evidence

To evaluate and synthesise the evidence, the researcher used extensive literature search. Empirical data from the participants and the inputs of the expert group were also used in the development of the immunisation safety surveillance pocket manual. Data was collected through a convergent mixed research method to obtain as much needed information as possible. Trustworthiness, validity and reliability of the study was maintained throughout.

Formulating recommendations

Through literature review and data from the respondents and participants, the researcher came up with evidence-based recommendations. Experts in immunisation safety

surveillance provided recommendations through inputs and discussions during the immunisation safety surveillance pocket manual development process.

Writing the guidelines

Topics for the immunisation pocket were developed in a simple language that the end user could understand. The immunisation pocket manual guidelines were further summarised for those who would prefer to refer to the summary.

Consulting and peer review

Contents of the immunisation safety surveillance pocket manual were discussed and shared with the experts before they were finalised. The reviewing expert team members were those health professionals and communication experts working both on immunisation and surveillance in the country. The framed immunisation safety surveillance pocket manual was reviewed by experts who contributed immensely in the process.

3.7 CONCLUSION

This chapter presented a detailed explanation of the study design and methodology that instructed the scientific procedures and activities of the study. The mixed method research design employed in this study about population and sampling; data gathering and analysis; validity and reliability including ethical issues were discussed. The chapter also includes the identification of gaps in the existing immunisation safety surveillance guidelines of Ethiopia and the development of the immunisation safety surveillance pocket manual for health care providers.

CHAPTER 4

PRESENTATION AND DISCUSSION OF THE RESEARCH FINDINGS

> "The main aim of immunisation safety surveillance is prompt tracing and analysis of adverse events, proper and prompt response in order to reduce the undesirable impact on the health of individuals and the immunisation programme" (Waldman et al 2011:25).

4.1 INTRODUCTION

Chapter 4 presents both the quantitative and qualitative research results and discussions thereof. It outlines different analysis tools, steps, functions and cut off points that were evaluated and verified through external statistical analysis tools. Analytic techniques used to produce these results were: Univariate, cross tabulation, bivariate and multivariate binary logistic regression, correlation, factor analysis using SPSS version 25 and thematic data analysis using ATLAS. ti 8 for the qualitative findings. Throughout this study the terms ''AEFI surveillance'' and ''Immunisation Safety Surveillance are used interchangeably. The presentation of the results is categorised into different parts to address the study objectives.

4.2 DATA MANAGEMENT AND ANALYSIS

Data management is an administrative procedure that contains gaining, confirming, storing, keeping, and running needed data to ensure the accessibility, reliability, and timeliness of the data for its beneficiaries (Galetto 2016:1).

In this study, data were gathered through he questionnaire (quantitative) and face to face interview (qualitative). Four trained research assistants collected the questionnaires and the data were entered into SPSS version 25. The data were tested for wholeness, errors, cleaning and transformed (recoding and computation) before analysis was done. The face-to-face interviews were conducted in Amharic language, the regional official language, using audio recorder. Each interviewee's audio was transcribed, renamed and translated into English and stored as a word document in the computer. Each translated

document was transferred to ATLAS ti 8 for analysis. In the draft, identification of quotations through highlighting and coding, using the comment space were done in the word document. The final coding, quotation, coding and recoding groups and analysis were done by using the ATLAS. ti 8.

4.3 QUANTITATIVE RESEARCH RESULTS AND DISCUSSION.

A total number of hree hundred (300) surveys were collected from 133 health facilities. All respondents were permanently employed health care providers working at government health facilities.

4.3.1 Socio-demographic characteristics of the respondents

Different characteristics have been found to contribute to individuals' improvement of health practices (Conner 2002:4). Demographic characteristics have consistent relations with the execution of health practices (Becker & Newsom 2003:742). According to Mosadeghrad (2014:81), the attributes and personality of HCPs change the quality of health care services.

4.3.2 Gender

A total number of 173 (57.7%) respondents were females and males were 127 (42.3%). This finding seems to highlight that health care delivery is a female dominated career in most countries including Ethiopia.

4.3.3 Age

The participants' ages ranged from 19 years to 47 years. The mean age was 26.9 years with SD of 4.4 (95% CI: 22.5-31.3). The presence of two respondents with age 46 and 47 years influenced the data to be slightly positively skewed (skew: 1.019) and steep (Kurt: 2.281) as depicted in Figure 4.1. The majority of the respondents were in the age of 25-30 years with 165 (55%) followed by 19-24 years 87 (29%), reflected in (Figure 4.2). Respondents, 25-30 years, were 0.35 (OR: 0.35, 95%CI: 0.15-0.81) and 19-24 years were 0.43 (OR: 0.43, 95% CI: 0.22-0.84) times less odds in immunisation safety surveillance practice than those who were above 30 years of age. A comparable research

on AEFI surveillance KPP in Nairobi, Kenya reveals that nurses practicing in their thirties were five times more likely to have good practices towards AEFI surveillance (OR: 5.01, 95% CI: 1.88–13.30; 0.001) (Masika et al 2016:4).

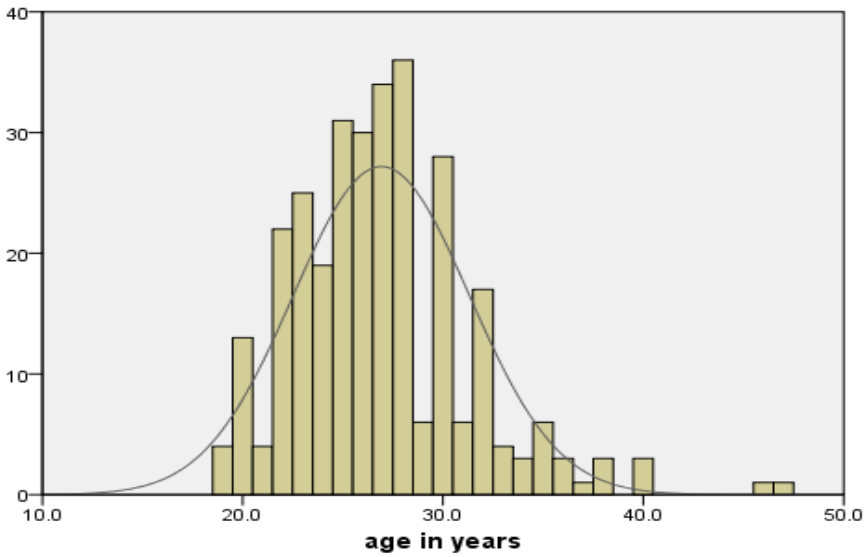

Figure 4.1 Age distribution of respondents (N=300)

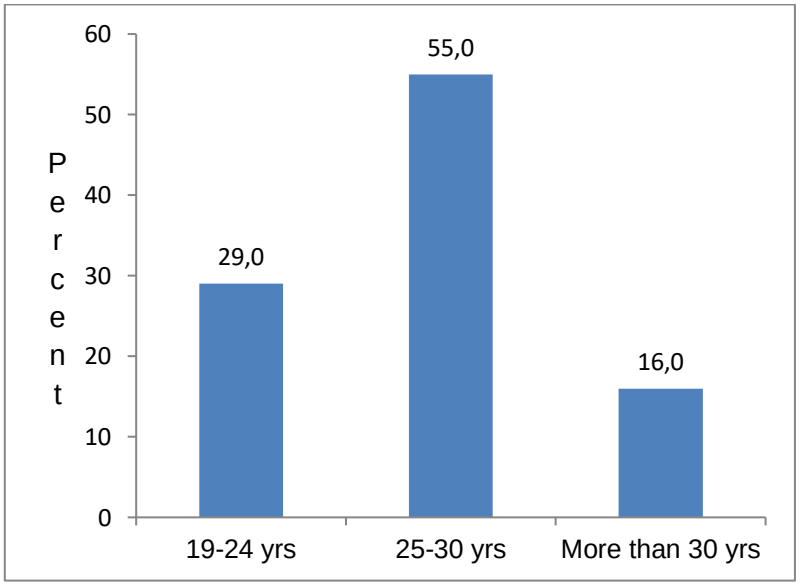

Figure 4.2 Age of respondents in range (N=300)

4.3.4 Level of education

Most respondents, 206 (68.7%) had a diploma, 65 (21.7%) had a certificate and 29 (9.7%) had first degree in their level of education, (x^2: 2.89, p: 0.24). Likewise, a cross-sectional study on nurses' KAP towards reporting of adverse drug reactions was done in the United

Arab Emirates and the results indicated higher knowledge levels among nurses with degree education and those less than thirty years of age (John et al 2012:3).

4.3.5 Woreda (district)

The largest study respondents were from Asosa woreda with 97(32.3%) followed by Bambasi with 50 (16.7%) and Homosha with the least of 22 (7.3%). Refer to Figure 4.3.

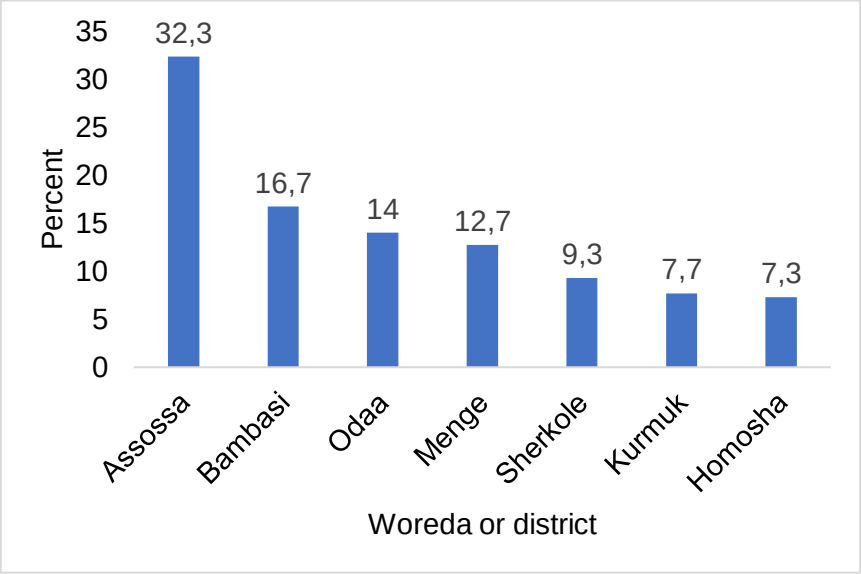

Figure 4.3 Respondents' distribution per assignment district (N=300)

4.3.6 Type of health facilities, profession and responsibility

The majority, 114 (86.4%) of the health facilities were health posts and only 2 (1.5%) were hospitals. Slightly more than half the number of respondents 164 (54.7%) were nurses by profession, followed by HEWs with 118 (39.3%) and 110 (36.7%) were health post outpatient nurses as depicted in Table 4.1.

Table 4.1 Type of health facilities, profession and responsibility of respondents (N=300)

Variables	Sub variables	Frequency	%
Type of health facilities	Health post (HP)	115	86.5
	Health centre (HC)	16	12.0
	Hospital	2	1.5
Profession	HEW	118	39.3
	Nurse	164	54.7
	Health officer (HO)	10	3.3
	Medical doctor	2	0.7
	Environmentalist	1	0.3
	Other	5	1.7
Position or responsibility	HEW	118	39.3
	HP out-patient department nurse	110	36.7
	HC paediatric nurse	16	5.3
	HC surveillance focal	16	5.3
	HC EPI focal	16	5.3
	HC Head	16	5.3
	Hospital EPI focal	2	0.7
	Hospital head	2	0.7
	Hospital paediatric nurse	2	0.7
	Hospital surveillance focal	2	0.7

4.3.7 Length of work experience

Length of service was reflected in three categories: 4 months to 4 years, 5 to 9 years, and 10 and above years. The mean length of service was 6.19 years with median and mode 6 years and SD: 4.18. The minimum and maximum service times were 4 months and 26 years, respectively. The service year is normally distributed with skew: 0.758 and kurt: 1.008. Based on the service years grouping, 117 (39%) of respondents were categorised under 0.3 to 4 years' service as reflected in Figure 4.4.

Shimabukuro et al (2015:2) emphasise that spontaneous surveillance means information is passively received from those who select to willingly report their experience, with no active effort conducted to find, detect and gather information. Hence, VAERS depends especially on the perceptions and practice of HCPs, but similarly of parents, patients, and care providers, to distinguish and report rare events following immunisation or suspected vaccine security problems.

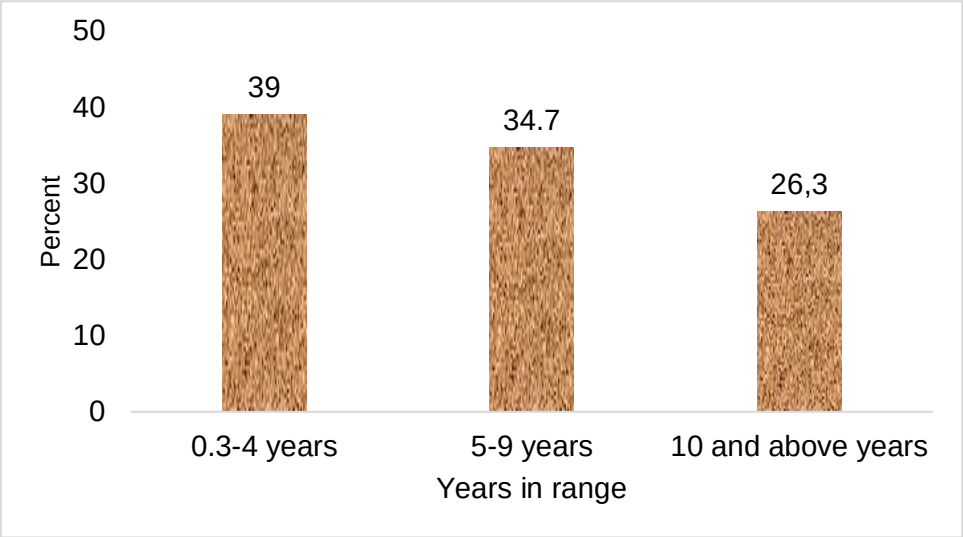

Figure 4.4 Respondents' work experience in years (N=300)

4.3.8 Health service access

4.3.8.1 Location and distance of health facilities

The majority, 261 (87%) of the respondents worked in rural health facilities and 248 (82.7%) travelled more than one-hour on foot for a single trip from their respective district town to their duty station health facility (Figure 4.5). Location of health facilities had a significant relationship with immunisation safety surveillance (x^2: 5.54, p: 0.01). The rural health facilities had 0.44 lower odds of practicing immunisation safety surveillance than urban health facilities (OR: 0.44, 95% CI: 0.22-0.88).

According to Ware (2013:4), a service's physical presence can function as a base for deciding strategy to improve service provision. In supporting this view, Kumar et al (2014:4092) found that distance is recognised to be one of the major vital noncash obstacles that hinder health care access, particularly in non-urban settings. Lengthy topographical distances to health care workers combined with a shortage of transportation services can negatively impact the use of health care and health benefits. In addition, Kyei et al (2015:1) found that the influence of distance and level of service provision on antenatal care (ANC) use in rural Zambia was strongly influenced by the quality of ANC obtained. For every 10 km increment in distance, the odds of women getting good quality ANC reduced by 25% (Kyei et al 2015:1).

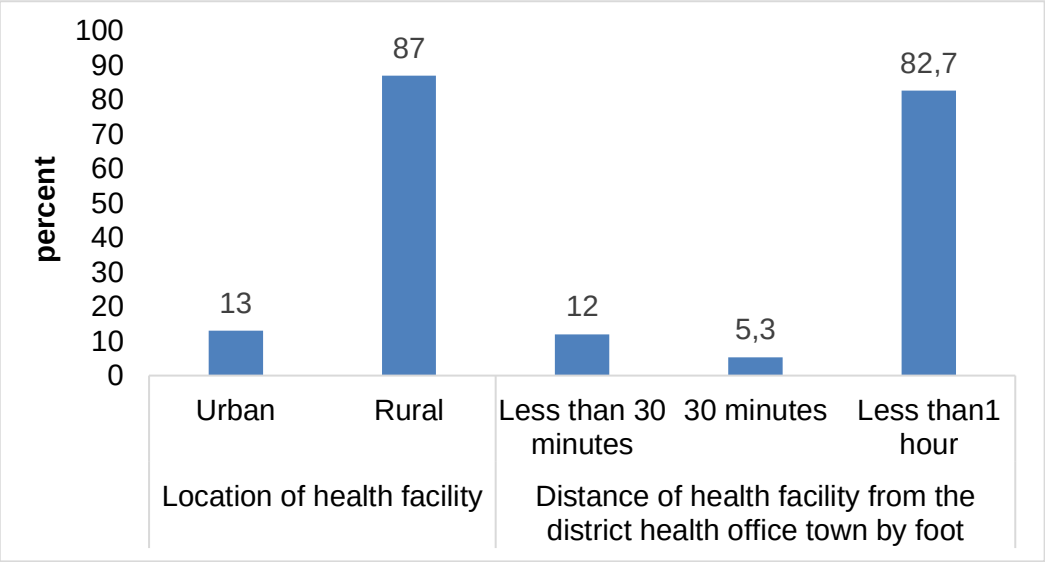

Figure 4.5 Location and distance of health facilities from district town (N=300)

4.3.9 Health facilities infrastructure

Of the total number of respondents, 215 (71.7%) mentioned that there was network access including internet service, but 66 (22%) claimed that there was only telephone network with no internet service. Two hundred and forty-two (80.7%) respondents affirmed that health facilities had road access and 179 (59.7%) used motorcycles as their means of transportation. Nevertheless, 216 (72%) of respondents reported that their health facilities lacked electricity (Table 4.2).

Availability of electricity (x^2:7.4, p: 0.02) showed relationship with immunisation safety surveillance detection and reporting. HCPs who worked in facilities where electricity rarely works had 0.43 less odds of adhering to immunisation safety surveillance detection and reporting than those working in health facilities where there was regular electricity service, (OR:0.43, 95% CI :0.23-0.80). Also, health facilities that had road access for a vehicle, (x^2:3.8, p: 0.04) and a motorcycle as means of transportation (x^2:6.46, p: 0.01) showed a relationship with immunisation safety surveillance detection and reporting. It could be argued that electricity and communication networks are very crucial for the exchange of information, update one's own knowledge and inform each other. Better capability in terms of expertise should also be complemented by the improvement of an infrastructure that assists on-going observing for the safe use of vaccines (Masika et al 2016:16; Zuber 2009:705). Similarly, a PHCWs survey on knowledge and reporting practices of AEFI in Alimosho, Lagos found reporting through telephone calls (65.2%) and of the 34

respondents who reported the AEFI encountered, 20% made telephone calls (Ogunyemi & Odusanya (2016:81).

Table 4.2 Health service access to service provider and service user (N=300)

Responses	Frequency	%
Availability of telephone service	66	22.0
Availability of network for internet services	215	71.7
Network was not available for telephone	19	6.3
Availability of electricity	58	19.3
Functional electricity	26	8.7
Non-functional electricity	216	72.0
Vehicle road accessibility from health facility to district	242	80.7
Used motorcycle as means of transportation	179	59.7
Used public transportation	133	44.3
Used Bajaj as means of transportation	113	37.7
Foot was means of transportation	91	30.3

4.3.10 Parents/caretakers' treatment seeking behaviour

A total of 85 (28.3%) respondents indicated that parents or caretakers' health seeking behaviour was very good, 191 (63.7%) said it was good, 21 (7%) fair and only 3 (1%) stated that it was poor.

UNICEF (2005:10-12) affirms that some of the principles of risk communication have to be recognised during production of a strategic communication plan and messages, particularly around AEFI. Behaviour change communication (programme communication) is one of the strategies to respond to AEFI through increasing vaccination awareness and positively affects beliefs and actions of people and groups towards vaccination. It can be targeted at caretakers as well as health professionals and other decision-making bodies. Behaviour change communication applies a combination of various channels: mass media, mini media and interpersonal communication channels (e.g. health workers).

4.3.11 Availability of focal person for adverse events following immunisation

Of concern was that a majority of the respondents, 285 (95%), had no AEFI surveillance responsible focal person in their respective health facilities, with only 11 (3.7%) stating that they had an AEFI responsible focal person and 4 (1.3%) who did not know if there was any responsible focal person for AEFI in their health facility (refer to Figure 4.7).

Low vaccination rates may be attributed to inadequate resources or substructures, but also from poor confidence on the vaccine (Hardt et al 2013:206). WHO (2010:2-3) states that in any normally serving health system the pattern of service provision should have the following vital features: accessibility, continuity, comprehensiveness, coverage, quality, person-centeredness, efficiency and accountability.

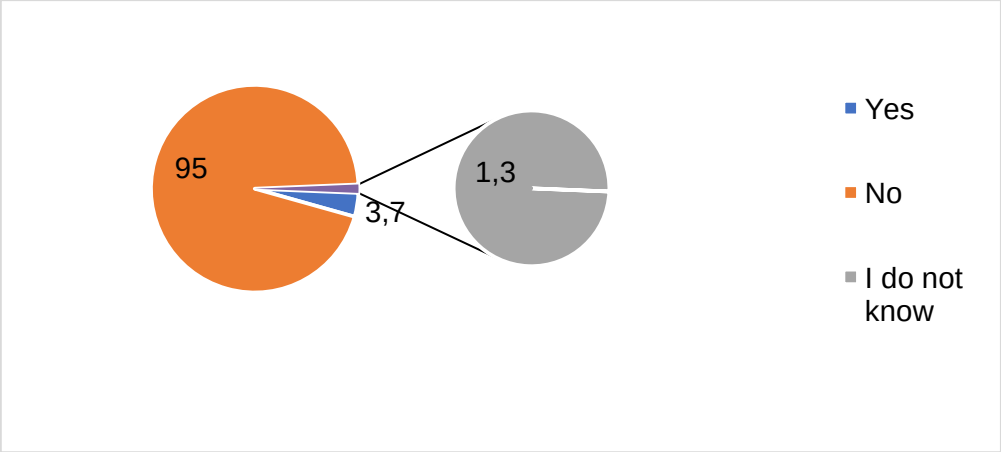

Figure 4.6 Availability of AEFI surveillance focal person in the respective health facilities (N=300)

4.3.12 Organisational and motivational factors

4.3.12.1 Respondents' readiness of immunisation safety surveillance

Only 36 (12%) of the respondents were officially delegated as immunisation or surveillance or paediatric treatment focal points. Very few of the participants 2(0.7%) had a clear job description for their positions and 298 (99.3%) had no job description. However, 281 (93.7%) believed that AEFI reporting is their mandate or day-to-day activity. Almost all, 296 (98.7%), of the respondents did not have their own specific activity annual plan and 298 (99.3%) noted that AEFI was not part of their health facility plan. A total number of 192 (64%) respondents promised to give guidance and or treat a case of AEFIs if they could have them at their health facility and only 96 (32%) claimed that they would manage and report to a higher level as reflected in Table 4.3.

The majority of 297 (99%) of the respondents had no performance evaluation, including self-evaluation, peer evaluation or supervisor evaluation. Only 36 (12%) respondents were delegated as immunisation or surveillance or paediatric treatment focal point. Lack of performance assessments might contribute to low morale and subsequent poor achievement of the AEFI surveillance.

Weldegebriel et al's (2016:166) study on health worker motivation and associated factors in hospitals, Ethiopia, explains that health worker motivation was positively predicted by the performance management job descriptions, supervisions, on-going education, and performance appraisal. Borghi et al (2017:193) argue that health sector accomplishments seriously have an impact on worker motivation.

A subjective norm denotes an individual's perception of the social forces to act or not to act. The subjective norm is decided by whether relevant referents accept or reject the accomplishment of behaviour, weighted by his/her motivation to obey those referents. These beliefs that motivate a person's subjective norm are called *normative beliefs*. This means that persons are likely to execute behaviour when they evaluate it positively and believe that significant others think they should accomplish it (Ajzen & Fishbein 1980; *Behavioural beliefs and attitudes* 2017:9).

Table 4.3 Factors assessing respondents' readiness for immunisation safety surveillance (N=300)

Responses	Frequency	%
Officially delegated for immunisation/surveillance/paediatric treatment focal person		
There was official delegation through a letter	36	12.0
No official delegation through a letter	256	85.3
Did not know or remember	8	2.7
Clear job description for the current position		
There was job description and document seen	1	0.3
here was a job description but document was not seen	1	0.3
There was no a job description	298	99.3
Is AEFI surveillance your mandate or part of your daily duty		
AEFI surveillance is my mandate	281	93.7
AEFI surveillance is not my mandate	14	4.7
Did not know about AEFI	5	1.7
Individual/specific annual activity plan		
Specific plan was available and document was seen too	3	1.0
Had annual plan but was not able to show document	1	0.3
Respondents had no specific activity plan	296	98.7
AEFI surveillance part of the annual plan		
AEFI is part of annual plan, but did not show document	2	0.7
AEFI surveillance was not part of a plan	298	99.3
What would you do when come across AEFI case?		
Manage the case and report to higher level*	96	32.0
Manage (advice and or treat) the case*	192	64.0
Only refer the case*	101	33.7
Refer and report to higher level*	16	5.3
Other answer*	4	1.3

*****Multiple response answers and sum of the percentage is more than 100%

4.3.12.2 Immunisation safety surveillance training

A significant number of 272 (90.7%) respondents had not received AEFI surveillance training, and only 28 (9.3%) had AEFI training. Of those 28 (9.3%) respondents who had AEFI training, 7 (25%) received it during supportive supervision and 21(75%) through seminars or workshops.

However, contrary to this low training finding of respondents, Okueso and Oke, (2017:59) state that the central component of successful surveillance system is HCP training and knowledge of vaccine surveillance processes. Doherty et al (2016:6708) and Hardt et al (2013:6701) emphasise that HCPs vaccine safety knowledge can be gained through different mechanisms such as before or after service training and field practice. Mohammed et al (2018:82) highlight that individuals accountable for ISS require maintaining awareness about the updated development of safety monitoring and immunisation current concerns. Similar to this study finding, Kurstak (2009:3380) and Masika et al (2016:15) acknowledge that only a few countries have readily available health workforce training and updating systems for AEFI surveillance even though training is important for HCPs. Among 26 European Union countries, only 35% had ready training programmes or manuals for nurses on prevention, detection and management of AEFI. This is an indication that HCPs training programmes are ignored not only in the European Union countries but also in most parts of the world.

4.3.12.3 Support and resources for adverse events following immunisation surveillance

Almost all respondents agreed that there was neither non-governmental organisations nor partners who supported AEFI Surveillance activities. Similarly, 275 (91.7%) and 276 (92%) respondents claimed that they had no standard AEFI surveillance reporting format or guidelines, respectively. However, of the 15 respondents who had the standard guidelines, 9 (64.3%) described the guidelines as friendly, 4 (28.6%) somewhat friendly and 1 (7.1%) claimed not to know how to describe the guidelines. A majority, 240 (80%) of the respondents reportedly had no resource shortage challenges for immunisation safety surveillance and, only 57 (19%) found that resource shortage was an obstacle to conduct immunisation safety surveillance. In this regard, the majority of resources gaps were reporting formats, drugs and human resource or time by 25 (8.3%), 23 (7.7%) and

22 (7.3%) respondents, respectively. The means of data transferring for surveillance whenever faced with an AEFI case were telephone calls 256 (85.3%) and in person 142 (47.5%) as reflected in Table 4.4. In this study availability of reporting forms was significantly related to immunisation safety surveillance, ($x2=10.21$, $p=0.03$).

Lack of drugs, unequal health service distribution and lack of equipment or guidelines must all be considered as components of basic health service management (*Service delivery* 2018:1-12). In addition, availability of AEFI reporting forms at the vaccination centres considerably affects reporting. A PHCWs survey on AEFI knowledge and reporting practices in Alimosho, Lagos points out one of the most common perceived barriers of not reporting AEFIs as inability to find reporting forms (50.6%) (Ogunyemi & Odusanya 2016:82). The 2009 national immunisation policy of Nigeria outlines that in order to increase immunisation providers' knowledge and practice, guidelines are important for constant on-the-job training for health professionals on immunisation biannually (Brown et al 2017:2). The types of interventions included in the review and in more recently published studies demonstrate that enhanced ADR reporting incorporate: updating forms for reporting, updating procedures for reporting; improving availability of reporting forms; enhancing feedback to reporters; giving incentives for reporting; and giving support from other experts at the time of reporting (Ribeiro et al 2016:5). It is important that all partners such as NIP, EFMHACA, vaccine developers, laboratories, HCPs and development partners practise vigorously to deliver documented evidence through a successful AEFI surveillance system. This will enhance the availability of the functional immunisation facilities to the population that have adequate monitoring and reaction to AEFIs. It is envisaged that stakeholders at all levels, should be part of the consolidation of the AEFI surveillance system in Ethiopia (EFMHACA 2016:4).

Table 4.4 Availability of resources for adverse events following immunisation surveillance (N=300)

Responses	Frequency	%
There was no NGO/partner support for AEFI surveillance	278	92.7
AEFI surveillance reporting form was available and seen	14	4.7
AEFI surveillance reporting form was available, but was not seen	3	1.0
AEFI surveillance reporting form was never available	275	91.7
Did not know about AEFI surveillance reporting form	4	1.3
There was AEFI surveillance implementation guideline	15	5.0
There was no AEFI surveillance implementation guideline	276	92.0
Resource shortage affected immunisation safety surveillance	57	19.0
Resource shortage did not affect immunisation safety surveillance	240	80.0
Reporting formats affected the surveillance*	25	8.3
Unavailability of drugs affected the surveillance*	23	7.7
Shortage of manpower affected the surveillance*	22	7.3
Community information gap affected the surveillance*	8	2.7
Budget affected the surveillance*	7	2.3
Others*	15	5.0
Telephone was means of communication for reporting AEFI case	256	85.3
Person was means of communication for reporting AEFI case	142	47.5
Other	8	2.7

*Multiple responses and their percentage sum are not 100%

4.3.12.4 Respondents' performance evaluation

Almost 297 (99%) respondents did not periodically evaluate their performance and 299 (99.7%) of their performance were not evaluated by their colleagues and immediate supervisors. However, 243 (81%) respondents got periodic supervisions from a higher level, which was verified by documentation and 213 (71%) received written supervision feedback on which a supportive document was verified (Table 4.5).

It is essential to decide the aspects on which progress would be measured in order to track improvements regarding health service provision. The number of health services and type of organisations may vary from one nation to another, however, all health care delivery systems should have these vital features: accessibility, continuity, comprehensiveness, coverage, quality, person-centeredness, efficiency and accountability (WHO 2010:2-3). Service provision monitoring has a direct relevance for health services management that distinguishes it from other health systems building blocks (*Service delivery* 2018:1-12).

Table 4.5 Practice on performance evaluation of respondents (N=300)

Responses	Frequency	%
Periodic self-performance evaluation using a check list was not done	297	99.0
Periodic performance evaluation by their colleague was not done	299	99.7
Periodic performance evaluation by their supervisor was not available	299	99.7
Periodic supportive supervision from higher level was available and document was seen	243	81.0
Periodic supportive supervision from higher level was reported, but document was not seen	12	4.0
Periodic supportive supervision from higher levels was not available	45	15.0
Written feedback from supervisor on the status of activity performance reported was available and document was seen	213	71.0
Written feedback from supervisor on the status of activity performance was available, but no document seen	6	2.0
Feedback from supervisor on the status of activity performance was provided verbally	28	9.3
Feedback from supervisor on the status of activity performance was not given	53	17.7

4.3.12.5 Reward system and recognition

Existence of rewarding system in their district was reported by only 96 (32%) respondents, 200 (66.7%) reported no reward system and 4 (1.3%) did not know availability of a reward system. Of those who were aware of the reward, 28 (29.2%) reported that they received some type of reward from different levels of the government system, and 68 (70.8%) did not get any reward. Lack of a rewarding system in any form may discourage workers from improving their performance and often leads to low motivation with resultant poor achievement of the AEFI surveillance. Ogunyemi and Odusanya (2016:3) note that the MOH, Ethiopia, found that lack of inspiration and personnel worries on the effect of programmatic mistakes adversely impacted surveillance of AEFI, particularly on adverse events reporting.

4.3.12.6 Case detection and reporting

As many as 77 (25%) respondents had ever detected AEFI cases and only 17 (5.7%) reported the cases to higher level, whilst 8 (2.7%) were using the standard AEFI surveillance reporting form.

In supporting this view, Ogunyemi and Odusanya (2016:80) and Waldman et al (2011:25) highlight that the whole purpose of ISS is prompt detection and reviewing of adverse events with proper and quick feedback in order to reduce the adverse outcome on

individual health and the vaccination programme. In addition, reporting AEFIs is important in recognising the occurrence of rare events for new vaccines, which may not be known during clinical trials or to monitor the rates of such events for well-established vaccines. The low detection reported in this study could be attributed to the passive surveillance. A passive surveillance system major restriction consists of variability in reporting quality and completeness, reporting bias, under-reporting of events, inability to compare cause and effect relationship between the vaccine and AEFI, and the inability to establish an accurate AEFI frequency rate due to lack of a clearly defined numerator (adverse events) and usually denominator (Parrella 2014:15; Shimabukuro et al 2015:4405; UNICEF 2005:30-34). LMIC lag behind in utilisation (Burton, Bigogo, Audi, Williamson, Munge & Wafula 2015:2) of standardised safety protocols and practices (for example International Classification of Diseases, Uppsala Monitoring Centre, Brighton Collaboration) and have a weakness in the identification of AEFIs that remains under-reported and under-investigated (Graham et al 2012:4953). Yamoah and Oosthuizen (2018:46) describe that globally, an AEFI reporting is problematic. It is approximated that about 95% of AEFIs do not ever get reported requiring major improvements.

4.3.12.7 Service provider confidence level

A majority, 215 (72%) respondents reported that they felt confident to conduct immunisation safety surveillance in their respective health facilities, while 82 (27.3%) and 3 (1%) were unsure and not confident, respectively, to do immunisation safety surveillance. Low vaccination rates may be because of inadequate resources or substructures, but also from lack of confidence in the vaccine. Reasons for poor vaccine confidence include doubts from caretakers and HCPs about vaccines, mainly vaccine safety (Hardt et al 2013:206). It is crucial to have confidence in the safety of a vaccine for the immunisation programme and public health worldwide. A complicated array of difficulties persists to threatening this confidence and is counter effective for vaccine safety systems operations, particularly in LMIC (WHO 2017:I), where hundreds of millions of vaccine doses are given per annum (Graham et al 2012:4989).

4.3.12.8 Parent expected response for AEFI

Most respondents 233 (61%) confirmed that parents whose children developed AEFI will visit health facilities for medical care and, 109 (28%) reported that parents did nothing

since they felt that AEFI is a self-limiting event. In supporting this view, Brown et al (2017:2) warn that inadequate knowledge regarding vaccinations and incompetence to communicate successfully with parents about vaccinations have been recognised as some of the reasons children are not immunised in Nigeria. Hardt et al (2013:206) also mention that when thinking about immunisation, parents may therefore stress more about possible adverse events than they do about the risks associated with exposure to disease.

4.3.12.9 Respondents' satisfaction

Regarding respondents' satisfaction on the current job or position, 121 (40.3%) indicated very good, 120 (39.7%) good, 44(14.7%) fair, whilst 14 (4.7%) were dissatisfied and 1 (0.3%) was very dissatisfied, as depicted in Figure 4.7.

Bonenberge, Aikins, Akweongo and Wyss (2014:4) note that service providers' work satisfaction is too mandatory in providing quality services. HCPs recognised nine organisational issues they thought affect their inspiration and accordingly work satisfaction. Participants mainly indicated their satisfaction with the job they were doing.

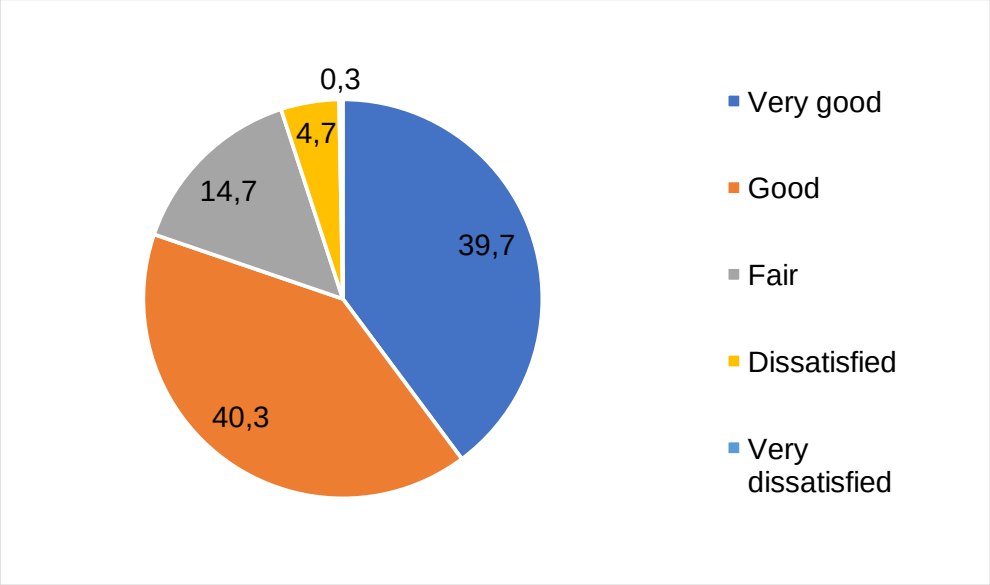

Figure 4.7 Respondents' satisfaction with their current job (N=300)

4.3.13 Health care providers' knowledge on immunisation safety surveillance

Thirty (30) indicators were utilised to assess the knowledge of HCPs on immunisation safety surveillance. In the sample, 284 (94.7%) respondents had ever heard about AEFI but only 67 (22.3%) were able to define AEFI as per WHO standard definition. Furthermore, 137 (45.7%) were not informed that AEFI surveillance should be done in each health facility. Thirty-nine (13%) of the respondents indicated that vaccination could not result in any adverse effect and only 186 (62%) replied that AEFI as a clinical event is not only restricted to immunisation. Also, 134 (44.7%) replied that AEFI could not be caused by immunisation injection anxiety. In addition, respondents mentioned the following: 32 (10.7%) AEFI could not be caused by inappropriate route or injection technique, 35 (11.7%) vaccines could not cause AEFI after exposure to excessive heat or cold, 41 (13.7%) AEFI could not be caused by reconstituted vaccine stored longer than recommended period and 22 (7.3%) vaccines stored beyond expiry date (Table 4.6a) could not cause AEFI.

Mosadeghrad (2014:81) maintains that practitioner's knowledge and technical skill matter for the competency and quality of health care services. In support, Mohammed et al (2018:82) explain that in order to obtain and sustain population trust in the safety of vaccines through functional AEFI surveillance, HCPs have important and crucial roles to play. These roles encompass delivering evidence-based information on the relevance and risks of vaccines: detecting and reporting AEFI. This study found better results contrary to the AEFI surveillance in Kwekwe District, Zimbabwe, 2009-2010 which found that none of the health care providers could perfectly describe an AEFI (Muchekeza et al 2014:2).

Table 4.6a Respondents' response on immunisation safety surveillance knowledge indicators (N=300)

Response	Frequency	%
I have heard about AEFI	284	94.7
Did not know AEFI definition	233	77.7
Defined AEFI as its standard definition	67	22.3
AEFI surveillance should not be done in every health facility	137	45.7
AEFI surveillance should be done in each health facility	153	51.0
Vaccination can bring any adverse effects	254	84.7
AEFI as a clinical event is solely restricted to immunisation	106	35.3
AEFI as a clinical event is not solely restricted to immunisation	186	62.0
AEFI can be caused by vaccine reaction	268	89.3
AEFI can be caused by anxiety due to the immunisation	161	53.7
AEFI can be caused by inappropriate route or injection technique	264	88.0
AEFI can be caused by vaccines exposed to excessive heat or cold	258	86.0
AEFI can be due to reconstituted vaccine stored beyond the recommended period	251	83.7
AEFI can be due to vaccines stored beyond expiry date	274	91.3

Slightly less than half the number of respondents, 144 (48%) mentioned that all injection site redness should not be reported to a higher level. AEFI rumour with 103 (34.3%) was the lowest and convulsion/seizure with 275 (91.7%) was the highest AEFI signals that needed to be reported to the next higher level. Nearly one-third (n=91 or 30.3%) expressed the view that health care providers should not always report the AEFI cases immediately to the next higher level. For the mean value of all the knowledge indicators, 41.3%, 2.7%, 56% of the respondents scored below (poor knowledge), equal (fair knowledge), and above (good knowledge) the mean value, respectively (Table 4.6b).

Miller et al (2018:8) found that in a national representative sample of different professions of health workers study in the USA aimed to assessing the detection and reporting of an AEFI to VAERS, knowledge and attitudes indicate that only 14% were highly acquainted with the paper reporting process to report an AEFI even though 71 % were acquainted with VAERS. An estimated 40% of the study respondents had detected a minimum of one AEFI, with only 18% describing they had reported to VAERS. Mehmeti et al (2017:7) identify that health professionals AEFI reporting knowledge, practice and approaches in Albania indicates that only 12.7% had good knowledge of AEFI. Most of them, 52.9% had fair knowledge level and a substantial percentage, 34.3% had poor knowledge level. Yamoah et al (2019:1) in a case study from Ghana on knowledge and perceptions of AEFI among HCPs in Africa, reveal that knowledge of AEFIs was high in 10.8% respondents, moderate in 47.0% respondents, and low in 42.2% respondents.

Tabld 4.6b Respondents' response on immunisation safety surveillance knowledge indicators (N=300)

Response	Frequency	%
Redness of all injection sites should be reported	152	50.7
Swelling of all injection sites should be reported	158	52.7
Abscess of all injection sites should be reported	251	83.7
Any convulsion/seizure should be reported	275	91.7
Any anaphylaxis should be reported	251	83.7
Fever >38^{o}C should be reported	164	54.7
Any rumour related to AEFI should be reported	103	34.3
Coincidental sickness management should be delayed until investigations confirmed	49	16.3
Adrenaline should be administered intramuscularly during anaphylaxis	139	46.3
Paracetamol is used to treat immunisation local reaction	280	93.3
If there is a history of anaphylaxis it is contraindication to a given vaccine	125	41.7
The health and life can be endangered through using local remedies for any severe vaccine reaction	276	92.0
Each vaccinating centre must have an emergency kit with adrenaline	295	98.3
HCPs should always report the AEFI cases immediately to next higher level	207	69.0
AEFI could be reported through telephone	276	92.0
AEFI could be reported by electronic mail or fax	251	83.7
AEFI investigation should be started within 1 day	283	94.3
All cases requiring hospitalisation that occur within one month of an immunisation should be investigated	218	72.7
All deaths that occur within one month of an immunisation should be investigated	207	69.0
Average value of all the indicators below the mean value	124	41.3
Average value of all indicators equal to mean value	8	2.7
Average value of all the indicators above the mean value	168	56

4.3.14 Health care providers' perceptions on immunisation safety surveillance

Thirteen (13) indicators were used to measure the health care provider perceptions on immunisation safety surveillance. A majority, 295 (99%) respondents believed that surveillance of immunisation safety is beneficial. More than half the number of respondents, 157 (52.3%) strongly disagreed and 18 (6%) disagreed that to report AEFI will not make vaccinator develop guilt for causing injury. However, 48 (16%) respondents strongly agreed and 192 (64%) agreed that reporting of an AEFI cannot lead to individual punishment. On the other hand, 22 (7.3%) respondents agreed with the perception that health care providers are not keen to report AEFI to the next higher level, but 87 (29%) strongly disagreed with this perception. For the indicator, the procedure of an AEFI surveillance is lengthy and boring, 35 (11.7%) agreed and 4 (1.3%) strongly agreed. The mean value of all the perception indicators, 134 (44.7%), 42 (14%), 124 (41.3%) of the respondents scored below (poor perception), equal (fair perception) and above (good perception) the mean value, respectively as shown in Table 4.7. Almost 99% respondents

believed that surveillance of immunisation safety is beneficial and health workers play a crucial role in identifying, reporting, investigating and managing AEFI. It makes sense that attitudes should guide behaviour and it has been a central focus of persuasion (Frymier & Nadler 2017:43). People's probability of caring out a specific behaviour will be robust if they hold a constructive attitude towards the practice of that behaviour. According to Ajzen and Fishbein (1980), the TRA is grounded on the idea that people are reasonable and systematically use existing information. People analyse the effect of their practice before they plan whether to engage in a given behaviour (Holdershaw & Gendall 2014:2-6; Tlou & Dyk 2009:26).

Table 4.7 Respondents' response on immunisation safety surveillance perceptions indicators (N=300)

Response	Freq/ %	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Surveillance of AEFI case has no benefit	Freq	1	3	1	105	190
	%	0.3	1.0	0.3	35.0	63.3
AEFI reporting will not make vaccinators sense guilt as causing harm	Freq	12	104	9	157	18
	%	4.0	34.7	3.0	52.3	6.0
Reporting of an AEFI will not lead to punishments	Freq	48	192	4	54	2
	%	16.0	64.0	1.3	18.0	0.7
Health care providers are not keen on reporting of AEFI to next higher level	Freq	5	22	3	183	87
	%	1.7	7.3	1.0	61.0	29.0
Health care provider is always busy and no time for surveillance of AEFI	Freq	4	12	3	209	72
	%	1.3	4.0	1.0	69.7	24.0
Detecting, reporting and investigating AEFI is none of health care provider's business	Freq	98	168	8	24	2
	%	32.7	56.0	2.7	8.0	0.7
Reported AEFI case feedback should not be sent back by higher level	Freq	5	43	5	212	35
	%	1.7	14.3	1.7	70.7	11.7
Every HEW/HW functioning at facilities level must know about AEFI surveillance	Freq	174	122	2	1	1
	%	58.0	40.7	0.7	0.3	0.3
HEW/HW plays a key role in diagnosing, reporting, investigating and managing AEFI	Freq	158	138	2	2	0
	%	52.7	46.0	0.7	0.7	0.0
The procedure for AEFI surveillance is lengthy and boring	Freq	4	35	6	192	63
	%	1.3	11.7	2.0	64.0	21.0
AEFI detection and reporting should be done by seniors and not by nurses or HEWs	Freq	11	33	3	180	73
	%	3.7	11.0	1.0	60.0	24.3
Increasing AEFI surveillance helps to build population trust in immunisation programme	Freq	188	108	3	1	0
	%	62.7	36.0	1.0	0.3	0.0
	Freq	110	145	5	35	5

Response	Freq/ %	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Immunisation achievement decrease can be due to weak monitoring of adverse events	%	36.7	48.3	1.7	11.7	1.7

4.3.15 Health care providers' practice with immunisation safety surveillance

Ten indicators were used to explore the experience and actions of health care providers' adherence to immunisation safety surveillance. Two hundred and nineteen (73%) had never observed injection site swelling/redness/abscesses/convulsion/shock/fever >38^{o}C following immunisation, while 77 (25%) had. Only 14 (4.7%) respondents had ever reported to a higher level and 69 (23%) ever treated an AEFI case. Most respondents practised by ruling out contraindications to vaccine(s) in a child prior to vaccine administration 274 (91.3%), informed caretaker of possible vaccine adverse reactions by (n=292 or 97.3%) and informed caretaker how to treat AEFI at home (n=284 or 94.7%).Furthermore, the majority, 269 (89.7%), 279 (93%) and 278 (92.3%) respondents reported that they had no AEFI surveillance standard guidelines, no reporting forms and had never reported an AEFI case to a higher level, respectively. In the mean value of all the practice indicators, 46.7%, 22%, 31.3% of the respondents scored below (poor practice), equal (fair practice) and above (good practice), respectively (Table 4.8). The WHO (2016:26) points out that when an AEFI occurs, HCPs at immunisation facilities are expected to identify or trace it. In addition, Twene and Yawson (2018:106) assert that health workers who conduct immunisation services in the district have the responsibility of identifying and reporting AEFIs to the district EPI focal person for onward submission to the region. This study's results could be compared to the study of nurses' KAP on AEFI Surveillance in Nairobi, Kenya, which found that a majority of nurses (85.8%) had no anaphylactic pack with adrenaline in their immunisation rooms. Some nurses (32.1%) had ever identified a child with BCG lymphadenitis, abscesses, shock, injection site swelling and redness, convulsion, fever >40^{O}C or acute flaccid paralysis and some (2.3%) of the participants had ever reported an AEFI (Masika et al 2016:2).

Table 4.8 Respondents' response on immunisation safety surveillance practice indicators (N=300)

Response	Frequency	%
Ever come across a child with any of the signs and symptoms of AEFI (either injection site redness/abscesses/swelling or convulsion or fever >40^{o}C)	77	25.7
Never reported an AEFI to higher level	278	92.7
Ever reported an AEFI to higher level	14	4.7
Ever treated an AEFI person	69	23.0
Never participated in AEFI investigation for detected persons	292	97.3
Ever participated in AEFI investigation for detected persons	1	0.3
Ruled out contraindications to vaccine(s) in a child before vaccinating	274	91.3
Informed parents of possible vaccine adverse events	292	97.3
Informed the caretaker how to treat AEFI at home	284	94.7
There was no anaphylactic pack with adrenaline in the vaccination room	157	52.3
There was an anaphylactic pack with adrenaline in the vaccination room	111	37.0
There were no AEFI standard guidelines at workstation	269	89.7
There were an AEFI standard guidelines at workstation	24	8.0
There was no AEFI reporting and investigation form at workstation	279	93.0
There was an AEFI reporting and investigation form at workstation	12	4.0
Below the mean value of all the practice indicators	140	46.7
Mean value of practice of all the practice indicators	66	22
Above the mean value of all the practice indicators	94	31.3

4.3.16 Challenges that hindered immunisation safety surveillance

The respondents were asked what challenges they faced to conduct immunisation safety surveillance. Among all the respondents, 25 could not justify or raise any issue, 25 indicated that there was no challenge and 250 proposed challenges. The respondents identified 39 different challenges, which were further grouped into 18 challenging categories. Among the stated challenges, there were no clarity on how to do immunisation safety surveillance, no standard reporting forms, the problem was mild, which could resolve by itself or care takers could manage it at home, there is no road and electricity access, and respondents' ability to treat the case at health facility level were mostly raised. Among all, 180 (60%) and 66 (22%) respondents had not reported AEFI cases since there was no AEFI case and no clear information on how to report it, respectively as shown in Table 4.9.

Research in the USA comprised 293 respondents, physicians, pharmacists and nurses or nurse practitioners, showed gaps to reporting comprised uncertain definitions of a reportable AEFI; lack of time due to other priorities than a report; and misunderstanding of whose responsibility it was to report. Reporting was associated with being advised to

observe the exact events (87%); disregarding another reason for the event (81%); if the event was observed recurrently (71%) and if the events happened in susceptible patient groups such as infants, pregnant women or patients ≥ 65 years of age (44%) (Parrella 2014:26).

Another study on gaps to HCPs' reporting AEFI in four regions of Ghana found that the major usual hindrances were fear of individual repercussions (44.1%), shortage of knowledge or training (25.2%), and not perceiving an AEFI was severely sufficient to report (22.2%) (Gidudu et al 2020:1).

Table 4.9 Challenges that hindered immunisation safety surveillance

Reasons/challenges	Freq	%	Reasons/challenges	Freq	%
No case of AEFI	180	60.0	Lack of attention or follow up from responsible bodies	20	6.7
No clear information or AEFI surveillance system	66	22.0	No training for AEFI separately or poor capacity to identify the problem	17	5.7
Absence of reporting format or other supplies	62	20.7	Community have no awareness of reporting AEFI	10	3.3
AEFI is a mild problem, it will resolve by itself or cases can be treated at home	44	14.6	HWs not working properly at duty station	4	1.3
No road or electricity	28	9.3	Service provider's fear of accountability	4	1.3
Indicated that there was no problem	25	8.3	No responsible person	3	1
Could not justify/raise issue or challenge	25	8.3	Wor load	3	1
Able to treat the case easily at HF level	22	7.3	No documentation	3	1
No network for telephone communication	20	6.7	Proper administration of the vaccine	2	0.6

*All are multiple responses

4.4 FACTORS ASSOCIATION AND REDUCTION

All the explanatory variables were tested with the dependent variable in order to conduct a bivariate analysis. Bivariate analysis is the analysis of two factors with the aim of describing the empirical relationship between explanatory and dependent variables (Bivariate Analysis 2019). Chi-square is applied to assess the relationship between the outcome and explanatory variables. The logistic model is a statistical model that is often employed to a dichotomous variable. It is used to estimate the probability of a dichotomous outcome based on one or more explanatory variables (Bivariate Analysis

2019). The dependent variable of this study was a dichotomous variable with Yes or No response. In this study, the binary logistic regression was used to determine the association and significant association between the dichotomous dependent variable and the independent variables. Factors that showed goodness of fit (chi-square) with the dependent variables were cross-checked with the bivariate binary logistic regression (Annexure G). All variables that showed association during the bivariate analysis were loaded to the logistic regression model to identify variables, which were significantly associated, and to control for confounding factors. This is called multivariate analysis (Table 4.14).

4.4.1 Chi-square test for socio-demographic variables

A bivariate analysis to identify relationships between socio-demographic and outcome variables was done by using chi-square test. Among the socio demographic characteristics: on type of health facilities (x^2:6.32, p: 0.04), age of respondents (x^2:7.74, p: 0.02), responsibility (x^2:17.12, p: 0.04) and work experience (x^2:13.59, p: 0.001), showed relationship with the outcome variable as shown in Table 4.10.

Table 4.10 Socio-demographic characteristics relationship test using chi-square

Variables	Response	Count			Chi-square test	
		Yes	No	Total	Value	P-value
District or Woreda	Asosa	29	68	97	9.75	0.14
	Bambasi	19	31	50		
	Homosha	6	16	22		
	Kurmuk	3	20	23		
	Menge	7	31	38		
	Odaa	8	34	42		
	Sherkole	5	23	28		
Type of health facilities*	HC	22	42	64	6.32	**0.04**
	Hospital	4	4	8		
	HP	51	177	228		
Age*	Greater than 30	16	32	48	7.74	**0.02**
	25-30	48	117	165		
	19-24	13	74	87		
Gender	Male	35	92	127	0.41	0.52
	Female	42	131	173		
Level of education	Certificate	14	51	65	2.89	0.24
	Diploma	52	154	206		
	First Degree	11	18	29		
Profession	HEW	27	91	118	2.39	0.79
	Nurse	44	120	164		
	Environmentalist	0	1	1		
	HO	4	6	10		
	Medical doctor	1	1	2		
	Other	1	4	5		

Variables	Response	Count			Chi-square test	
		Yes	No	Total	Value	P-value
Responsibility or P\position*	HEW	27	91	118	17.12	**0.04**
	HP OPD nurse	24	87	111		
	HC Head	7	8	15		
	Hospital head	1	1	2		
	HC EPI focal	3	12	15		
	Hospital EPI focal	0	3	3		
	HC surveillance focal	6	9	15		
	Hospital surveillance focal	2	1	3		
	HC paediatric nurse	5	11	16		
	Hospital paediatric nurse	2	0	2		
Work experience*	10 and above years	29	50	79	13.59	0.001
	5-9 years	31	73	104		
	0.3-4 years	17	100	117		

*Variables, which showed significant relationship with the outcome variable

4.4.2 Chi-square test for health facilities accessibility to provider and user

Among variables under this category: location of health facility (x^2=5.54, p=0.01), status of electricity (x^2:7.4, p: 0.02), vehicle road access (x^2:3.88, p: 0.04), Bajaj transportation (x^2:6.46, p: 0.01), parents treatment seeking behaviour (x^2:7.93, p: 0.04) showed relationship (Table 4.11).

Table 4.11 Health facilities access and immunisation safety surveillance chi-square test

Variable	Response	Count			Chi-square	
		Yes	No	Total	Value	Sig (2-sided)
Location of Health facility	Urban	16	23	39	5.54	0.01
	Rural	61	200	261		
Status of telephone communication in the HF	Available telephone service	10	56	66	5.53	0.06
	Network available for internet	63	152	215		
	No network for telephone	4	15	19		
Availability of focal persons AEFI surveillance	Available	2	9	11	1.77	0.41
	Not available	75	210	285		
	Do not know	0	4	4		
Status of electricity in the health facility	Available and functional	23	35	58	7.4	0.02
	Available but rarely works	6	20	26		
	Not available at all	48	168	216		
Vehicle road accessibility from HF to district	Available	68	174	242	3.88	0.04
	Not available	9	49	58		
Possible means of transportation	Public transportation	40	93	133	2.43	0.12
	Motorcycle	42	137	179	1.13	0.29

Variable	Response	Count			Chi-square	
		Yes	No	Total	Value	Sig (2-sided)
	Foot	22	69	91	0.15	0.69
	Bajaj	38	75	113	6.46	0.01
Rate of parents or caretakers' treatment seeking behaviour	Very good	22	63	85	0.93	0.04
	Good	52	139	191		
	Fair	1	20	21		
	Poor	2	1	3		
Parents reason for did not seek treatment care against AEFI	It is self-limited	71	193	264	1.74	0.19
	Not know AEFI seeks treatment	8	14	22	1.42	0.23
	Residence far from HF	5	9	14	0.78	0.38
	Family workload	2	8	10	0.17	0.68
	The disease is because of the nature of the vaccine	5	6	11	2.34	0.13
	Others	0	9	9	3.2	0.07

4.4.3 Chi-square test of organisational and motivation factors

Factors under organisational and motivational categories which showed a relationship were: standard AEFI surveillance reporting form (x^2:10.21, p: 0.03), means of communication (x^2:5.85, p: 0.01), satisfaction with current position (x^2:9.98, p: 0.04), self-assessment (x^2:6.16, p: 0.04) and parent response (x^2:5.22, p: 0.02) (Table 4.12).

Table 4.12 Organisational and motivational variables chi-square test

Variable	Response	Count			Chi-square	
		Yes	No	Total	Value	P-value
Health facility working hours	24 hours	53	168	221	1.66	0.43
	8 hours	23	54	77		
Official delegation being focal person	There was delegation letter	8	28	36	1.06	0.59
	There was no delegation letter	68	188	256		
Clear job description for the position	Available and document seen	0	1	1	0.69	0.71
	Available but document was not seen	0	1	1		
	There was no job description	77	221	298		
Is AEFI surveillance reporting part of your daily duty	Yes, it is	72	209	281	0.15	0.93
	No, it is not	4	10	14		
Individual annual activity plan	Yes, document seen	1	2	3	3.00	0.22
	Yes, document not seen	1	0	1		
	No activity plan	75	221	296		
AEFI surveillance part of the plan	Yes, document not seen	0	2	2	0.69	0.40
	Not part of the plan	77	221	298		
Training	Got training	7	21	28	0.007	0.93
	Did not get training	70	202	272		

Variable	Response	Count			Chi-square	
		Yes	No	Total	Value	P-value
Type of training	On job training through Seminar/Workshop	6	15	21	0.04	0.85
	On job through supportive supervision training	2	6	8		
Standard AEFI surveillance reporting form	Available and seen	3	11	14	10.21	0.03
	Available but not seen	3	0	3		
	Available but not now	1	3	4		
	Never	70	205	275		
Respondent colleague reporting AEFI case	Yes, reported	7	8	15	3.71	0.16
	Not reported	69	211	280		
Immunisation safety guideline	Yes, available	1	14	15	4.17	0.12
	Not available	75	201	276		
Guideline user friendly	Yes, it is	0	9	9	2.69	0.26
	Some what	1	3	4		
Resource shortage	Yes, available	18	39	57	2.23	0.33
	No resource shortage	59	181	240		
Type of resources which affect immunisation safety surveillance	Manpower or time shortage	6	16	22	0.03	0.86
	Community information	4	4	8	2.55	0.11
	Drugs	8	15	23	1.04	0.31
	budget	1	6	7	0.48	0.48
	Formats	7	18	25	3.00	0.22
	Other	4	11	15	0.008	0.93
Means of communication	Telephone	70	186	256	2.57	0.11
	Person and written	34	108	142	0.42	0.52
	Other means	5	3	8	5.85	0.01
Respondent satisfaction with the current position	Very good	13	70	83	9.98	0.04
	Good	46	122	168		
	Fair	12	23	34		
	Dissatisfied	5	8	13		
	Very dissatisfied	1	0	1		
Self-evaluation using checklist	Yes, document seen	0	1	1	6.16	0.04
	Yes, document not seen	2	0	2		
	No	75	222	297		
Performance evaluation by colleague	Available but document not seen	1	0	1	2.91	0.08
	No document	76	223	299		
Performance evaluation by supervisor	Yes, but document not seen	0	1	1	0.35	0.56
	No supervisor evaluation	77	222	299		
Periodic supervision from higher levels	Yes, document seen	60	183	243	0.74	0.69
	Yes, but document not seen	4	8	12		
	No periodic supervision	13	32	45		
Feedback from the supervisor on the status of performance	Yes, document seen	52	161	213	0.68	0.88
	Yes, but document not seen	2	4	6		
	Yes, but verbal feedback	8	20	28		
	No feedback at all	15	38	53		
Confidence to conduct immunisation safety surveillance	Confident	53	162	215	1.71	0.42
	Somewhat	24	58	82		
	I cannot	0	3	3		
System of reward for best performer	Yes, there is reward system	24	72	96	0.04	0.98
	No, reward system	52	148	200		
Ever got reward	Yes, got reward	8	20	28	0.23	0.63
	Not got reward	17	54	71		
What will parents do if their family member or child develop AEFI	Nothing done because it is self-limited	37	109	109	6.15	0.01
	Will take to HF	67	166	233	5.22	0.02
	Any other reasons	8	33	41	0.94	0.33

4.4.4 Total mean value of knowledge, perceptions and practice (KAP) relationship with the dependent variable

Each indicator of KAP was summed up per respondent and the total mean value of the KAP indicators was calculated. The relationships of the total mean values were tested with the outcome variable, knowledge and practice indicators showed a relationship (Table 4.13).

Table 4.13 Chi-square tests of average value of knowledge-perception-practice indicators

Variable	Response	Count			Chi-square	
		Yes	No	Total	Value	P-value
Total average knowledge	Above the mean	36	132	168	8	0.02
	Equal to the mean	5	3	8		
	Below the mean	36	88	124		
Total average perception	Above the mean	32	92	124	0.26	0.87
	Equal to the mean	12	30	42		
	Below the mean	33	101	134		
Total average practice	Above the mean	70	24	94	173	0.001
	Equal to the mean	7	59	66		
	Below the mean	0	140	140		

4.4.5 Bivariate and multivariate binary logistic regression analysis

Variables with a statistically significant relationship in bivariate logistic regression (Annexure G) were modelled for multivariate binary logistic regression. Problems of multi-collinearity were checked for explanatory variables before running the logistic regression and the variables were free of these problems (Annexure H). The respondents who indicated that parents do nothing for their children who had AEFI, since they know the event would resolve by itself, had 0.24 times less chance of detecting AEFI cases than those who did not indicate that (AOR: 0.24, 95% CI: 0.07-0.75). The respondents who reported that parents would seek medical care, when their children developed AEFI had 0.23 times less chance of detecting AEFI cases than respondents who did not report (AOR: 0.23, 95% CI: 0.06-0.88). Respondents who scored average practice value above the mean, had 43 times more chance of AEFI case detection than those who scored average practice indicators below the mean value, (AOR: 43.3, 95% CI: 13.2-142.1). Refer to Table 4.14.

Table 4.14 Multivariate analysis of associated factors

Variables	Exp (B)	95% C. I. for EXP(B)	
		Lower	Upper
Age of respondents			
Above 30 years	1.00		
25-30 years	1.96	0.32	11.92
19-24 years	1.10	0.27	4.48
Work experiences			
10 and above years	1.0		
5-9 years	0.29	0.06	1.39
0.3 to 4 years	0.72	0.20	2.54
Location of health facilities			
Urban	1.0		
Rural	0.72	0.15	3.50
Status of electricity in the health facility			
Yes, available and functional	1.0		
Yes, available but rarely works	2.36	0.59	9.45
Not at all	4.96	0.94	26.05
Bajaj as means of transportation			
Yes	1.0		
No	0.62	0.21	1.85
Other means of surveillance data report communication			
Yes	1.00		
No	0.46	0.05	3.97
Satisfaction with your current position			
Very good	1.0		
Good	2.06	0.22	18.99
Fair	1.02	0.11	9.54
Dissatisfied	1.12	0.11	11.26
Nothing done for AEFI case because it will resolve by itself			
Yes	1.00		
No	0.24	0.07	0.75
AEFI cases will go to health facility for medical care			
Yes	1.0		
No	0.23	0.06	0.88
Mean knowledge value			
Below the mean value	1.0		
Equal to mean value	0.93	0.33	2.60
Above the mean value	0.14	0.01	2.28
Mean practice value			
Below the mean value	1.0		
Equal to mean value	598	0.0001	1.00
Above the mean value	43.27	13.17	142.14

4.4.6 Factor reduction

4.4.6.1 Principal component and factor analysis

Principal component analysis (PCA) is a dimension-reduction instrument that can be used to decrease a large number of factors to a small set that still comprises majority of the information in the large set. PCA is a mathematical procedure that transforms a number

of (possibly) correlated factors into a (smaller) number of uncorrelated factors called principal components (*Factor analysis* 2014; Jolliffe & Cadima 2016:1-12).

4.4.6.2 Factor analysis of health care provider immunisation safety surveillance knowledge indicators

Steps of the analysis

SPSS ➔ Analyse ➔ Dimension Reduction➔ Factor

1. Descriptive statistics ➔ Statistics ➔ Initial solution and Correlation matrix KMO and Bartlett's Test of Sphericity
2. Extraction ➔ Method ➔ Principal component analysis
   ⇨ Display ➔ un-rotated factor solution
   ⇨ Extract ➔ Based on Eigenvalue greater than 1
3. Rotation ➔ Method ➔ varimax
   ⇨ Display ➔ rotated solution
4. Options ➔Missing values ➔ exclude cases list wise
   ⇨ Coefficient display method ➔ sort by size and supress small coefficient absolute value 0.3.

4.4.6.2.1 Kaiser-Meyer-Olkin (KMO) test

The KMO is a measure of sampling adequacy. As value close to one is a sign, which strengthens, and 0.5 is the minimum standard to run PCA and factor analysis in a given data (Stephanie 2016). In this analysis, the KMO value of the knowledge indicators is 0.72, which is in the normal range.

4.4.6.2.2 Total variance explained

Eigenvalues: The eigenvalues estimate the quantity of difference in the total sample contributed for by each factor. The ratio of eigenvalues is the ratio of explanatory importance of the factors with relation to the variables. If a factor has a low eigenvalue, it could contribute little to the explanation of variances in the variables and could be ignored as redundant, with factors that are more important. Eigenvalues greater than one are the

factors, which will be extracted for further analysis (Ledesma, Valero-mora & Macbeth 2015:4; *Principal Components Analysis* … 2014). As can be seen below in Table 4.15 based on the PCA, 10 components extracted from 30 knowledge immunisation safety surveillance indicators, in both Extraction Sums of Squared Loadings and Rotation Sums of Squared Loadings. The ten components that have eigenvalue greater than one, contributed the major variability among all others. These variables have Initial Eigenvalues greater than 1, which is the lowest cut-off point. Similarly, the extracted component explained 61% of the variability. In social science, as a general rule, the data should be able to extract minimum 60% of variance, but sometimes could go up to 55% and less than 50% would be less useful data (*exploratory factor analysis*) (Table 4.15).

Table 4.15 Total variance explained for health care providers' immunisation safety surveillance knowledge indicators

Total variance explained									
Compo-nent	Initial Eigenvalues			Extraction sums of squared loadings			Rotation sums of squared loadings		
	Total	% of variance	Cumula-tive %	Total	% of variance	Cumula-tive %	Total	% of variance	Cumula-tive %
1	4.48	14.93	14.93	4.48	14.93	14.93	3.09	10.29	10.29
2	2.46	8.19	23.13	2.46	8.19	23.13	2.53	8.45	18.73
3	2.17	7.25	30.38	2.17	7.25	30.38	2.28	7.59	26.33
4	1.59	5.31	35.69	1.59	5.31	35.69	1.74	5.79	32.13
5	1.51	5.04	40.73	1.51	5.04	40.73	1.73	5.78	37.91
6	1.42	4.74	45.47	1.42	4.74	45.47	1.64	5.47	43.37
7	1.33	4.43	49.90	1.33	4.43	49.90	1.43	4.77	48.14
8	1.17	3.89	53.80	1.17	3.89	53.80	1.41	4.68	52.82
9	1.12	3.72	57.52	1.12	3.72	57.52	1.26	4.19	57.01
10	1.02	3.39	60.91	1.02	3.39	60.91	1.17	3.90	60.91
11	0.962	3.21	64.12						
12	0.945	3.15	67.27						
13	0.837	2.79	70.06						
14	0.824	2.75	72.81						
15	0.763	2.55	75.35						
16	0.719	2.395	77.75						
17	0.692	2.31	80.05						
18	0.645	2.15	82.21						
19	0.613	2.04	84.25						
20	0.603	2.01	86.26						
21	0.567	1.89	88.15						
22	0.538	1.79	89.94						
23	0.505	1.68	91.63						
24	0.444	1.48	93.10						
25	0.421	1.41	94.51						
26	0.400	1.33	95.84						
27	0.372	1.24	97.08						
28	0.336	1.12	98.20						
29	0.293	0.976	99.18						
30	0.247	0.822	100.00						
Extraction method: Principal component analysis									

4.4.6.2.3 Rotated component matrix

Rotation of the factor structure entails moving the factor axes in order to provide a new perspective on patterns in the underlying factor structure. The purpose of factor rotation is to qualify the interpretability of the factor solution by attaining easy structure (Rhna no date).

As component one, a total of seven variables were loaded and a combination of these seven variables created a factor or construct which were named signs and symptoms of AEFI. The variables are fever >38^{o}C, injection site swelling, injection site redness, immediate reporting of AEFI cases, any anaphylaxis, injection site abscesses and any rumour related to AEFI.

As component two, four variables were loaded and named a construct causes of AEFI related to improper handling. The variables are vaccines, which are exposed to excessive heat or cold, reconstituted vaccine stored more than the standard time, wrong route or injection and stored expired vaccines.

As component three, four variables were loaded and named a construct means of AEFI reporting and signs to be reported. The variables are injection site abscesses, AEFI could be reported through telephone, AEFI could be reported by electronic mail or fax and any convulsion/seizure.

As component four, three (3) variables were loaded and named a construct cut off point for AEFI case investigation. The variables are the health worker should commence investigation of an AEFI within 24hrs of after detection, all cases requiring hospitalisation that occur within one month of an immunisation should be investigated and all deaths that occur within one month of an immunisation should be investigated.

As component five, four (4) variables were loaded. The variables were: vaccine reaction, vaccination cannot bring any adverse effect and ever heard about AEFI.

As component six, three (3) variables were loaded and named construct knowledge for treatment of AEFI. The variables are emergency kit with adrenaline, local remedies for any serious vaccine reaction and paracetamol to treat immunisation local reaction.

As component seven, two (2) variables were loaded and were named construct knowledge of precaution of AEFI cases before vaccination or investigation. The variables were: if there were a history of anaphylaxis to a given vaccine or its constituents in prior immunisations, management of a coincidental sickness falsely attributed as a vaccine reaction and should not be reported until a diagnosis is made.

As component eight, three variables were loaded. The variables were: AEFI as a clinical event is not solely restricted to immunisation, definition of AEFI and any rumour related to AEFI should be reported.

As component nine, five variables were loaded but three of these were loaded well in another component. The two remaining variables were: AEFI surveillance has to be done in each health facility and AEFI can be caused by anxiety about the immunisation (Table 4.17).

Generally, from this analysis, signs and symptoms, causes of AEFI, means of AEFI reporting, cut off points for AEFI investigation, AEFI treatment issues and precautions during vaccination were identified. A pocket safety surveillance manual will be prepared based on these components and variable loadings (Table 4.16).

Table 4.16 Varimax rotation of rotated component matrix for health care provider immunisation safety surveillance knowledge indicators

Rotated component matrix										
Variables	**Component**									
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Fever >38^{o}C should be reported	0.73									
Swelling of all in injection site must be reported	0.72									
Redness of all injection site must be reported	0.68									
HCPs should always report the AEFI cases immediately to next higher level	0.64									
Any Anaphylaxis must be reported	0.56									
Abscess of all injection site must be reported	0.52		0.40							
Vaccines exposed to excessive heat or cold		0.81								
Reconstituted vaccine stored more than the standard time		0.78								
Wrong route or injection method		0.73								
expired vaccine storage		0.64			0.34					
AEFI could be reported through telephone			0.83							
AEFI could be reported by electronic mail			0.81							
AEFI investigation must began within 1 day			0.55	0.31						0.32

Rotated component matrix										
Variables	**Component**									
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Any Convulsion/seizure should be reported	0.39		0.49						0.34	
All cases requiring hospitalisation that occur within one month of an immunisation should be investigated				0.83						
All deaths within one month of an immunisation should be investigated				0.80						
Have you ever heard about AEFI					0.81					
AEFI can be caused by vaccine reaction					0.63					
Vaccination cannot bring any adverse effect					-0.50					
Emergency kit with adrenaline should be available in every immunisation station						0.78				
Health and life can be endanger through using local remedies for any severe vaccine reaction						0.77				
Paracetamol is used to treat immunisation local reaction						0.47				- 0.32
It is forbidden if there is prior anaphylaxis to a given vaccine							0.79			
Treatment of a coincidental illness should not be late yet diagnosis are assured							0.61		0.37	
AEFI as a clinical event is not solely restricted immunisation								0.74		
Define AEFI								0.71		
Are you informed that AEFI surveillance has to be done in each health facility									0.63	
Any rumour related to AEFI should be reported	0.41							0.33	- 0.49	
AEFI can be caused by anxiety about the immunisation									0.42	0.37
Adrenaline should be administered IM during anaphylaxis										0.71

4.4.6.3 Factor analysis of health care providers' immunisation safety surveillance perceptions indicators

4.4.6.3.1 KMO test

The KMO test-sampling adequacy is 0.73, which is above the acceptable range 0.5 and possible to run the PCA and factor analysis for the perception indicators.

4.4.6.3.2 Scree plot

Scree plot is a method used to extract best factors or factors that determine other less determinant factors. As seen above even if the Eigenvalue extracted five factors but the scree plot extracted four factors. It is used as another option of total variance explained (Figure 4.8).

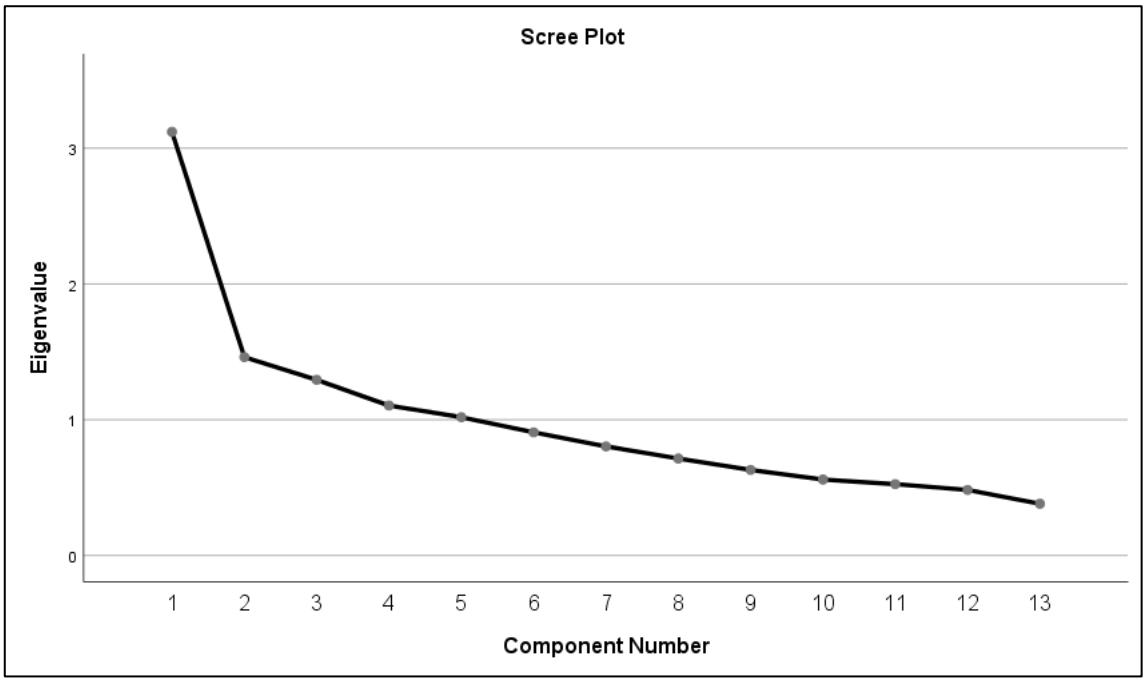

Figure 4.8 Scree plot representation for health care providers' immunisation safety surveillance perception indicators

4.4.6.3.3 Rotated component matrix

Before running the orthogonal rotation (rotations that assume the factors are not correlated) an oblique rotation was the first to be run, (rotation that assumes factors are correlated each other). A component correlation matrix is the results table, which indicates the preferable rotation. The assumption is that if the component correlation matrix table values are less than 0.32, use the orthogonal rotation, usually the varimax rotation (Brown 2009:21).

Therefore, in this study the orthogonal type of rotation, the varimax, was used because of a weak correlation when the variables were rotated obliquely, which is Direct Oblimin rotation. Four principal components were selected by using Eigen and scree plot methods. The health care provider immunisation safety surveillance perception indicators or variables are loaded in the four principal components (PCs).

PC 1: Five factors loaded: namely, the procedure of an AEFI surveillance is lengthy and boring, health care providers are not comfortable in reporting of AEFI to next higher level, health care provider is always overburden and no time to AEFI surveillance, AEFI detection and reporting should be done by senior clinical officers or doctors and

surveillance of AEFI case has no benefit. These variables can be given a construct name of HCP perceptions to immunisation safety surveillance procedure.

PC 2: Three (3) factors loaded; namely, every HEW/HW functioning in each health facilities must know about AEFI surveillance, HEW/HW play a crucial role in diagnosing, reporting, investigating and managing AEFI and increasing AEFI surveillance can assist to strengthen population trust in vaccination programme. These variables can be given a construct name of HCP perceptions to immunisation safety surveillance responsibility.

PC 3: Three factors loaded namely, reported AEFI case feedback should not be sent by higher level, weak follow up of adverse events can lead to reduction of vaccination achievement, detecting and reporting investigating AEFI is none of health care provider's business. These variables can be given a construct name of HCP perception to immunisation safety surveillance monitoring.

PC 4: Two factors loaded: namely, reporting of an AEFI will not make vaccinator feel guilty about having caused an injury and reporting of an AEFI cannot lead to individual punishment. These variables can be given a construct name of HCP perceptions to immunisation safety surveillance reporting (Table 4.17).

In general, all the HCP's immunisation safety surveillance indicators were loaded into four factors. So, using this analysis, it was possible to identify four factors namely, *procedure, responsibility, monitoring and reporting*.

Table 4.17 Varimax rotation rotated component matrix for health care providers' immunisation safety surveillance perception indicators

Rotated component matrix				
Variables	**Component**			
	1	**2**	**3**	**4**
AEFI surveillance is lengthy and boring	0.72			
HCPs are not comfortable with reporting of AEFI	0.60			
HCPs are overburdened and no time for AEFI surveillance	0.60	-0.30		
AEFI detection and reporting should be done by senior clinical officers or doctors	0.59			-0.41
Surveillance of AEFI case has no benefit	0.52	-0.35		
HEW/HW functioning in every health facility must know about AEFI surveillance		0.81		
HEW/HW play a crucial role in diagnosing, reporting, investigating and managing AEFI		0.78		
Increasing AEFI surveillance can assist to strengthen population trust in vaccination programme		0.55	0.54	
Reported AEFI case feedback should not be given by higher level			-0.65	
Weak follow up of adverse events can lead to reduction of vaccination achievement			0.61	
Detecting, reporting and investigating AEFI is none of health care provider's business		0.35	0.53	
Reporting of an AEFI will not make vaccinator feel guilty about having caused injury				0.73
Reporting of an AEFI cannot lead to personal repercussions				0.68

4.4.6.4 Principal component and factor analysis for health care providers' immunisation safety surveillance practice indicators

4.4.6.4.1 KMO test

The KMO value for HCP immunisation safety surveillance practice is 0.53, which is near to the minimum value. Still with this value, it is possible to run the PCA and factor analysis.

4.4.6.4.2 Scree plot

The scree plot assured that four principal components were the variables, which able to explain the total variation contributed by all other practice factors (Figure 4.9).

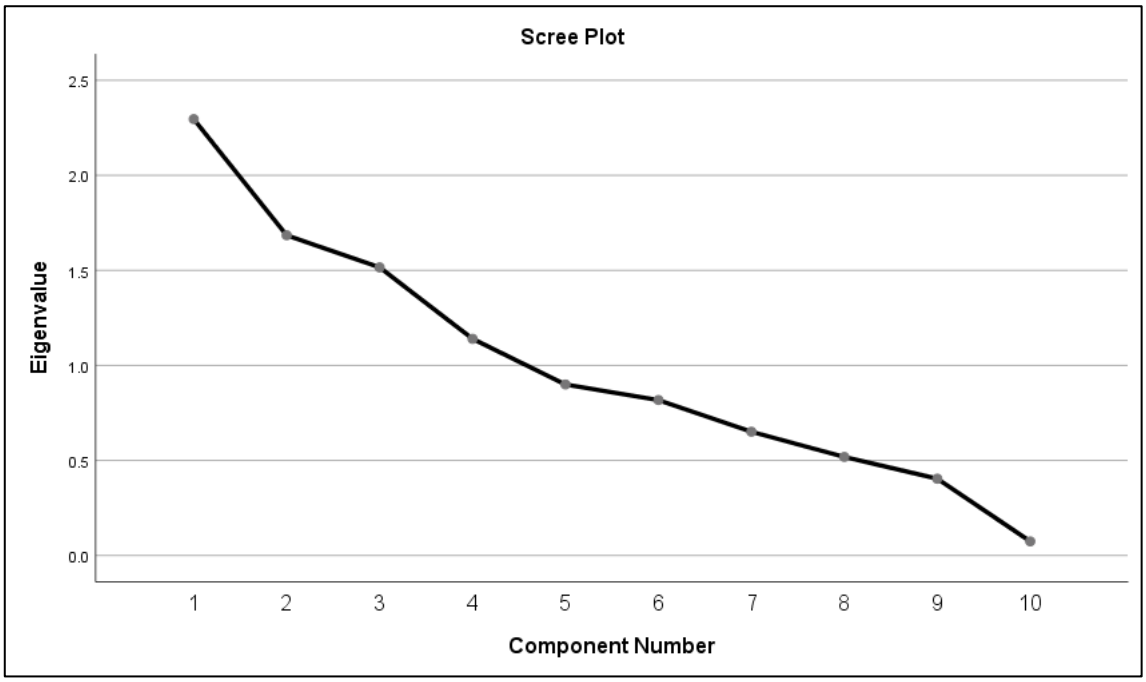

Figure 4.9 Scree plot representation for health care providers' immunisation safety surveillance practice indicators

4.4.6.4.3 Rotated component matrix

The health care provider immunisation safety surveillance practice indicators are loaded in the four principal components.

PC 1: A total of two factors were loaded namely, ever come across a child with injection site swelling/redness, abscesses/convulsion/shock/fever >38^{o}C and ever treated an AEFI case. These variables were given a construct name of HCP experience with an AEFI case.

PC 2: Two factors were loaded namely, informs the caretaker how to manage AEFI at home and informs the caretaker of possible vaccine adverse reactions. These variables were given a construct name caretakers communication practice on AEFI.

PC 3: Two factors were loaded namely, availability of AEFI reporting and investigation form at workstation and AEFI standard guidelines at workstation. These variables were given a construct name of basic supplies for AEFI surveillance practice.

PC 4: Four factors were loaded namely, participated in AEFI investigation of detected AEFI cases, ever reported an AEFI to higher level, availability of anaphylactic pack with adrenaline in the vaccination station, and rules out contraindications to vaccine(s) in a child before vaccinating. These variables were given a construct name, practices of caretakers for AEFI prevention and detection, (Table 4.18).

In general, the factor analysis of immunisation safety surveillance practice indicators were loaded into four factors namely, HCP experience to AEFI case, caretakers communication practices on AEFI, basic supplies for AEFI surveillance practice and practices of caretakers for AEFI prevention and detection.

Table 4.18 Varimax rotation rotated component matrix for health care provider immunisation safety surveillance practice indicators

Rotated component matrix				
Variables	**Component**			
	1	**2**	**3**	**4**
Have you ever come across a child with injection site swelling/redness, abscesses/convulsion/shock/fever >38^{o}C?	0.96			
Have you ever treated an AEFI case?	0.95			
Informs the caretaker how to treat AEFI at home		0.86		
Informs the parents of possible vaccine adverse reactions		0.84		
Having a reporting and investigation AEFI form at workstation			0.84	
Have AEFI standard guidelines at workstation			0.83	
Participated in AEFI investigation for detected AEFI cases				0.66
Have you ever reported an AEFI to higher level?	0.47			0.57
Have an anaphylactic pack with adrenaline in the vaccination station				0.54
Rules out contraindications to vaccine(s) in a child before to vaccinating		0.38		0.51

4.4.7 Conclusion

Univariate, cross tabulation, bivariate and multivariate binary logistic regression, correlation and factor analysis were used to analyse the quantitative data of this study and results are presented and discussed comprehensively in view of relevant literature. With reference to the null hypotheses predicted in Chapter 1 of this study, HCPs socio demographic and availability of standard reporting system have no relationship with immunisation safety surveillance. The existence of immunisation safety/AEFI surveillance guidelines has no relationship with immunisation safety surveillance, knowledge, perceptions and practice of HCPs working in the study area have no relationship towards

immunisation safety surveillance. Knowledge and practice hypotheses are rejected and perceptions hypothesis is accepted.

4.5 QUALITATIVE FINDINGS AND DISCUSSIONS

In the qualitative research paradigm, the objectives were to describe immunisation safety surveillance and identify challenges that hinder conducting immunisation safety surveillance. Nine sampled participants were interviewed regarding their knowledge, perceptions and practice experienced during immunisation safety surveillance. A semi-structured interview was employed to gather one on one data. The interview lasted 45-50 minutes for each participant. Field notes were taken and an audio-recorder was used for data recordings with the participants' permission. These were transcribed verbatim. After the recorded data were transcribed and translated, coding was done for the word text through highlighting. The translated data were transferred to ATLAS ti 8. Based on the text highlight coding, final coding, recoding, grouping and regrouping were done using the ATLAS ti 8. Following coding analysis was done for codes and contents.

4.5.1 Demographic characteristics of participants

Nine participants from two districts and Asosa Zone Health Department were included in this qualitative research design from a total of 19 HCPs. Three participants in each work discipline namely, Immunisation, Surveillance and HMIS were considered. The two districts were selected based on their distance from Asosa Zone town. The nearest district is Asosa town and Sherkole district, the furthest to the Zone town. In all the disciplines, the experts were permanently employed government staff. Refer to Table 4:19.

Table 4.19 Socio demographic characteristics of in-depth interview participants

Respondent code	Socio- demographic characteristics					
	Gender	Age	Education	Profession	Current position	Experience in years
P1	M	30	2nd degree	MPH	Immunisation	9
P2	F	34	1st degree	Health Education	Surveillance	15
P3	M	28	1st degree	Statistics	HMIS	6
P4	M	36	1st degree	EHS	Immunisation	11
P5	M	34	1st degree	EHS	Surveillance	14
P6	M	24	Diploma	IT	HMIS	2.5
P7	M	32	1st degree	Nurse	Immunisation	13
P8	M	27	1st degree	Health Education	Surveillance	6
P9	F	25	Diploma	HIT	HMIS	5

4.5.2 Organisation of the themes and sub-themes

Six major themes with associated sub-themes emerged from the analysed data. Each major theme and the respective sub-themes that emerged have been supported using relevant verbatim quotes from the participants. The participants were represented with codes to conceal their identity. The themes and their respective sub-themes are depicted in Table 4.20.

Table 4.20 Themes and sub-themes

1 Health service delivery	• Health service coverage • Inadequate infrastructure (electricity, road and network) • Community health seeking behaviour • Service affordability for community members
2 Motivating HCPs to improve immunisation safety surveillance	• AEFI training for HCPs • Incentives offered for hardworking HCPs • Rotation of staff in units/departments • Supervision of staff
3 HCPs knowledge regarding immunisation safety surveillance	• Role of participants • Ability to define AEFI • Strategies to update AEFI surveillance knowledge
4 HCPs perception of immunisation safety surveillance	• Importance of AEFI surveillance • Responsibility of immunisation safety surveillance monitoring • Perception of reporting many AEFI cases at a time • Perception on availability of clear reporting procedure
5 HCPs practice for immunisation safety surveillance	• AEFI surveillance training for HCPs • AEFI cases reporting system • Follow-up of AEFI reporting • Responsible department • Availability of AEFI reporting forms • Partner support for AEFI safety surveillance
6 Challenges experienced in/during immunisation safety surveillance implementation	• Poor infrastructure • Lack of guidelines for reporting AEFI cases • Lack of parental/caretaker insight about AEFI • Absence of department responsible for AEFI safety surveillance • Inadequate AEFI training of HCPs • No forms for reporting AEFI

4.5.3 Theme 1: Health service delivery

The health service delivery status was assessed through health service coverage, availability of infrastructure, community treatment seeking behaviour and service affordability. Service delivery strengthening is vital to achieve health related indicators. Guaranteeing accessibility of health services that fit the best quality indicator and

safeguarding access to them are crucial functions of a health system. Sekhon et al (2017:1) state that both service providers' and receivers' successful implementations depend on the acceptability of the services. Acceptability is a multifaceted concept that reflects the degree to which people providing or getting a health care intervention recognise it to be suitable, based on predicted or practiced cognitive and emotional reactions to the intervention.

- **Health service coverage**

All participants were convinced that health service coverage had been improving in the respective areas. They attributed the improvement to the Health Extension Programme, which reaches up to village level. Some participants expressed their views this way:

> "In Asosa Zone, out of 211 kebeles (villages) there are health posts almost in 185 kebeles and there are health workers in all 185 kebeles." (P1)

> "In our woreda the total health coverage is around 93%, there are 69health posts and 5 health centres. The total number of community served by these facilities is around 116,000. From this point of view, it fulfils the direction set by the government so more or less the majority are serving well." (P5)

> "There are two health centres and 13 health posts including five private clinics. As per the number of facilities, they are accessible but there are problems based on availability of the services. There is problem of drug availability." (P8)

This finding is reflected in the EPI, which was launched in Ethiopia in 1980 when it was started with the aim of 10% coverage increment yearly. Although, the achievements in the initial two decades were extremely minimal, during the 1990's, encouraging achievements were obtained through universal child immunisation (FMOH Ethiopia 2015:viii).

- **Infrastructure infrastructure (electricity, road and network)**

Most participants complained that electricity access was the major problem related to infrastructure. Some participants had this to say:

> “In relation to infrastructure, very limited health care providers and health care workers have electricity. In almost the majority of health posts, there is no electricity and the roads are bad, especially during bad weather.” (P1)

> “There is no electric light access in all kebeles. However, regarding roads there were health facilities difficult to reach especially during the rainy season and there were some kebeles (large villages) which were without network coverage.” (P8)’

Similarly, the quantitative results in this study confirmed lack of network service and electricity at health care facilities including surrounding communities. Irrespective of the setting, information should advisably be gathered and be readily available at the district level. Principally, the protocols for controlling health system properties are designed at the district level because information important for decision making is available there. Therefore, the key goal is forming a district-based system with the support of the national or regional or provincial levels (Frontline Service Delivery Monitoring … 2017:10; WHO 2010:7).

- **Community health seeking behaviour**

Most participants were content that the community health seeking behaviour had improved. Health extension workers’ house-to-house health education and the availability of free services for selected health packages have increased the community awareness and demand for health services. However, some challenges such as low income of most community members to purchase the service and unavailability of drugs or other medical supplies interrupted the community health seeking behaviour. Participants mentioned:

> “The community members are always eager to consult when experiencing any illness and most bring their children for immunisations regularly.” (P2)

> “Some issues such as lifestyle of communities which are gold mining where people go out early in the morning and come back in the night. In the rainy season, they work far away from residents. At times they move with all the family members and stay for longer periods, making it difficult to bring their child for immunisation.” (P3)

Courtot et al (2014:2) emphasise that clear understanding of the relevance of immunisation and potential adverse events is required by each health worker and vaccinator and they need to be able to communicate these openly to parents.

- **Service affordability for community members**

The government has minimally increased (25%) health service logistics and most services are provided through free packages. In addition, the local administration now covers the cost for those who had not been able to pay. All participants confirmed that the services have been delivered in an affordable way. However, two participants reported that their community has paying capacity but lacks supplies, especially drugs. Four participants expressed that the community could not afford to pay for health services. Participants said:

> "The free service has increased the community treatment seeking behaviour and it has to be continued." (P4)

> "For sure our community cannot afford to pay. The government set some directions on mothers and children like providing free service for treatment, EPI, and delivery service. Providing free service for these services to the community is very helpful. This increased community treatment seeking behaviour." (P6)

> "Assigning ambulances in every health centres. This is very good if we make this with payment, we will be back to the previous like the community will deliver at home, no vaccination access, will miss many things. Therefore, our community remained with so many things in relation to payment." (P3)

> "The service is delivered in an affordable way. Beyond that pregnant women and children less than five years are getting the service freely." (P1)

Sekhon et al (2017:1) note that assuring health services availability that meet the lowest quality standard and getting access to health services are core components of the health system. Both service providers and receivers' successful implementations depend on the acceptability of the services.

4.5.4 Theme 2: Motivating HCPs to improve immunisation safety surveillance

Motivating factors such as providing training, rotation of staff, scholarships, incentives, recognition, close supportive supervision, periodic performance feedback and taking immediate corrective action were explored. All participants expressed that there were no means of motivation implemented in their respective areas. Training, supervision, review meetings, education opportunities have been carried out in their respective districts, but not in ways that motivate good performance or equip them to teach others. In addition, there are some locations where motivation mechanisms were initiated but only through social networks. Some participants stated:

> "The good thing is the opportunity of providing education, the district has no budget for education opportunity but based on the Zone and region we gave opportunity for health professionals. This is motivation. However, the education opportunity was given based on social networks." (P8).

> "Supportive supervision is conducted and for the better performing health care providers, on site appreciation is given. For us we use training as motivation." (P4)

> "P6 mentioned, "Even if we do not have any financial award but recognising and certifying better performer has started, for health facility level those having good capacity, attitude, at woreda level. Beyond this, certain professional working at health centre and health post level are awarded at regional and federal level recognition. Currently the government has direction to make their rotation based on their performance. For example, those best performers working in hard-to-reach areas will be motivated by assigning in nearby areas."

> "Sometimes using few opportunities for better performing workers invited to participate in review meeting. Otherwise, considering health workers who served very well and offering them educational opportunity and providing recognition certificate, is not common and is not being practiced. No such service is given. In this regard majority of the professionals, starting from health post to woreda health office including the health centres have complained." (P7)

Shortage of motivation and staff concerns about consequences of programmatic mistakes adversely contribute to AEFI surveillance, particularly on adverse events reporting. These comprise conscientiousness, reporting system unawareness, fear of

lawsuit, and shortage of time are some of the reasons (Mohammed et al 2018:82). McPake et al (2013:841) reveal that health service provision is extremely labour-intensive, and thus, health workers inspiration mediates care excellence, effectiveness, and fairness through applying themselves in their duties.

4.5.4 Theme 3: HCPs knowledge regarding immunisation safety surveillance

The role of the participants, defining an AEFI and strategies for updating one's knowledge, were sub themes assessed under this theme.

- **Role of participants**

Most participants explained that they are experts for coordination, activity and budget planning, supervision, facilitating training, community motivation and awareness creation against rumour, immediate verification for anything reported, ensuring data completeness, conducting performance evaluation, performing data analysis, distributing logistics and taking administrative decisions.

It is relevant to enhance awareness of vaccine safety, to reduce the frequency of vaccine adverse events and sustain population trust in vaccines and thus improve the production and utilisation of safer vaccines. In order to gain and sustain population trust in the safety of vaccines through operational AEFI surveillance health workers have an important and crucial role to play. These roles encompass delivering evidence-based information on the relevance and risks of vaccines including detecting and reporting adverse events following immunisation (Mohammed et al 2018:82).

- **Ability to define AEFI**

One of the determinants used to assess the knowledge of the participants was the ability to define AEFI as per the standard WHO definition. Only three participants knew the concept with one participant defining according to the standard AEFI definition.

Responses are summarised as follows:

> "AEFI as unexpected medical occurrence following vaccination. It may be related to company, vaccine product related reaction and product quality. In addition to that AEFI is related to cold chain, professional safety or accidental complication following vaccine administration." (P1)

> "AEFI, I guess is the side effects after vaccination. Meaning fever, swelling, irritability, and there may be infection. The fever can be back and the infection may be because of error." (P8)

> "Adverse Events Following immunisation is the English word when we changed it to Amharic; it is health problems happening in relation to immunisation. There are five types, first it may be caused because of the vaccine, and second, it is not related to the vaccine but happens by chance what we call it coincidental and may occur because of fear of the injection." (P7)

Similar findings were reported in a study on KPP of nurses on surveillance of AEFI in Nairobi, Kenya where only some participants (37.4%) distinguished the causes of AEFI, up to 10.3% of the participants distinguished reportable AEFI cases, 25.5% distinguished that AEFI investigation should be initiated within one day and less than 40% of the participants explained how to handle a child with post-immunisation anaphylaxis. Generally, 194 (70.8%) of the participants had poor knowledge whereas 80 (29.2%) had good knowledge on AEFI surveillance (Masika et al 2016:81).

- **Strategies to update AEFI surveillance knowledge**

All participants mentioned that onsite and cluster or centre level trainings were means of strategies to update health care providers' knowledge. Participants explained that during onsite training, it is possible to transfer skill, save time, cost, increase the ability to ensure that activities were performed as per the guidelines, ability to cross check documentation, and provide a chance for trainees to remember and to allow recollection of challenges and create a chance for discussion. With the exception of one participant, all indicated that onsite training is the best strategy to update one's knowledge.

Groseclose and Buckeridge (2017:59) emphasise that for an effective surveillance system facilitating HCP training and knowledge of vaccine surveillance processes is a fundamental component. The individual accountable for ISS must have updated

information about the current developments on safety, controlling, and emerging issues related to immunisation (WHO 2015a:65). In addition, Leask et al (2014:2601) and Jelleyman and Ure (2015:1) reveal that health workers' perceptions and behaviour was enhance with improved training and development.

4.5.6 Theme 4: HCPs perceptions of immunisation safety surveillance

The perceptions of participants towards the importance of AEFI surveillance, responsibility of monitoring of immunisation safety surveillance, responsible department for immunisation or surveillance, reporting of increased numbers of AEFI cases at a time, fear of accountability or guilt feelings and availability of clear reporting procedures were explored. Some participants had this to say:

> "All starting from senior to junior staff have the responsibility to ensure safety surveillance. But health extension health workers, those who are working at kebele level are more responsible because they are very close to the community and spend 24 hours with them." (P2)

> "It is the responsibility of all stakeholders to ensure immunisation safety." (P8)

> "It is not only the health workers; it is also for woreda, HEWs and the mothers. The responsibility should be taken by all stakeholders from top to down level." (P9)

Similarly, assessment of KAP of pharmacovigilance in a tertiary care hospital in India showed that respondents were of the view that ADR monitoring is important (33%) and that it should be compulsory as agreed upon by 67% of the respondents. Respondents said that 59% and 67% medical students and nurses respectively have a role to act in pharmacovigilance and 50% participants reported that each hospital should have an ADR reporting station (Garg et al 2017:1499). According to Mehmeti et al (2017:13) knowledge, practice and approaches of health care providers to AEFI and their reporting in results of a study in Albania, most of the participants (88.2%) revealed that increasing AEFI surveillance could enhance vaccine safety.

4.5.7 Theme 5: HCPs' practice for immunisation safety surveillance

Participants' practices related to AEFI surveillance training, experience with and reporting of AEFI cases, conducting of immunisation safety surveillance, clarity and comprehension of AEFI reporting form, presence of guidelines, and availability of partner support were explored and their responses summarised.

- **AEFI surveillance training for HCPs**

In relation to AEFI trainings, onsite trainings, whether each respondent took training or not, frequency of the training, who facilitated the training and importance of refresher trainings were discussed. Generally, there was confusion about AEFI surveillance training because AEFI surveillance has been one of the modules in Immunisation in Practice (IIP) modular training, AEFI surveillance. Some of the participants referred to that training and others mentioned separate AEFI surveillance training. However, to strengthen the AEFI surveillance, a separate session of AEFI surveillance training is important. Two of the surveillance officers reported to have taken the special AEFI surveillance training once in 2014 delivered by the WHO.

Most of the participants (n=7), reported that they did not receive separate AEFI surveillance training. Those who took the training a long time ago reported that it was not detailed and was insufficient. Some participants had this to say:

> "In 2014 actually, it was not training, it was a 10 minutes orientation session. It was presented at the end of another event session. It was not separate AEFI training and it was delivered by the WHO." (P2)

> "Regarding refresher training, there are new updates every time so there shall be refresher training at least once in a year. Based on this, it is possible to update the available knowledge in the world." (5)

All respondents believed that onsite training is important and some of the participants argued that it is much better than other types of training.

Some participants preferred to the centre level training and said that onsite training was important because it was more informative. However, centre level training is better than onsite training because when you go to central level training, there is gathering of many professionals where there will be sharing of many experiences/practices.

As Masika et al (2016:15) report, health professionals should show capability, existing evidence-based knowledge and understanding of AEFI. A study to establish the familiarity of health workers in the USA with VAERS, found that such familiarity was dependent on training in AEFI. Training was associated with higher reporting rates among health workers, especially nurses. Okueso and Oke (2017:59) are of the opinion that an operative surveillance system should confirm health care provider training and knowledge of vaccine surveillance processes since it is a central constituent of the system. As well, Doherty et al (2016:6708) and Hardt et al (2013:6701) acknowledge that pre-and post-in-service training and field practice are means to deliver vaccine safety knowledge for HCPs. Li et al's (2014:435) study on KAP towards reporting of AEFI within the military health system conducted in the USA describes that 90% of the respondents identified three factors deemed to facilitate AEFI reporting as training in detecting AEFI, information on when to report AEFI and information on how to report to the surveillance system.

- **AEFI cases reporting system**

Only two participants had come across AEFI cases in their professional experiences. Seven of the participants reported that they never came across any AEFI case except some who had heard of AEFI during vaccination campaigns, from the child's mother and during report evaluation. None of the participants had reported AEFI cases to a higher level nor received from a lower one. Five of the respondents claimed to know that there was a reporting form in the AEFI surveillance guideline. All participants emphasised that, there was no clear procedure of reporting for immunisation safety surveillance.

In supporting this view, Tew et al (2016:1) mention that it has been known that doctors were not reporting AEFI even when they encountered and identified it. A study in Kuala Lumpur Malaysia indicate that of all 350 participants, 81.4% expressed that even if they did not report ADR, they had suspected it, however around 40% of the participants were unclear about the presence of the countrywide reporting system in Malaysia. Another survey planned to explore demographics and professional factors, knowledge and attitudes of detecting and reporting an AEFI to VAERS, HCPs basis of information about VAERS and how to enhance awareness of reporting, showed that though 71 % were acquainted with VAERS, only 14% were accustomed with the paper reporting process and an estimate of one third were not familiar with the process when it was needed to

report an AEFI. Roughly 40% of all study respondents had detected a minimum of one AEFI, with only 18% specifying they had reported to VAERS (Miller et al 2018:8). In addition, Constantine et al (2018:1) verify that AEFI surveillance system evaluation in Guruve district, Zimbabwe showed 45% of the HCPs had encountered AEFIs but no one had reported.

- **Follow-up of AEFI reporting**

In responding to whether participants had ever asked PHCWs to report AEFI, most participants did not make any follow up on the status of AEFI surveillance. From this response, it is evident to accept the quantitative part of this study's result of 25% detection and 5.7% reporting rate of AEFI case surveillance.

William and Flora Hewlett Foundation (2018:1-12) highlights that service delivery monitoring has immediate relevance for the management of health services, which distinguishes this area from other health systems building blocks. The WHO (2015b:35) emphasises that in many countries with a single monitoring system, surveillance of AEFI tends to be overlooked. Different reporting pathways and responses to AEFI need to be built into the existing system of adverse drug reaction reporting. The importance of post-licensure vaccine safety monitoring cannot be understated. As vaccines are given mainly to healthy individuals, most often infants and young children (Pasquale et al 2016:6672) acknowledge that in preventing, rather than treating disease, public expectation of vaccine safety is high (Parrella 2014:1; Waldman et al 2011:1). The reporting flow of an AEFI is similar to ADR in many PV systems. According to Tew et al (2016:1), ADRs are worldwide difficulties of most concern.

- **Responsible department**

Participants were asked to indicate which department was responsible for AEFI case reporting, immunisation or surveillance. Four of the participants (n=7) recommended that surveillance department should be responsible; two indicated that both immunisation and surveillance should follow and one expressed that immunisation department should take over.

- **Availability of AEFI reporting forms**

One of the key tools for immunisation safety surveillance is availability and utilisation of AEFI surveillance reporting forms. No participants had ever used the AEFI reporting form to report an AEFI case. Only one participant had reported to distribute three forms per health post, five indicated that there was no reporting form and the remaining three explained that the reporting form was available in the guideline, could be reprinted and distributed. The majority of participants said that the reporting form was not clear or was difficult to understand because of the language used coupled with absence of prior training and mandate for format adherence. In this relation, some participants expressed:

> "We did not take a separate training for filling forms. We can fill through reading but there are some issues which are vague specially those which are related to shock and serious reactions that are a little bit difficult." (P5)

> "The format is prepared in English, either at regional, partner or EPHI/Federal level. It will be good, if those who are at the federal level take this into consideration or in their discussions." (P2)

> "The form can be developed in our own district computers and should be printed and utilised. In addition, for the health extension workers, the reporting form has to be simplified and translated to Amharic language to make it easy for everyone to understand the surveillance process." (P4)

The reporting form for AEFI is attached in the national AEFI guidelines (Annexure F). However, Muchekeza et al (2014:2) highlight that for AEFI surveillance in Zimbabwe, (80%) of the health workers were aware of the number of forms to be filled on notification and reporting AEFIs.

- **Partner support for AEFI safety surveillance**

Similar to quantitative results of this study, all participants reported that there was no partner or stakeholders who provided special support on immunisation safety surveillance. Two of the participants mentioned that WHO infrequently raised the issue during supportive supervision.

The question was: ‘What type of support have you gained from NGO/partners related to AEFI?’’. Almost all participants reported that there was no NGO partner who provided special support on immunisation safety surveillance.

> “No NGOs are providing support for AEFI surveillance in a separate way. It is integrated in other programmes especially when there is new vaccine introduction.” (P1)

> “The World Health Organization (WHO) slightly touches it. When they come sometimes for support, it is not continuous; they asked us seriously about AEFI. It is impossible with one person or one organisation request but it will be good if all other organisations work side by side.” (P2)

Hardt et al (2013:217) propose that to sustain trust in vaccines, partnerships between all stakeholders in the public health sector, such as health authorities, policy makers, national and supranational organisations, health care providers, vaccine manufacturers and others, are needed to ensure high vaccine uptake rates, identify and allow the introduction of new vaccines and inform the public and others of the benefits of vaccines and how vaccine safety is constantly assessed, assured and communicated.

4.5.8 Theme 6: Challenges experienced during immunisation safety surveillance implementation

Both the Zone and district level experts mentioned that the performance related to immunisation safety surveillance was minimal. Poor infrastructure, lack of adequate information about AEFI; absence of proper AEFI reporting system; no training for AEFI; community members are not informed about reporting AEFI and treatment of mild cases at home were some of the challenges mentioned by the participants. Other similar qualitative studies in Australia on health care providers’ knowledge, experience and challenges of reporting AEFI show common barriers to reporting AEFI including time constraints and unsatisfactory reporting processes (Parella et al 2013:1)

4.6 SUMMARY

This chapter provided the discussion of a study results on knowledge, perceptions and practices, associated factors and challenges experienced with AEFI safety surveillance

in the study area. Combining quantitative and qualitative approaches benefitted the researcher with more understanding of the research problem than either approach alone. A needs assessment is important before decisions are taken about the type of activities to be included in the immunisation safety surveillance pocket manual and the development of the pocket manual should be based on the assessed and identified needs. The findings from the qualitative design, confirmed the quantitative results on knowledge, perceptions including challenges of health care providers regarding immunisation safety surveillance. In comparing the results of previous researchers to this study, it emerged and was concluded that AEFI knowledge and practice of health care providers needed urgent attention. In addition, an immunisation safety surveillance pocket manual, could assist HCPs when confronted with AEFI problems and address identified gaps in the national guidelines.

CHAPTER 5

INTEGRATION AND TRIANGULATION OF QUANTITATVE AND QUALITATIVE FINDINGS OF THE STUDY

5.1 INTRODUCTION

The quantitative and qualitative results of this research were presented separately in the previous chapter. In this chapter the findings of the two research methodologies are presented in an integrated and triangulated manner to indicate variation or support for each other. O'Cathian, Murphy and Nicholl (2010:c4587) refer to triangulation as the use of data sources in qualitative research to develop a comprehensive understanding of the phenomenon. Integration has been used to describe the interaction and conversation between findings from quantitative and qualitative components of a research programme often conducted in series to produce the proverbial "whole greater than the sum total of its parts."

This study was a convergent parallel mixed design in which both the quantitative and qualitative findings were merged to provide a concrete analysis of the research problem. In convergent parallel design the data were roughly collected simultaneously and then the overall results were integrated for interpretation as was done in this study. Bentahar and Cameron (2015:6-12) recommend that the combination should have a logical flow with the research design. Results from the quantitative research design are triangulated with the qualitative results, as depicted in Figure 5.1.

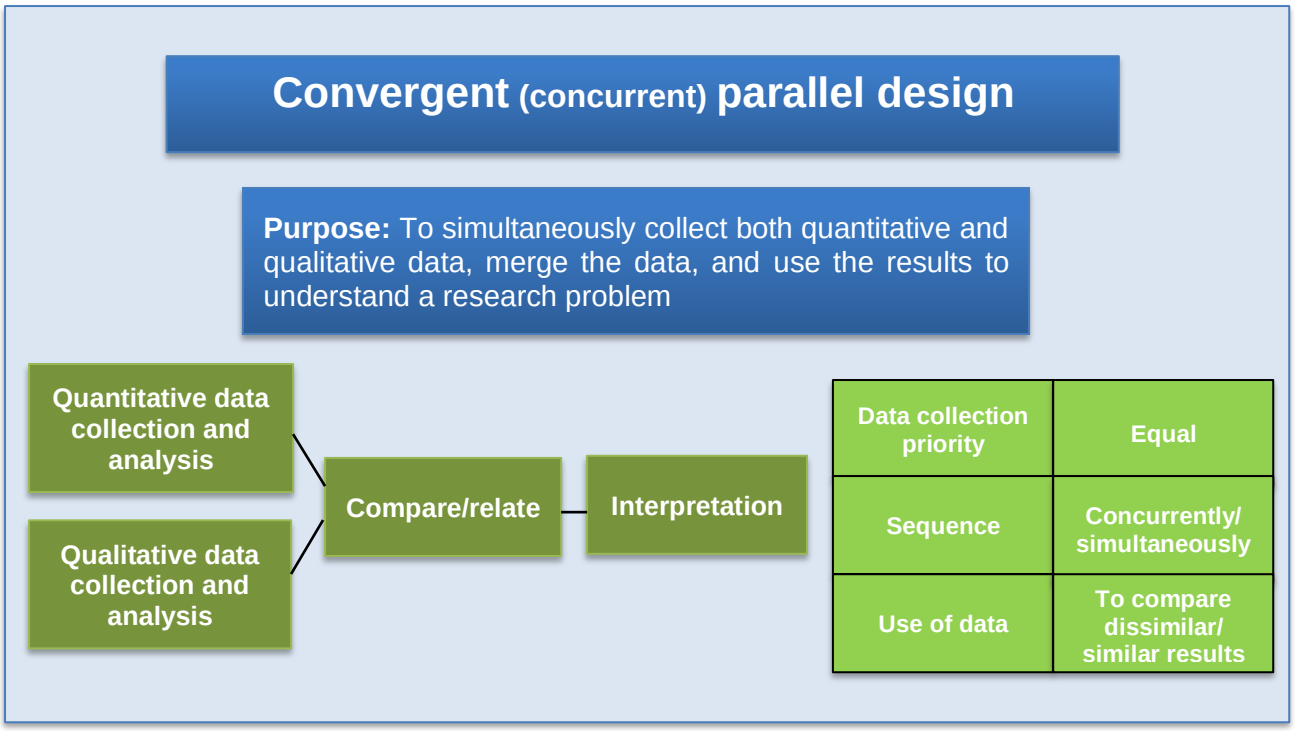

Figure 5.1 Integration of quantitative and qualitative data, findings and interpretation

5.2 DISCUSSION OF THE MERGED FINDINGS

5.2.1 Demographic characteristics

The results from quantitative data indicate that respondents, 25-30 years, were 0.35 (OR=0.35, 95%CI 0.15-0.81) and 19-24 years were 0.43 (OR=0.43, 95% CI 0.22-0.84) times less odds in immunisation safety surveillance practice than those who were above 30 years of age, (x^2=7.74, p=0.02). This might be due to prolonged exposure for the work and adapting to the work environment. Individual factors such as age of respondents affect a care provider's job satisfaction and subsequently dedication in delivering quality services (Weldegebriel et al 2016:163). Respondents who had 10 or more years of work experience (37%) had 0.29 less odds (OR=0.29, 95% CI 0.15-0.58) than 5-9 years' work experience and 0.40 times less odds (OR=0.21-0.78) than those 0.3-4 years of work experiences in not practicing immunisation safety surveillance (x^2=13.6, p=0.001). This result has similar findings with a survey of nurses KPP on AEFI surveillance in Nairobi, Kenya which explains that AEFI surveillance practice synergised with length of work

experience since participants with experience of approximately 30 years (75.9%) had good practice (χ2=31.47; P < 0.0001).

More females 173 (57.7% than males 127 (42.3% participated in the quantitative design compared to more males (7) than females (2) in qualitative design. In terms of level of education, respondents from the quantitative design, 206 (68.7%) had diploma, 65 (21.7%) had obtained a certificate and 29 (9.7%) had first degree, whereas most (7) participants in the qualitative design had degrees with two having diploma qualifications. The higher level of education amongst the qualitative participants tallied with their work designations and responsibilities.

According to Conner (2002:4) different characteristics have been shown to contribute to an individual's progress of health practices. Becker and Newsom (2003:742) highlight that demographic characteristics show consistent relations with the advances in health care system whilst Mosadeghrad (2014:81) affirms that the attributes and personality of HCPs change the quality of health care services rendered.

5.2.2 Health service accessibility

The types of health facilities showed significant relationship with the immunisation safety surveillance practice, (x^2=6.3, p=0.04). In Ethiopia health centres and health posts are the primary care units with clearly identified responsibilities. Health posts are much close to the community and engaged in providing primary health care services focused on preventive strategies such as health promotion, social mobilisation, immunisation and surveillance activities. The minimum number of health posts is expected to be five times the number of health centres. Health centres are responsible for providing direction, training, monitoring and follow up of the health posts. Health centres are also the primary recipients of referrals from health posts as well as being the main primary medical care providers. Hospitals have better clinical care provision capacities as compared to health centres and health posts but in this country, the number of hospitals is very minimal as compared to the global standard. They are referral sites for health centres. Therefore, whenever people require medical care, health centres are the first line health facilities. Due to this and other issues, the type of health facilities showed significant relationship with immunisation safety surveillance.

Sekhon, Cartwright and Franc (2017:1) stress that assuring health services availability that fits quality standards and having access to health services are core components of the health system. Both service providers' and receivers' successful performance depend on the acceptability of the services.

5.2.3 Availability of Infrastructure

Results from the quantitative design of this study revealed that 71.7% respondents had network access for internet service and 22% reported that there was only telephone service. Furthermore, 72% reportedly had no electricity in their health facilities. Availability of electricity (x^2=7.4, p=0.02) showed a strong relationship with immunisation safety surveillance detection and reporting. HCPs who worked in facilities where electricity is hardly available, had 0.43 less odds in immunisation safety surveillance detection and reporting than those who worked in health facilities where there was regular electricity supply, (OR=0.43, 95% CI 0.23-0.80). This result concurs with the office level, technical and administrative issue of decision makers' interview responses; all participants mentioned that lack of and poor electricity supply was a major problem in the infrastructure. Similarly, all participants interviewed, verbalised that they had been trying to access most facilities by using roads, but some were difficult to reach especially during the rainy seasons and some kebeles had no network coverage. Respondents (n=179) used motorcycles as means of transportation, or x^2=6.46, P=0.01).

Vast geographic distances or increased travel times to a HC combined with poor transportation infrastructure and a shortage of public transportation facilities can negatively influence the use of health services and health outcomes (Delamater 2012:1). Electricity and communication networks are very crucial to exchange of information, for the update one's own knowledge and update each other. Currently most reports are done through SMS or web-based softwares using mobile apps.

5.2.4 Parents/caretakers' care seeking behaviour

Most respondents, 191 (63.7%) ranked the parents or caretakers' treatment seeking behaviour as good and only 3 (1%) ranked it as poor. Respondents' rate for their community medical seeking behaviour had a significant relationship with immunisation safety surveillance, (x^2=7.93, P=0.04). This result is also supported by the qualitative

interviews of this study. Participants confirmed that the local community medical care seeking behaviour had improved despite constraints which hinder their medical seeking behaviour. People's probability of practising a specific behaviour will be robust if they hold a positive attitude towards the practice of that behaviour. Fishbein (1993) distinguished between attitude towards an *object* (for example, attitude towards AEFI event) and attitude towards a *behaviour* (for example, attitude towards seeking an AEFI examination). According to Ajzen and Fishbein (1980), attitude towards a behaviour (for example, AEFI screening) is much more explanatory of that behaviour than attitude towards the target of the behaviour (for example, AEFI-negative status) (*Behavioural beliefs and attitudes* 2017:8; Tlou & Dyk 2009:29).

5.2.5 Detection of AEFI cases

Of concern was that only 77 (25%) respondents had ever detected AEFI cases of whom 17(5.7%) had reported the cases to a higher level and a further 8 (2.7%) used the standard AEFI surveillance reporting form. This low AEFI case surveillance result is similar to the qualitative findings where only two participants had come across AEFI cases in their professional experiences and none of them had ever reported AEFI case to a higher level nor received one from lower levels. This was the major outcome variable of this study. The aim of ISS is to identify, correct and prevent programme mistakes, to detect risk factors associated with AEFIs, to monitor increase in frequency of known AEFIs and to alert the population about AEFIs falsely attributed to a given vaccine due to coincidental events (Waldman et al 2011:3). The low detection finding of this study might be attributed to the passive type of surveillance done.

5.2.6 Motivating health care providers

The variables included in this study to measure motivating mechanisms for health care providers were those applicable locally. The percentages of the following show the status of motivating factors for health care provider in their day-to-day performance:

Availability of a reward system in their district as reported by only 32% of respondents and of these, 9.3% reported to have received some type of reward from different levels the government system. In all, 99% of respondents were not evaluated by their peers and also were not evaluated by their immediate supervisors, and only 12% reported that they

were officially delegated as immunisation or surveillance or paediatric treatment focal persons. Few (0.7%) participants had clear job descriptions in their position whereas 99.3% had no job descriptions. Among the respondents 90.7%, had not received immunisation safety surveillance training and of those, 28% respondents had taken the training. These results were also triangulated with the qualitative interviews, participants emphatically expressed that motivation was an area not attended to.

As Sonnentag et al (2012:428) report that while guaranteeing resource availability, worker capabilities are vital to effective service delivery, even though not adequate in themselves to guarantee outstanding worker performance. In addition, worker accomplishment is dependent on the servants' readiness to work continuously, perform diligently, be flexible, and execute the required duties. In addition, Bonenberge et al (2014:4) indicate that service providers' work satisfaction is mandatory in providing quality services. HCPs recognised nine Organisational issues they thought affected their motivation and peak work performance. Participants reported being satisfied with the job they were doing. Frontline Service Delivery Monitoring (2017:10) and WHO (2010:7) mention that irrespective of the setting, information should advisably be collected and made available at the district level. Principally, the protocols for managing health system resources should be designed at the district level because information important for decision making is available there. Therefore, the key goal is forming a district-based system with the support of the national or regional or provincial levels.

If the HCPs were motivated, they could evaluate their own performance. This is because a subjective norm is determined by whether key referents agree or disagree with the behaviour and stimulates motivation to please those referents. These beliefs, which underlie a person's subjective norm, are termed normative beliefs. This means that people are likely to execute behaviour when they consider it positively and believe that significant others think they should exercise it (Ajzen & Fishbein 1980; Behavioural beliefs and attitudes 2017:9).

5.2.7 Department or staff responsible for immunisation safety surveillance

Quantitatively, a majority of respondents (95%) reported that there was no AEFI responsible focal person in their respective health facilities and only 12% were officially delegated as focal persons for immunisation or surveillance or paediatric treatment. In

addition, the Woreda and Zone participants (one to one participants) explained that immunisation safety surveillance had no responsible department. They were asked to recommend an appropriate department for immunisation safety surveillance. Seven participants recommended that the surveillance department should be responsible, two suggested both immunisation and surveillance and one suggested that the immunisation department should take over the responsibility. Thus, the availability of a responsible focal person/s for immunisation safety surveillance to monitor progress and take immediate corrective action is paramount. This may be the major contributor of non-improvement in immunisation safety surveillance since there was no accountable and accessible person. In the same vein, the WHO (2010:2) remarks that it is essential to decide the scale at which improvement would be measured in order to track improvement in health service provision. The amount of health services and type of organisation may vary from one to another country, while the normally operating health system pattern of service provision should have the following vital features: accessibility, continuity, comprehensiveness, coverage, quality, person-centeredness, efficiency and accountability. However, the Ethiopian AEFI surveillance guidelines recommend that the report from health facilities should be submitted to the district immunisation officer (DIO) (EFMHACA 2016:29). Generally, to clearly identify which department is responsible for immunisation safety surveillance requires serious attention and decision by the Federal ministry of health decision makers.

5.2.8 Training in AEFI

Another important aspect which could contribute to HCPs motivation but scored low in this study was training, where 90.7% respondents had not received immunisation safety surveillance training and of those, 25% of the training was during supportive supervision. Similar results were found for the Woreda and Zone experts during the interviews where only two out of nine were trained. The surveillance officers had taken that special AEFI surveillance orientation once in 2014 which was delivered by the WHO and seven of the interviewed participants had not received AEFI surveillance training. To strengthen the AEFI surveillance, separate session/s of immunisation safety surveillance training is/are important because vaccination programmes require special training techniques (Ildarabadi et al 2015:1). Importantly, in view of health care providers central role is maintaining population trust related to vaccines, it is important to be up to date with information and necessary to have confidence in delivering advice when fear surfaced

(eHealth Ontario 2014:4). This requires a lot of time to be spent in the area of immunisation in medical and nursing institutes and an enormous attention on continual medical education in this topic (WHO 2015a:4). Community engagement is further supported through better designed communication materials when shared through proper channels (Hardt et al 2013:216-217).

In 2002, 4,600 children were immunised during a MMR operation from Nahrin district, Afghanistan. Five weeks following the immunisation, vaccination facilitators from a National Immunisation Day (NID) operation reported in four villages roughly 150 children with abscesses, which were perceived to have been related to the prior measles immunisation. Members of the community accused the vaccinators and health workers. Subsequently, routine vaccination coverage reduced from 100 to 8 children a month. The investigation identified the AEFI to a programme error related to poor sanitation safety measures, unskilled vaccinators and utilisation of an incorrect diluent. The major lesson learnt was that, primarily health workers were not capacitated on adverse events and likely management techniques. Afghanistan had no AEFI surveillance guidelines when the events occurred (UNICEF 2005:29).

5.2.9 Availability of reporting forms

In the sample analysis, 91.7% and 92% respondents from the quantitative design had no standard reporting format and guidelines for AEFI surveillance, respectively. Availability of reporting forms showed a significant relationship with immunisation safety surveillance, (x^2=10.21, p=0.03). One of the key measures for immunisation safety surveillance is availability and utilisation of AEFI surveillance reporting forms. However, there was no respondent who used the AEFI reporting form for reporting an AEFI case. Participants from the qualitative approach gave different answers for the availability of reporting forms. Only one respondent reported that they distributed three forms per health post, five reported that there was no reporting form which the remaining three reportedly had reporting forms available in the guideline and were possible to print and distribute.

Participants were also asked about the reporting form clarity. The majority affirmed that the reporting form was not clear or understandable because of the language issue, absence of prior training and mandate to adhere to format designing. The unavailability of reporting forms and other logistics have a negative impact on the immunisation

safety surveillance achievement. In addition, supply of reporting formats is used to decrease under-reporting and advance the quality of reports. This is also supported by other findings. William and Flora Hewlett Foundation (2018:1-12) highlights that monitoring of service delivery distinguishes other health system building blocks since it has instant significance for the delivery of health services. Lack of medicines, irregular supply of health services, and the unavailability of logistics or guidelines must all be taken into account as part of essential management of health service delivery. Furthermore, availability of AEFI reporting forms at the vaccination centres meaningfully affects the reporting. In Dodoo et al's 10 months prospective study in Ghana noted a six hundred percent improvement in AEFI reporting rate due to training, monitoring trips and supply of AEFI reporting forms (Masika et al 2016:19-20).

Unexpectedly, 80% respondents reported that resource shortages were not a hindrance for immunisation safety surveillance and only 19% indicated that resource shortage was an obstacle to accomplish immunisation safety surveillance. In this regard the major resource gaps were formats, drugs and manpower/time reported by 8.3%, 7.7% and 7.3% respondents, respectively. Other studies also support that the availability of resources do not guarantee immunisation safety surveillance. According to Graham et al (2012:4953), efforts to solve certain vaccine safety difficulties began when the biological standardisation expert committee of the WHO suggested that all countries shall have vaccines safety, efficacy, and quality monitoring National Regulatory Authority (NRA) in 1981. In 1997, of the 190 WHO member states only 37(19%) had NRAs, counting 20 (38%) among the 52 vaccine developing countries. In 1999, WHOs targeted country capacity strengthening project on immunisation safety as a priority. This initiative was gaining ground in 2008 as of 193 member states 58 (30%) had dependable, complete functioning NRAs counting 33 (69%) of 48 vaccine developing countries. WHO (2015b:117) reported by the end of 2010, the number had increased to 60 (31.5%) including the 34 (77%) of 44 vaccine producing countries. Graham et al (2012:4953) explain that despite these substantial enhancements, yet even in developed countries only one out of four LMIC have a dependable NRAs with adequate manpower and logistic assets to review and control antigen safety and with real-time active surveillance for AEFI continues an ideal. Detecting, monitoring, responding and reporting of AEFIs continue to be an ideal of vaccine producers, regulators, HCPs, and the public.

5.2.10 Partner support

Results from the quantitative paradigm reveal that respondents (92.7%) and (7.3%) reported that there was no NGO partner or they did not know that there was a NGO partner which supported them for immunisation safety surveillance respectively. This issue was also explored from the qualitative interviews for those who had the responsibility to monitor partner activities. The question was '*What type of support have you gained from NGO/partners related to AEFI?'* Almost all participants reported that there was no NGO partner who provided special support on immunisation safety surveillance.

It becomes evident from these findings that immunisation safety surveillance activity was neglected both in the government as well as by NGOs. Vaccines are sensitive biological substances which require involvement of different stakeholders. This is in line with the idea that private sector health care delivery in LMICs is sometimes argued to be more resourceful, responsible, and maintainable than public segment delivery. Conversely, the public segment is usually explained as delivering more and providing scientific care (Basu et al 2012:1). Qualified country target information about the proportion of the total health expenditure in the private sector reveals that the private sector has a substantial role in health service provision globally (WHO 2017:149). Faith based organisations and NGOs are the major providers of private preventive care, usually in partnership with the public sector (WHO 2017:6). In global networks, the immunisation discussion has moved from the classical top-down model of information delivery to one of social media discussion, where every contributor is observed as an equal player (Hardt et al 2013:216). Doherty et al (2016:6707) suggest that, compared to drugs, vaccines are given not only for the advantage of the individual, but also for the advantage of the population. Hence, AEFI may be perceived as being the responsibility of the population, unlike drug reactions. The WHO (2015b:35) agrees that variations do not impede a monitoring system for adverse drug events being used to monitor AEFI, but the system must be sensitive to the specific nature of vaccines. In several countries with a single monitoring system, surveillance of AEFI tends to be unnoticed. Diverse reporting flows and reactions to AEFI are require to be built into the existing system of ADR reporting.

5.2.11 Health care provider knowledge

The WHO's definition of AEFI, "An adverse event following immunisation is any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine" (EFMHACA 2016:17).

According to the quantitative results, majority (94.7%) of respondents had heard about AEFI but only 22.3% were able to define it as per the WHO standard definition. Defining AEFI was also triangulated with the interview participants who were responsible for cascading and delivery of immunisation safety surveillance training for the health facility level respondents. Some (four participants) of the immunisation and surveillance experts knew the correct concept but others failed to explain the concept AEFI and only one respondent was able to define it according to AEFI definition given by the WHO.

In supporting this view, Ogunyemi and Odusanya (2016:80) point out that poor knowledge of AEFI among health care workers will result in many cases of AEFI going unreported and unaddressed. In another study also nearly one third (30.3%) of respondents indicated that health care providers should not always report the AEFI cases immediately to next higher levels and (55.3%) felt that previously vaccine is not contraindicated if there is a history of anaphylaxis to a given vaccine. This is a very critical area because it could be the cause for immunisation dropout as well as poor health outcomes of the child. Similarly, Owino et al (2009) identified fear of adverse effects following immunisation (AEFIs) to in contribute to the high vaccination drop-out rates (Masika 2014:18-19).

In this study the most common AEFI symptoms identified to be reported to higher levels by the respondents were convulsion (91.7%), anaphylaxis (83.7%), abscess (83.7%), fever >38^{o}C (54.7%), swelling (52.7%), redness (50.7%) and rumor (34.3 %). This is an indication that attention was not given to minor AEFI signs and symptoms. On the contrary, a survey of PHCWs AEFI knowledge and reporting practices in Alimosho, Lagos found the most common AEFI symptoms identified by the respondents were fever (84.8%), redness (82.9%), swelling at injection site (89.6%) and pain (83.5%). Less than half of the respondents were familiar with encephalopathy/encephalitis, hypotonic and hypertonic responses responsive episodes and convulsions as symptoms of AEFI. More than two-thirds of the respondents knew correctly that all cases of immunisation-related hospitalisations (69.5%), immunisation-related unusual medical incidents (69.5%) and

immunisation-related deaths (67.1%) were reportable AEFIs. According to the WHO (2016:17) vaccine anaphylaxis is very rare. However, it is commended that readiness to deliver emergency management for anaphylaxis be mandatory in all clinic settings. All vaccinators are required to be trained and have the capability in identifying and treating anaphylaxis.

5.2.12 Health care providers' perceptions towards immunisation safety surveillance

Nearly 99% of respondents believed that surveillance of immunisation safety is beneficial and HEWs/HWs play a crucial role in diagnosing, reporting, investigating and managing AEFI. A similar perception among all participants interviewed was that immunisation safety surveillance is important and proposed their own justification to include immediate detection, take immediate action, prevent future harm and address identified gaps. This result is encouraging and concurs with a study on KPP of nurses on surveillance of AEFI in Nairobi, Kenya which shows that 77.4% of respondents recognised that nurses play a crucial role in diagnosing, reporting, investigating, and treating AEFI (Masika et al 2016:2-3). In addition, HCPs have an indispensable and key role to play in achieving and keeping population trust in the safety of vaccines through active AEFI surveillance. These roles include delivering scientific information on the advantages and disadvantages of vaccines as well as detecting and reporting AEFI (Mohammed et al 2018:82).

The perception of weak monitoring on adverse events can lead to reduction for vaccination achievement was disagreed by 11.7% and strongly disagreed by 1.7% respondents. All the zone and woreda respondents agreed on the importance of AEFI monitoring to enhance immunisation outcomes. It is clear that poor monitoring of any activity implementation leads to poor achievement of the direct and indirect outcomes of that action. The post marketing vaccine safety monitoring benefit cannot be underestimated. As antigens are mostly administered to healthy people, usually infants and young children (Pasquale et al 2016:6672) indicates that in order to prevent, rather than manage disease, public expectation of vaccine safety is substantial (Parrella 2014:1; Waldman et al 2011:1).

Somewhat greater than half (52.3%) the number of respondents strongly disagreed and 6% disagreed with the perception that reporting of an AEFI would not make a vaccinator feel guilty about having caused injury. However, 16% strongly agreed and 64% agreed that reporting of an AEFI would not lead to individual bad reputations. The participants in a qualitative design, who were supervisors of the health facilities, all except one, all felt that they would report all the AEFI cases they identified. However, two participants underscored that they would verify before reporting the cases to next higher level. Similarly, except one participant, all mentioned that they would neither feel guilty nor fear accountability because of reporting many numbers of AEFI cases. This result as compared to other similar study shows a high feeling of guilt for causing harm and a low feeling of fear of consequences. A study on KPP of nurses on surveillance of AEFI in Nairobi, Kenya showed that 41.9% of the respondents believed reporting an AEFI would not lead to personal negative repercussions. Less than half (42.3%) of the nurses sensed that reporting an AEFI could make them feel guilty about having caused injury and be held accountable for the event (Masika et al 2016:2-3). Also, UNICEF (2005:14) points out that from experiences it is known that due to fear of guilt or sanction several health workers do not report an AEFI. It is imperative to inspire and assist health workers particularly in case of programme mistakes to report AEFI. Furthermore, the safety of the native health worker and vaccinator has to be guaranteed, if a real or perceived AEFI happens, as they might become the focus of aggression or be confronted by members of the affected community. The WHO (2011) warns that if for a long period of time the AEFI cases are not reported, health workers lose interest or forget appropriate procedures to treat AEFI cases (Masika et al 2016:18).

5.2.13 Health care providers' immunisation safety surveillance practices

A large number of respondents were well versed on how to rule out contraindications to vaccine(s) in a child before vaccination (91.3%), inform the parents of likely vaccine adverse reactions (97.3%), inform the caretaker how to treat AEFIs at home (94.7%). On the other hand, the majority, 89.7%, 93% and 92.3% of respondents reported that they had no standard guidelines, had no reporting form and not have ever reported AEFI case to higher levels, respectively. This result is also supported by the qualitative findings stating that no participant had ever used the AEFI reporting form to report AEFI case.

Other studies for instance AEFI surveillance from 2009-2010 in Kwekwe District,

Zimbabwe found that 60.7% knew the correct notification time for a severe AEFI case. In addition, 45.7% knew a minimum of two possible indicative signs of AEFIs (Muchekeza et al 2014:2). Another study on knowledge, practice and approaches of health care providers to AEFI and their reporting in Albania found that although most (63.7%) of the respondents had indicated that they knew how to complete an AEFI reporting form, (31.4%) of them had never filled an AEFI reporting form. Though 70.6% of respondents knew where to obtain an AEFI reporting form, only 63.7% of them really had the AEFI reporting form in their work setting.

In total, 64% of respondents had no anaphylactic pack with adrenaline in the vaccination room. This result is similar to the study done on KPP of nurses on surveillance of AEF in Nairobi that found that majority of nurses (85.8%), had no an anaphylactic pack with adrenaline in their vaccination rooms.

For the mean value of all the practice indicators, 46.7%, 22%, 31.3% of respondents scored below mean (poor practice), equal to mean (fair practice) and above the mean value (good practice). Respondents who scored above the mean practice value had 43 times more chance of detecting AEFI cases than those who scored below the mean practice value, (AOR 43.3, 95% CI 13.2-142.1). This might be the respondents who reported that what they really practiced in their workstation. This result is supported with the response of the interviewed participants who are the supervisors for the respective study areas, as they responded that there was no clear procedure and no follow up for immunisation safety surveillance.

All interviewed participants did not make any follow up on the status of AEFI case surveillance. From this response, it is reasonable to accept the poor achievement findings of the 25% detection and 5.7% reporting rate of AEFI cases from the quantitative data result. The major cause for this was that immunisation safety surveillance had no clearly defined responsible offices. This was because of task confusion. Previously AEFI cases follow up was under immunisation as it is vaccine related. On the other hand, searching for those cases who developed AEFI has been the responsibility of the surveillance department. Four of the interviewees recommended that the surveillance department should be responsible, two added that both immunisation and surveillance should be responsible or do follow up and one agreed that the immunisation department could be responsible. So, based on the number of recommendations, the surveillance department

should take the responsibility. Almost similar responses given for the question: ‘’Do you think there is a clear system of upward and downward AEFI surveillance?’’ Responses by all interviewees were: “Never, it does not have clear systems.”

5.2.14 Challenges for immunisation safety surveillance

Both the quantitative and qualitative participants were asked what challenges hindered them from conducting immunisation safety surveillance activities. Of the total quantitative study respodents, 275 proposed a total of 39 different problems which were further grouped in to 22 topics/issues. However, 25 respondents did not give any ideas and another 25 responded that there were no challenges related to immunisation safety surveillance. The major challenge was raised 180 times and the least was mentioned once. The major proposed challenges were: no AEFI case was found (180), no clarity on how to do immunisation safety surveillance (66), no standard reporting form (62), the problem was mild which could resolve by itself or care takers managed it at home (35), there was no transportation access and respondents were able to treat the case at health facility level (25) were the major issues raised. Similarly, all the nine participants interviewed mentioned almost similar challenges such as lack of awareness on AEFI, lack of attention, no follow up or guidance given from higher level, no supplies such as reporting format and guidelines, poor commitment of health workers, lack of information sharing, immunisation safety surveillance has no specific and clear ownership at different levels (Zone, Woreda and Lower level) and no partner provided support on AEFI surveillance. Lack of attention from higher bodies and lack of ownership for the work were mentioned by the interviewees as huge obstacles.

Despite the benefit of knowledge sharing in enhancing a facility’s knowledge, which ultimately build a facility’s cutting edge, there are reasons to believe that employees are not volunteering to share their knowledge willingly (Pangil & Nasurddin 2012:349-350). For example, a study by Michailova and Husted (2003:1) discovered five reasons why the workforce is hesitant to share knowledge. The reasons include: the fear to reduce personal value, cost involved, uncertainty of how the receiver will use the shared knowledge, accepting and respecting a strong hierarchical and formal power, and actual negative consequences of sharing knowledge with subordinates (Husted et al 2012:756). The population obtains contradictory information about the benefits and security of vaccinations from different sources including, HCPs and the media (Buxton et al

2013:e516). The excellence of health care services mostly depends on practitioners' knowledge and technical skills (Mosadeghrad 2014:81). The experience of Information Providers (IPs) in the delivery of vaccination, independent of vocation, is intuitively a positive predictor of vaccination knowledge (Buxton et al 2013:e516).

Agarwal et al's (2013:58) systematic reviews of 45 studies conducted in Europe, United Kingdom, Asia and USA identified most repeatedly attitudes that contributed to health care workers not reporting ADRs were: negligence of what to report or negligence of a reporting system in 95% studies; fatigue in 77% studies; hesitancy in 72% studies; indifference and insecurity regarding causation in 67% studies; a perception that only harmless drugs are out into the market in 47% studies; and fear of likely involvement in lawsuits or scrutiny by 24% of the respondents. Parrela (2014:29) states that in Malaysia a qualitative study involving 16 community pharmacists, the gaps identified in this study were similar to findings obtained in the quantitative studies on ADR reporting: not able to get an ADR, poor understanding for procedure of reporting, reporting procedure difficulty and absence of feedback from leadership. According to Tew et al's (2016:1) study, though under-reporting of AEFI may happen because of inability to identify an ADR, it has been known that doctors were not reporting AEFI even when they encountered and identified it in Kuala Lumpur Malaysia because the participants were unclear of the presence of the countrywide reporting system in Malaysia (40%). Gupta et al (2015:7) identified contributing variables for PV underreporting in South India as: no payment, time shortage to report ADR, perception that ADR database will not be affected because of one unreported case, difficulty identifying whether an ADR occurred or not, lack of training, unfamiliarity with the ADR reporting form, unawareness of the rules and procedure for reporting. AEFI surveillance system evaluation in Guruve district, Zimbabwe identified the major rationale for defaulting to report AEFIs comprised: HCPs' fear of personal negative consequences and assuming that an adverse event was not severe enough to report (Constantine, Cremance, Juru, Gerald, Notion, Peter & Mufuta 2018:1).

5.3 SUMMARY

The chapter presented the triangulated and integrated findings from the quantitative and qualitative approaches of the study. Various aspects where the respondents and participants shared similar views are presented, including aspects where there were differences in certain findings. It can thus be concluded that health care providers and

their senior officials share similar views regarding AEFI immunisation safety surveillance. The combined findings of this study contributed to the formulation of the immunisation safety pocket manual for health care providers in the study site.

CHAPTER 6

REVIEW OF THE IMMUNISATION SAFETY SURVEILLANCE GUIDELINES OF ETHIOPIA AND DEVELOPMENT OF THE IMMUNISATION SAFETY SURVEILLANCE POCKET MANUAL

6.1 INTRODUCTION

Chapter 6 presents Stages 1 and 2 of Phase 2 of this study. Full details of the processes are clarified in these respective stages.

6.2 PHASE 2

6.2.1 Stage 1: Identified gaps in the existing immunisation safety surveillance guidelines of Ethiopia

6.2.1.1 Introduction

The WHO has prepared global immunisation safety surveillance guidelines which have been revised several times. Ethiopia has also prepared its own AEFI surveillance guidelines in 2016, in line with the global one. However, there has been no revision or update done on the guidelines, which is prepared in English language only, and is difficult to read and understand by some frontline health workers. There is low AEFI surveillance detection in Ethiopia. Lack of update on the guidelines might be one of the reasons for the low improvement in AEFI surveillance performance. Thus, one of the objectives of this study was to identify gaps in the existing national immunisation safety surveillance guidelines to be in line with the latest WHO standard guidelines. The gaps are summarised in Table 6.1 by using criteria such as, responsible organisation, AEFI Signs and symptoms to be reported to higher levels, investigation, procedure for investigation and reporting, feedback, involvement of NGOs and private sector in AEFI reporting and investigation, differences between the WHO global and Ethiopia national guideline and proposed possible recommendations.

Table 6.1 Identified gaps in the existing national immunisation safety surveillance guidelines

Criteria	Identified gaps	Evidence and corrective measures
Responsible organisation	The existing system for monitoring drug safety (pharmacovigilance) in Ethiopia is coordinated by the National Regulatory Authority (NRA) namely, Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA). Monitoring vaccine safety has been challenging as there exist two safety data systems in the country. The national NIP, which has been actively engaged in increasing vaccination coverage principally gathering vaccine safety data from the districts and AEFI reports, but did not find their way to EFMHACA for further regulatory actions (EFMHACA 2016:4). The federal guidelines given to the primary reporting body is the district immunisation officer (DIO) (EFMHACA 2014:29). At national level, EFMHACA is responsible for vaccine safety regulation but does not have supporting structures in the region.at lower levels there is task shifting AEFI. The result is major confusion of responsible bodies for AEFI surveillance.	The national level AEFI data analysis, response and follow up task mixing between NIP and the pharmacovigilance in EFMHACA should be given to NIP or EPHI which has structures up to district level or EFMHACA should establish structures up to district level for simple data sharing and accountability or design clear strategy of how to harmonise data exchange between NIP and EFMHACA. At the ground level, there should be clear responsible department because the guidelines indicate that the DIO is responsible but operationally changed to DSO. The majority of interviewed participants recommend that the DSO shall be the primary data recipient from health facilities (health posts, health centres and hospitals). An encouraging statement in the national guidelines states: 'Guidelines for Surveillance and Response to AEFI for all those involved which will be kept under review as necessary' (EFMHACA 2016:4).

Criteria	Identified gaps	Evidence and corrective measures
AEFI Signs and symptoms to be reported to higher level	Health workers should advise vaccine recipients or their parents/care givers about minor home treatments (e.g. accurate positioning of the child when sleeping, increasing consumption of fluids, sponging, breast-feeding, antipyretics etc.). If home treatments do not function, vaccine receivers themselves and/or parents or caretakers of vaccinated infants/children should be advised to report the event to health care providers at vaccination or other health care facilities, (EFMHACA 2016:33).	Local responses occurring at increased incidence, even if not severe, should also be reported (WHO 2016:45). Home treatment is one of the major indicators for low AEFI reporting. It is not spelled out in the WHO guidelines. This statement explains that the responsibility given for the parents to judge which signs and symptoms and at what stages to be reported. Generally, it should state that all AEFI signs and symptoms should be reported to the district level and decision shall be made by HCPs.
Investigation	All severe AEFI cases should be inspected and a finalised AEFI investigation form directed to the national level (EFMHACA 2016:33). Thorough investigation is not necessary if it is a simple and not severe AEFI. The DIO should indicate this on the reporting form and email/fax the same to the state and national levels to the next levels (EFMHACA 2016:33). This statement undermines need of assessment for minor cases. The crude data is important to do the assessment for the decision of need for investigation.	Up-to-date WHO guidelines states that the term “investigation” can be used for a simple assessment or a more rigorous scientific evaluation of the reported AEFI in order to distinguish its likely cause(s). All AEFI reports do not require investigation. Once the report has been obtained, an evaluation should be made to decide whether an investigation is required (WHO 2016:51). The statement of the national guidelines shall be shaped as per the WHO statement. “Data is important for minor cases to

Criteria	Identified gaps	Evidence and corrective measures
		do the assessment for the decision of importance of further investigation".
Procedure for investigation and reporting	Flow of AEFI surveillance data; DIO, Regional Immunisation Officer (RIO), the National Immunisation Programme (NIP), EPI focal person and the NRA (EFMHACA 2016:34-35). When the national AEFI focal point of the NIP gets and/or the pharmacovigilance centre in EFMHACA the filled AEFI reporting form, it is important to analyse it (EFMHACA 2016:36). There are two major challenges; First, there is no clear reporting procedure and accountability between NIP and EFMHACA. Second Ethiopian Public Health Institute (EPHI) is the national responsible legal structure to do the surveillance in the country. Even if it is surveillance activities, the national guideline gives the work to the Immunisation and EFMHACA sectors.	The profile of investigators who carry out full AEFI field investigation should be decided by the functional structure and the expertise available to the surveillance system in the country. Several developed countries have national capability to conduct investigations up to the grass root level of the health system, but this may not exist to several LMICs (WHO 2016:52). Clear investigation and reporting flow should be set from national to lower levels. EPHI shall be the responsible department, EFMHACA shall have the structure up to ground level, or NIP should take all the responsibility rather than link to EFMHACA.
AEFI case reporting	Events to be reported, when to report, how to report, does not clearly show in subtopics as the global guidelines are presented clearly, (WHO 2016:43-45). These are major points to be known and have to be shown in narrative form clearly, but are not presented in this way (EFMHACA 2016:40).	The national guidelines shall be updated and should outline which events should be reported, when to report, and how to report, as reflected in the global guidelines (WHO 2016:44-45).

Criteria	Identified gaps	Evidence and corrective measures
Feedback	The statement ''Positive feedback to health workers is essential'' as stated in the global guidelines. This is also written in the Ethiopia AEFI surveillance guidelines (EFMHACA 2016:37). But the global statement is suitable to reduce health worker fear of accountability, feelings of guilt for harming the vaccinated in reporting AEFI case (WHO 2016:48).	Constructive feedback to HCPs' is important (WHO 2016:48). The feedback should comprise the result of investigations or causality assessment when these are takenover, and recommendations on the management of the vaccine, especially related to the requirement for future immunisation.
NGOs involvement in AEFI reporting and investigation	The manual has listed that key stakeholders are parents/guardian, health workers, DIO, RIO, NIP, EFMHACA (EFMHACA 2016:36-39). It excludes NGOs partners contribution especially those working in immunisation and surveillance.	The global manual states that alertness can extend to connecting all stakeholders linked to the vaccination programme – including academia, teachers, volunteers, NGOs, policy-makers, politicians and the media (WHO 2016:34). So, the national (Ethiopia) AEFI guidelines should give emphasis for the involvement of NGOs.
Private-sector involvement	The Global WHO guidelines indicates the importance of private sector reporting, (WHO 2016:48). However, the Ethiopia guidelines mention the word private in the reporting form if in case there may be a report from there. However, the private sectors have to be part of the surveillance system from the beginning rather than expecting unconditional case report from them.	The delivery of health-care services in the private sector impacts in opportunities for AEFI case detection and reporting (WHO 2016:34). As in public sectors, all private-sector medical organisations running vaccination services and managing AEFI cases should report all AEFI to the corresponding ISS focal points or national pharmacovigilance centres, (WHO 2016:48). Hence, it is advisable to involve the private sector in the whole process (training, supply of report format and guideline) of immunisation safety surveillance.

6.2.1.2 Concluding remarks

In conclusion, the national immunisation safety surveillance guidelines of Ethiopia lack domains of guideline quality assessment criteria; scope, clarity of presentation and applicability. AEFI reporting has increased over the past sixteen years worldwide, and requires strengthening in majority of LMICs including Ethiopia. Additional efforts are needed to ensure and improve data quality, AEFI reporting and surveillance of immunisation safety in every country (Lei et al 2018:1577). The identified gaps and recommended corrective measures, provide a golden opportunity to the development of an immunisation safety surveillance pocket manual for health care providers. Furthermore, if these recommendations and corrective measures could be implemented, then immunisation safety surveillance in the study area will be improved and public trust in immunisations will improve for the benefit of all involved in promoting quality care.

6.2.2 Stage 2: Development of an immunisation safety surveillance pocket manual for health care providers

6.2.2.1 Introduction

The results that emanated from the analysis and synthesis of both quantitative questionnaires and qualitative face-to-face interviews were the basis for the development of a pocket manual for health care providers' immunisation safety surveillance. In addition, corrective measures from the gaps identified in the national immunisation safety surveillance guideline, were included in the immunisation safety surveillance pocket manual.

6.2.2.2 Development process

This section presents the steps followed in the development of the immunisation safety surveillance pocket manual for health care providers. In Step 1, the researcher drew evidence for the formulation of the immunisation pocket manual from the summary and conclusions of the triangulated and integrated findings of this study. In Step 2, the researcher also consulted key stakeholders and experts in the immunisation safety surveillance field through meetings, emails and telephone calls during which findings from the literature review, research findings and gaps identified from the national immunisation

guidelines were presented. The process was also influenced by Ajzen' and Fishbein's (1980) TRA model and "A guideline on guideline development" (Ansari & Rashidian 2012). This process is outlined as follows:

- Defining the purpose and scope of the immunisation safety surveillance pocket manual.
- Review of both findings of the study.
- Review of the literature.
- Development of the first draft of the manual.
- Establishment of an expert group.
- Review by the group through discussions, to reach consensus on first draft of the pocket manual.
- Revised pocket manual produced.
- Seek inputs from the reference group.
- Present to stakeholders and expert group.

6.2.2.2.1 Defining the purpose and scope of the immunisation pocket manual

The topic of the manual is "Development of the immunisation surveillance safety pocket manual for health care providers". The purpose is to equip health care providers with a readily available and accessible manual which they could use as reference and guidance when confronted with challenging scenarios during health service delivery.

6.2.2.2.2 Forming the immunisation pocket manual development group

The group was constituted by eight members who are experts in immunisation safety surveillance. This group comprised the principal investigator and seven experts in immunisation safety surveillance.

6.2.2.2.3 Scoping of the guidelines

To scope the immunisation pocket manual, the objectives for the study were clearly defined, the participants in the development group were experts in nursing practice and immunisation safety surveillance. The timeline for the process was over a period of four

months. After the results and findings of the study had been analysed, they were shared amongst the immunisation pocket manual development group. The group communicated frequently and a session to consolidate the process and findings was held. Communication was mainly through meetings, phones and emails. The group members declared that there was no conflict of interest in participating in the study. Ideas, procedures, and strategies which are important to enhance immunisation safety surveillance and the barriers for health care providers in relation to knowledge, perception and practice were addressed.

6.2.2.2.4 Development of first draft of the pocket manual

The first draft of the immunisation safety surveillance pocket manual was developed and shared with the development group for inputs. The group made commendable contributions which were included in the final draft.

6.2.2.2.5 Identifying the evidence

Systematic literature search was done ahead for the research to support and identify the already existing literature. The integrated research findings of the study formed the basis for the pocket manual development. The gaps from the national immunisation safety surveillance guidelines were identified and corrective actions were suggested to enhance the pocket manual.

The review identified the following aspects of immunisation safety surveillance:

- Adverse events following Immunisation
- Health care provider knowledge regarding immunisation safety surveillance
- Motivation and perceptions of health care providers
- Detection and reporting of AEFI
- Health care access and infrastructure
- Parents/caretaker treatment seeking behaviour.
- Support of immunisation safety surveillance
- Challenges experienced by health care providers and senior officials

6.2.2.2.6 Evaluating and synthesising the evidence

To evaluate and synthesise the evidence, the researcher used extensive literature search. Empirical data from the participants and the inputs of the expert group were also used in the development of the immunisation safety surveillance pocket manual. Data were collected through a convergent mixed method to obtain as much needed information as possible. Trustworthiness, validity and reliability of the study were maintained throughout.

6.2.2.2.7 Formulating recommendations

Through literature review and data from the respondents and participants, the researcher came up with evidence-based recommendations. Experts in immunisation safety surveillance provided recommendations through inputs and discussions during the immunisation safety surveillance pocket manual development process.

6.2.2.2.8 Writing the guidelines

Topics for the immunisation pocket were developed in a simple language that the end user could understand. The immunisation pocket manual guidelines were further summarised for those who would prefer to refer to the summary.

6.2.2.2.9 Consulting and peer review

Contents of the immunisation safety surveillance pocket manual were discussed and shared with the experts before they were finalised. The reviewing expert team members were those health professionals and communication experts working both on immunisation and surveillance in the country. The draft immunisation surveillance pocket manual was reviewed by experts who contributed immensely in the process.

6.2.2.2.10 Updating and reviewing

Comments raised by participating experts were reviewed and updated by the principal investigator. Above all, the final draft of the pocket manual was completed and will be shared with health care providers from the study area.

6.3 IMMUNISATION SAFETY SURVEILLANCE POCKET MANUAL FOR HEALTH CARE PROVIDERS: AM ALEMU

6.3.1 About the immunisation safety surveillance pocket manual

This immunisation safety surveillance pocket manual is prepared for health care providers working in the Ethiopian health systems as a convenient reference material to the immunisation safety surveillance activities. It commences with the definition of basic concepts, describes the types of surveillance, causes of adverse events following immunisations and signs and symptoms of AEFI. The manual also outlines the roles and responsibilities of immunisation service providers such as detecting, recording, reporting, investigating, taking corrective action, analysing surveillance data, and how to communicate with the public. The pocket manual also points out the cut off point for AEFI case investigation and reporting in relation to events to be reported, deadlines for reporting, how to report, action time and treatment of AEFI. Furthermore, the manual addresses contraindications and precautions of AEFI cases, health care provider immunisation safety surveillance procedure, how to collaborate during monitoring, supervision and training, basic supplies for AEFI surveillance practice, how to prevent and detect AEFI and the importance of private sector involvement in AEFI surveillance. It is separately ready with its own table of content for utilisation.

6.3.2 Contents

6.3.2.1 Vaccine

A vaccine is a biological preparation that develops immunity to a specific illness. Vaccines rarely cause serious adverse reactions but there are common minor reactions. Health care providers should monitor the potency, efficacy and safety of vaccines. It can be monitored by looking for AEFI (Mandala 2018:1-4).

6.3.2.2 Adverse events following immunisation (AEFI)

An AEFI is any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine (EFMHACA 2016:17).

6.3.2.3 Immunisation safety surveillance

It is a system for guaranteeing immunisation safety through detecting, reporting, investigating and responding to AEFI (Masuka & Khoza 2019:2).

6.3.2.3 Health care providers

These are people certified by a licensing body to facilitate and or provide health care services and report.

6.3.2.4 Training

Training is educating, or developing in oneself or others, any skills and knowledge or awareness that relate to specific useful competencies. Training has specific goals of advancing one's capability, capacity, productivity and performance.

6.3.2.5 Immunisation safety surveillance pocket manual

It is a small portable paperback book for quick reference regarding immunisation safety surveillance.

6.3.3 Types of immunisation safety surveillance

According to WHO (2016:27) there are two major types of surveillance:

6.3.3.1 Passive surveillance

Passive surveillance includes all voluntarily AEFI reporting from vaccinators or patients to the next level in the surveillance system.

6.3.3.2 Active surveillance

It is primarily used for description of AEFI profile, rates and risk factors. Active surveillance can also be conducted within the community.

6.3.4 Causes of adverse effect following immunisation

Most vaccine adverse reactions are simple and resolve immediately on their own. Severe adverse reactions happen too infrequently. Yenyi (2019:24) outlines five major causes of AEFI as follows:

6.3.4.1 Vaccine product-related reaction

It is an AEFI that is caused or triggered by a vaccine due to one or more of the intrinsic properties of the vaccine product.

6.3.4.2 Vaccine quality defects in-related reaction

An AEFI that is caused or triggered by a vaccine that is due to one or more quality defects in vaccine product, including devices used to administer the vaccines as supplied by the manufacturer.

6.3.4.3 Immunisation error-related reactions

It is an AEFI that is caused by incorrect antigen handling, prescribing or administration. By its nature it is avoidable.

- **Vaccine handling error:** it happens when the antigen exposed to cold or heat beyond the recommended scale. It may result due to incorrect vaccine (its diluents where applicable) storage, transport or handling or expired product usage.
- **Vaccine prescribing error**:
- It is due to administration of the antigen when contraindicated and or administration of a vaccine at incorrect dose or schedule**.**
- **Administration error:** Use of an incorrect diluent or injection of a product other than the intended vaccine.

Note: Immunisation error-related reactions are preventable and they may divert the community's attention from the benefits of vaccination programme. Early detection and taking timely and appropriate corrective actions have great importance for the immunisation programme.

6.3.4.4 Immunisation anxiety-related reactions

It is an AEFI that occurs as a result of anxiety/worries about the vaccination.

6.3.4.5 Coincidental events

An event may happen coincidentally with vaccination and infrequently be wrongly attributed to the vaccine. It is an event occurring following vaccination that is wrongly taken to be due to the vaccine.

6.3.5 Signs and symptoms of AEFI

There are various types of signs and symptoms of AEFI (WHO-Bangladesh 2014:4) such as:

6.3.5.1 Common and minor vaccine reactions

The common signs and symptoms are due to local site reaction such as swelling, redness, and or pain at the injection site and systemic symptoms such as irritability, loss of appetite, fever, and malaise.

6.3.5.2 Serious and rare vaccine reaction

The common signs and symptoms are high-grade fever, anaphylaxis, seizures, thrombocytopenia, and hypotonic or hypertonic responses.

6.3.5.3 Signs and symptoms listed in the AEFI reporting form

Some of the AEFI signs and symptoms are listed in the national AEFI reporting form (AnnexURE F). These are severe local reactions which persist more than three days and beyond the closest joint, abscess, seizures, encephalopathy, sepsis, toxic shock syndrome, fever >38^0C, thrombocytopenia, anaphylaxis and others.

6.3.6 Roles and responsibilities of immunisation service providers

Vaccination service-providers are at the lowest administrative unit where vaccination services are delivered to the population. The major duties of vaccination service providers are detection, recording, reporting, investigation, implementing corrective action, analysis of AEFI data and public education/communication on AEFI (WHO 2016:30-31).

6.3.6.1 Detection of AEFI

The primary essential step in the surveillance of AEFI is case detection.

- It is the responsibility of the health service provider working in the clinic, health post, health centre and hospital to detect and report cases of AEFI.
- The first AEFI reporter may be a health care provider, a volunteer, parent or any other person who detects the AEFI.
- Health facilities should encourage those who report the AEFI case (parent or guardian or recipient).
- When treatment is required for a certain presentation of the AEFI, they should be referred to closest better health facility.

6.3.6.2 Recording of AEFI

AEFIs should be reported in a standard form and registered with specific registers. The required registers and forms for the surveillance of vaccination safety should be available and utilised. All important information should be recorded in a form or register.

6.3.6.3 Reporting of AEFI

- For AEFI only suspicion is adequate for reporting, and the first reporter is not anticipated to appraise causality.
- Minor AEFIs should be reported and strictly controlled since they may be indicative of a possibly greater problem with the antigen or vaccination, or have an effect on the importance of vaccination in general.

- All serious AEFIs (including death) and or infrequent AEFI should be promptly reported to the next higher administrative/operational level.
- Other cases should be reported regularly, as guided by the higher administrative/operational level.

6.3.6.4 Investigation of AEFI

- Investigation can be done at the service delivery station but this is practical when the capacity required to conduct an investigation is available.
- All necessary investigations as mentioned in the national guidelines must be conducted as soon as possible for the reported AEFI.
- Investigations should be reinforced with laboratory testing.
- The population should be made aware of what has been done during the investigation process, the investigation outcome and its conclusion.
- The investigation result should be communicated with other investigation team members, the service provider and should be reported to the next higher leadership.

6.3.6.5 Corrective action

- Corrective measures, especially with regard to vaccination error related events, should be implemented as soon as possible based on the investigation outcomes.

6.3.6.6 Analysis of AEFI data

- It is advisable to document separately, line listing and detailed information.
- Based on the capability of existing staff, only basic variables may be analysed.

6.3.6.7 Public education/communication

- In each step of data sharing, trust is the vital component.
- In several situations communication is required to be done with health staff, parents, the community and the media.
- Keep regularly communicating about the investigation process with all relevant bodies: do not propose any assumption

- The population should be made aware of what is being conducted as much as possible.
- Population should be given correct information regarding AEFI.
- It is helpful to establish communication linkages with leaders of the community and local health care providers so that information can be quickly exchanged.

6.3.7 Cut off point for AEFI case investigation and reporting

In AEFI surveillance there are clearly set cut off points regarding which, when, and how AEFI events are to be reported and types of management for AEFI cases (Ghana FDA 2013:27-30).

6.3.7.1 Events to be reported

- Every AEFI that creates anxiety among caretakers or health care providers should be reported, it is incumbent on health care providers to report.
- Serious AEFI.
- Newly introduced antigen related side effects and untoward events.
- AEFI that may have been due to vaccination error.
- Noteworthy events of that are uncharacteristic occurring within 1 month following immunisation.
- Events leading to significant parental or community concerns.
- Reporting all minor AEFI such as high fever and minor local reactions is optional.

Minor AEFI are predictable vaccine events and, if reported, the quantity of reports would overwhelm the system with insignificant information. However, it is useful to follow and register crude numbers and compare them with baseline rates that could help identify product quality defects, vaccination errors or even greater vulnerability to vaccine reactions among a special population.

6.3.7.2 Time bound for reporting

Reports have to be made immediately so that quick decisions can be taken on the requirement for measures and investigation.

The next higher functional leadership should be quickly made aware of all serious events (including death) and/or unusual AEFI.

6.3.7.3 How to report

- Reports should be made on a standard AEFI reporting form.
- An immediate phone call/fax/email for incidents with many cases or significant population concern to the decision maker is relevant.
- Using other locally available technologies is important.
- Causality assessment should be done for major reactions of uncharacteristic events within one month following immunisation.

6.3.7.4 Time of action

- Appropriate measures, especially with regard to vaccination error related events, should be taken as soon as possible based on the investigation outcomes.

6.3.7.5 Management of AEFI

- Vaccine is contraindicated if there is a history of anaphylaxis in prior immunisation to a specific vaccine or its components.
- Antipyretic drugs, in a recommended dose and time, can be taken as recommended by the prescriber. For instance, paracetamol is useful for common minor reactions.
- A febrile case can be cooled down with tepid sponging or wash, and by dressing with light cool cloth. For a minor reaction, a cool towel put to the area may relieve the pain.
- Additional fluids should be taken by child with fever.
- Applying local treatments for all serious vaccine recipient events can endanger the well-being and life of the vaccine and is highly discouraged.
- Instructions should be given to caretakers on treating the minor events, in addition to advice on seeking appropriate medical care if there are more serious symptoms.
- Quick clinical care by certified professionals will decrease any undesirable effect and guarantee quick recovery, and may save lives.

- Vaccine anaphylaxis is too infrequent. However, it is commended that readiness to deliver emergency management for anaphylaxis be mandatory in all facility arrangements.

6.3.8 Contraindications and precautions of AEFI cases

The major contradictions and precautions of AEFI cases (WHO 2016:10) are:

- Immunisation is contraindicated in a recipient if it would aggravate or predispose to a serious adverse reaction.
- Anaphylaxis is among the most serious reactions after immunisation that is the only contraindication valid to succeeding doses of a similar vaccine.
- Precautions are not contraindications, but are situations that should be taken into consideration when deciding if the usage of the vaccine poses more risks (especially if the target is pregnant or immunosuppressed).
- There is no available evidence that vaccinating pregnant women risks the foetuses.
- Live attenuated vaccines given to a pregnant mother poses a theoretical risk to the foetus. Nevertheless, the benefits of immunising a pregnant mother often outweigh the dangers when the probability of disease occurrence is significant, when infection would pose a danger to the woman or foetus, and when the vaccine is unlikely to lead to injury.
- The type of immunodeficiency and degree of immunosuppression determines the safety and efficiency of antigens in immunosuppressed individuals.
- The incident of anaphylaxis can happen following within minutes but rarely up to two hours after immunisation. The development of symptoms is fast and often includes various body systems, usually with skin involvement (generalised erythema and/or urticaria), as well as signs of upper and/or lower respiratory tract obstruction and/or circulatory collapse.
- In young children, (though anaphylaxis occurs at any age) limpness, pallor or loss of consciousness may reflect hypotension.
- Every immunisation post must have an emergency kit with adrenaline. The adrenaline date of expiry should be printed on the outside of the emergency kit and check-up should be done every 3 to 4 times a year for the whole kit.

- In general, the faster the incident, the more serious is the event. Symptoms restricted to only one system can happen, leading to lateness in diagnosis.

6.3.9 Health care provider immunisation safety surveillance procedure

- The report should be forwarded immediately to higher level from community/parent to local health worker to subnational and national level.
- Develop a feedback mechanism to update regularly the AEFI surveillance system (including statistics, investigation findings, and new developments).

6.3.10 Training, monitoring and supervision

Monitoring, supervision and training are key functions of the sub national level health staff (WHO 2016:32-33).

- The authorities at this level need to develop the capacity to carry out these functions efficiently and effectively.
- Whenever necessary, the national level can assist subnational level with these activities, including providing standard formats for supportive supervision, guidelines and training materials.
- Other than the immunisation service or health service provider at the periphery of the health system, who may be in the private sector, all other key staff and structures for collation of data, management of AEFI, and corrective action and feedback will usually be from public facilities.

6.3.11 Basic supplies for AEFI surveillance practice

- The existences of sufficient resources affect the sustainability of at each stages of the surveillance system. Hence, tracing and location of resources is vital at the national level (and possibly subnational level).
- Supply of sufficient reporting forms is mandatory.

6.3.12 Prevention and detection of adverse events following immunisation

- Counteractive and protective measures should be carried out as soon as possible. Nevertheless, the measures should be based on the outcome of the investigation.
- From experience, taking both logistic and administrative corrective measures is largely the responsibility of the subnational level. For instance, enhancing joint supportive supervision, capacity building/training and substitution of logistics is the responsibility of the subnational level if immunisation error related reactions have occurred.
- All vaccination providers require training and enhancing competency in distinguishing and treating anaphylaxis.

6.3.13 Private sector involvement

The WHO clearly mentions the role of private sector in AEFI surveillance. According to WHO (2016:34-5):

- The private sector health service delivery enhances AEFI identification and reporting. People getting vaccines at government vaccination services could get medical care for AEFI in the private sector. It is hence, mandatory to establish links to report AEFI cases from the private sector to the government health sector.
- Encourage NGOs and other stakeholders' involvement to enhance AEFI surveillance.

6.4 SUMMARY

This study endeavoured to close the identified gaps by developing interventions. Assessments supported these guidelines gaps with possible corrective measures by using the global standard AEFI surveillance and the development of an immunisation safety surveillance pocket manual. Therefore, health systems, partners and stakeholders should cooperate and work jointly to update and follow the identified gaps in the national guidelines, effectively and efficiently use the developed immunisation safety surveillance pocket manual based on their needs.

CHAPTER 7

CONCLUSION, LIMITATIONS AND RECOMMENDATIONS

7.1 INTRODUCTION

This chapter presents the summary, major conclusions, limitations and suggests recommendations for policy makers, health care provider education, health care practice and further research. The summaries and conclusions are presented according to the aim and objectives of the study. The purpose of the study was to assess health care providers' knowledge, perceptions and practice towards immunisation safety surveillance, review, identify gaps in the existing AEFI surveillance guidelines of Ethiopia, and develop an immunisation pocket manual for health care providers to improve AEFI surveillance.

7.2 RESEARCH DESIGN AND METHODS

This study employed a convergent mixed research methods design. Both quantitative and qualitative data were collected in parallel, analysed separately, and merged to realise the purpose of the study. The reason for applying a mixed method design was based on the principle that neither quantitative nor qualitative methods individually were adequate to answer the research questions. The target population were all HCPs working in Asosa Zone. Three hundred (300) participants from 133 health facilities (2 hospitals, 16 health centres and 115 health posts) for the quantitative design and nine participants from two districts in Asosa Zone for the qualitative paradigm. The results were presented after data were analysed through SPSS 25.0 Version and Atlas ti 8 for quantitative and qualitative approaches, respectively. Gaps were identified in the national guidelines for AEFI and suggestions were based on the findings from the study. The conclusion drawn from the study findings pointed to the need to develop an immunisation safety surveillance pocket manual for health care providers in Asosa Zone, Ethiopia.

7.3 SUMMARY AND INTERPRETATION OF THE RESEARCH FINDINGS

7.3.1 Assess health care providers' knowledge, perceptions and practice on immunisation safety surveillance

Of the total sample, 94.7% had heard about AEFI, but only 22.3% were able to define AEFI as per WHO standard definition. Nearly half the number, 45.7% of respondents were not informed that AEFI surveillance had to be practised in each health facility. Among all the respondents, (90.7%) were not trained in immunisation safety surveillance. Nearly 42% of the respondents had below the average value (poor knowledge) and 56% had more than the mean value (good knowledge) of knowledge indicators. Almost 99% of the respondents believed that surveillance of immunisation safety is beneficial, however, 56% agreed and 32.7% strongly agreed that detecting, reporting and investigating AEFI is none of a health care provider's responsibility. The respondents' overall mean value for all the perception indicators of immunisation safety surveillance were 44.7% and 41.3%, which were below mean value (poor perception) and above the mean value (good perception), respectively. Only 5.7% respondents had ever reported to a higher level and 23% had treated an AEFI case. The mean values for all the practice indicators of immunisation safety surveillance scored by respondents were 46.7% and 31.3% which were above mean (good practice), and below the mean (poor practice), respectively.

7.3.2 Identify and describe factors affecting health care providers' immunisation safety surveillance

Among the socio demographic characteristics, type of health facilities (x^2=6.32, p=0.04), age of respondents (x^2=7.74, p=0.02), responsibility (x^2=17.12, p=0.04) and work experience (x^2=13.59, p=0.001) showed a relationship with the outcome variable. Among health service access variables, location of health facility (x^2=5.54, p=0.01), status of electricity (x^2=7.4, p=0.02), vehicle road access (x^2=3.88, p=0.04), bajaj transportation (x^2=6.46, p=0.01) showed relationship. Organisational and motivational factors, which showed relationships were standard AEFI surveillance reporting form (x^2=10.21, p=0.03), means of communication (x^2=5.85, p=0.01), satisfaction with current position (x^2=9.98, p=0.04), self-assessment (x^2=6.16, p=0.04) and parent response (x^2=5.22, p=0.02).

7.3.3 Analyse challenges, which affect surveillance for safety and vaccine reporting system after immunisation

The major challenges of immunisation safety surveillance included; no clarity on how to conduct an immunisation safety surveillance, lack of standard reporting forms, undermining the problem which they felt could be managed at home, poor roads and electricity access, poor AEFI case reporting and respondents' inability to treat the case at health facility level.

7.3.4 Identify gaps in the existing immunisation safety surveillance to be in line with the latest WHO standard guidelines

The national guidelines showed deficits in the following aspects: responsible department for AEFI surveillance, clearly defined AEFI signs and symptoms to be reported to higher levels, investigation, how to investigate and reporting procedure, AEFI case reporting, feedback mechanism, NGOs involvement in AEFI reporting and investigation and private sector involvement. The guideline is prepared in English, which is difficult to read and understand by some frontline health workers. This implies that the guideline lacks Scope, Clarity of Presentation and Applicability in the six domains of methods used to check the quality of guidelines.

7.3.5 Develop immunisation safety surveillance pocket manual for HCPs

An immunisation safety surveillance pocket-training manual was developed based on the findings from the quantitative and qualitative paradigms of the study including identified gaps in the national immunisation guidelines. The constructs developed based on the PCA findings, provided guidance and classification of information.

7.4 CONCLUSION

Despite having ever heard about AEFI, most of the participants lacked knowledge, had poor perceptions and poor practice based on the importance of immunisation safety surveillance indicators. In addition, some of the respondents could not define AEFI and could not identify minor AEFI signs and symptoms. There was no clear reporting procedure and no responsible structure for immunisation safety surveillance. The overall

detecting and reporting rate of AEFI cases was very low. It was encouraging that most of the participants believed that immunisation safety surveillance is beneficial, did not fear accountability in reporting a number of AEFI cases at a time and there was better knowledge in identifying severe forms of AEFI cases as compared to minor signs and symptoms. Length of work experience, age, location of health facilities, status of electricity in the health facility, bajaj transportation, parents or caretakers' treatment seeking behaviour and means of surveillance data transportation were some of the factors, which showed significant association with outcome variables. Gaps were identified in the existing national AEFI surveillance guidelines. Therefore, correcting the gaps observed in the existing immunisation safety surveillance should be a health system priority activity to strengthen the surveillance implementation. The researcher developed an immunisation safety surveillance pocket manual which could improve the health system immunisation safety surveillance.

7.5 RECOMMENDATIONS

The recommendations are derived from the findings of the study and are presented according to policy makers, health care provider education, health care practice and research as follows:

7.5.1 Policy makers

- Policy makers should ensure that AEFI national guidelines are revised in line with the WHO guidelines and the country national language. Amharic should be included for those who may not be comfortable in using English.
- Availability and affordability of health care services should be improved to the communities to utilise without difficulties.

7.5.2 Health care provider education

- All health care providers assigned to departments caring for AEFI clients/cases should be trained in AEFI surveillance to be better equipped in attending to such patients.
- Periodic in-service education should be conducted to update health care providers about the latest developments in immunisations.

- The developed immunisation safety surveillance pocket manual could be made available in immunisation surveillance, paediatric treatment departments for quick access including reference purposes when confronted with AEFI clients/patients.

7.5.3 Health care practice

- Staff working with AEFI should be empowered in handling AEFI clients/cases.
- Line of authority should be clear for reporting AEFI clients/cases.
- Appropriate forms must always be available and staff should be informed about the immunisation safety surveillance process.

7.5.4 Further research

- Further research should be conducted in other Zones of Ethiopia for the benefit of the country.
- Other AEFI research areas could focus on community members with more emphasis on parents/care givers.

7.6 CONTRIBUTION OF THE STUDY

The vital contribution of the study could be summarised as production of local evidence, sensitisation of HCPs, supervisors, decision makers, policy makers and stakeholders on immunisation safety surveillance and its appropriate guidelines. In addition, the national AEFI surveillance guidelines were reviewed and gaps were identified with suggestions of how they should be addressed. The developed immunisation safety surveillance pocket manual is a significant outcome which could increase the knowledge, perceptions and practice of HCPs on AEFI surveillance. Scientific data analysis results on major issues raised have the potential to assist the implementers and decision makers to further assess, learn, take action and replicate the study in other areas. Importantly, the research results could improve public trust on immunisation following active immunisation safety achievements.

7.7 LIMITATIONS OF THE STUDY

This study was limited to one of the nine regions in Asosa Zone. The research results cannot be generalised to other parts of Ethiopia, but are limited to health facilities in Asosa Zone. However, health care providers in other areas could use the immunisation safety surveillance pocket manual for reference when confronted with AEFI cases in health facilities.

7.8 SUMMARY

This chapter gave an account of how the overall purpose and the objectives of the study were achieved. The conclusions that emanated from Phase 1 of the study endorsed the significance of the developed immunisation safety surveillance pocket manual to enhance health care providers' response towards AEFI in Asosa Zone. The study was concluded with a number of recommendations for policy makers, health care provider education, health care practice and research. The study was challenging, yet fulfilling to the principal researcher who is also a health care specialist.

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ANNEXURES

ANNEXURE A: UNISA Health Studies Research Ethics Committee Research approval

UNISA university of south africa

RESEARCH ETHICS COMMITTEE: DEPARTMENT OF HEALTH STUDIES

REC-012714-039 (NHERC)

19 November 2019

Dear Muluken Asres Alemu

HSHDC/933/2019

Student: Muluken Asres Alemu

Student No: 64095118

Supervisor: Prof T Maja

Qualification: PhD

Decision: Approval

Name: Muluken Asres Alemu

Proposal: Immunisation safety surveillance in Assosa Zone, Ethiopia

Qualification: DLitt et Phil

Risk Level: Low risk

Thank you for the application for research ethics approval from the Research Ethics Committee: Department of Health Studies, for the above mentioned research. Final approval is granted from 19 November 2019 to 19 November 2024.

The application was reviewed in compliance with the Unisa Policy on Research Ethics by the Research Ethics Committee: Department of Health Studies on 05/11/2019.

The proposed research may now commence with the proviso that:

1) *The researcher/s will ensure that the research project adheres to the values and principles expressed in the UNISA Policy on Research Ethics.*

2) *Any adverse circumstance arising in the undertaking of the research project that is relevant to the ethicality of the study, as well as changes in the methodology, should be communicated in writing to the Research Ethics Review Committee, Department of Health Studies. An amended application could be requested if there are*

substantial changes from the existing proposal, especially if those changes affect any of the study-related risks for the research participants.

3) *The researcher will ensure that the research project adheres to any applicable national legislation, professional codes of conduct, institutional guidelines and scientific standards relevant to the specific field of study.*

4) *You are required to submit an annual report by 30 January of each year that indicates that the study is active. Reports should be submitted to the administrator HSREC@unisa.ac.za. Should the reports not be forthcoming the ethical permission might be revoked until such time as the reports are presented.*

Note:
The reference numbers [top middle and right corner of this communiqué] should be clearly indicated on all forms of communication [e.g. Webmail, E-mail messages, letters] with the intended research participants, as well as with the Research Ethics Committee: Department of Health Studies.

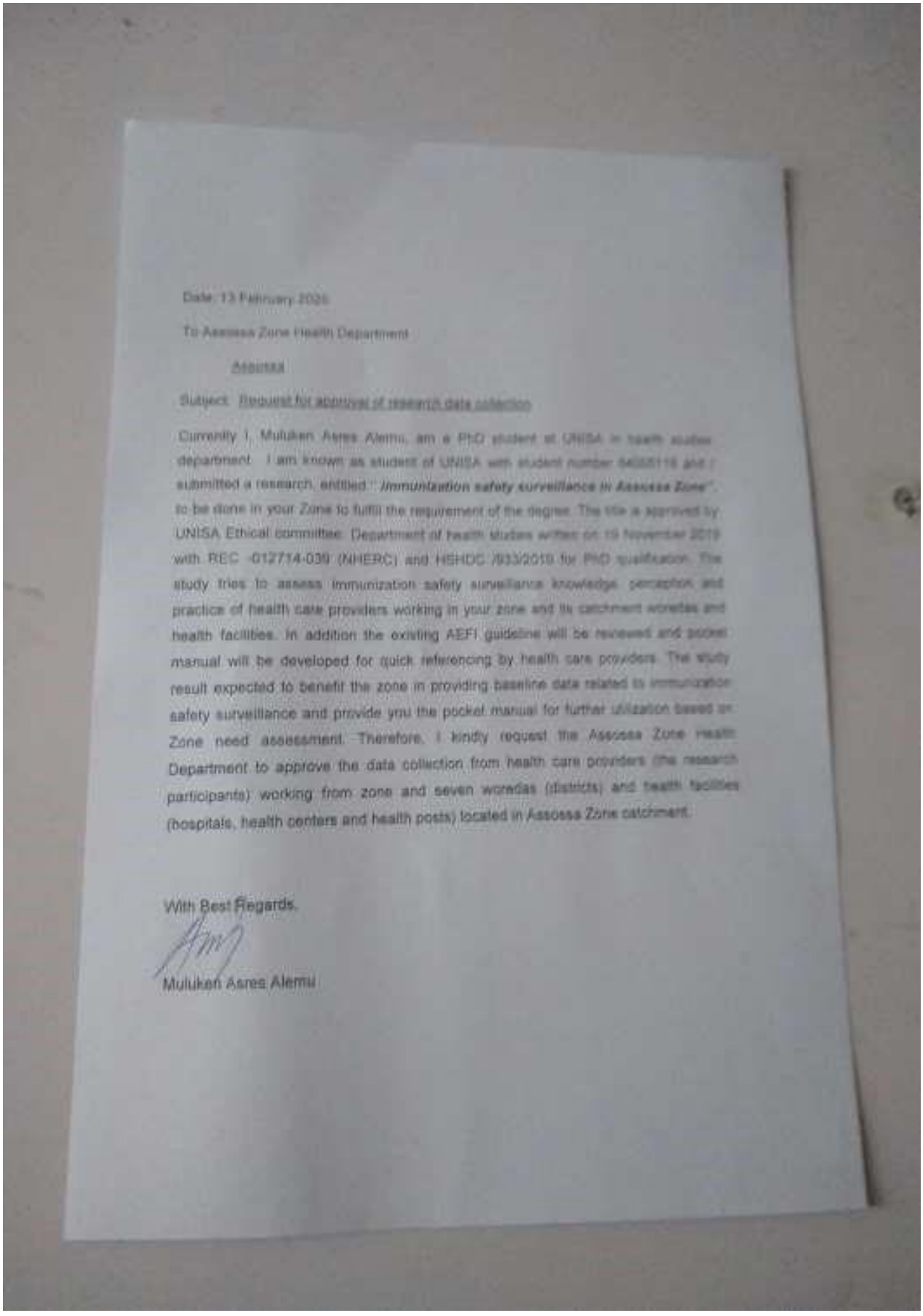
Kind regards,

Prof L Roets
ACTING CHAIRPERSON
roetsl@unisa.ac.za

Prof A Phillips
DEAN OF COLLEGE OF HUMAN SCIENCES

www.unisa.ac.za

ANNEXURE B: Request for approval of research data collection



Date: 13 February 2026

To Assosa Zone Health Department

Assosa

Subject: Request for approval of research data collection

Currently I, Muluken Asres Alemu, am a PhD student at UNISA in health studies department. I am known as student of UNISA with student number 64555116 and I submitted a research, entitled " ***Immunization safety surveillance in Assosa Zone***", to be done in your Zone to fulfil the requirement of the degree. The title is approved by UNISA Ethical committee, Department of health studies written on 19 November 2019 with REC -012714-039 (NHERC) and HSHDC /933/2019 for PhD qualification. The study tries to assess immunization safety surveillance knowledge, perception and practice of health care providers working in your zone and its catchment woredas and health facilities. In addition the existing AEFI guideline will be reviewed and pocket manual will be developed for quick referencing by health care providers. The study result expected to benefit the zone in providing baseline data related to immunization safety surveillance and provide you the pocket manual for further utilization based on Zone need assessment. Therefore, I kindly request the Assosa Zone Health Department to approve the data collection from health care providers (the research participants) working from zone and seven woredas (districts) and health facilities (hospitals, health centers and health posts) located in Assosa Zone catchment.

With Best Regards,

Muluken Asres Alemu

ANNEXURE C: Asosa Zone Health Department data collection approval letter

Date 25 February 2020

Ref Number- 0539/12

To Whom It May Concern

Subject: **Data collection Approval**

Mr Muluken Asres who are student of UNISA with student number 64095118 submitted a research, entitled immunization safety surveillance in Assossa Zone, to be done in our Zone which approved by UNISA Ethical committee written on 19 November 2019 with REC -012714-039 (NHERC) and HSHDC /933/2019 for PhD qualification. Looking the benefit of the study and no harm for the study participants the zone approved the student to collect the data from health care providers (the research participants) working from zone, woredas (districts) and health facilities (hospitals, health centers and health posts) located in Assossa Zone catchment.

With Regards,

Department Head

ANNEXURE D: Participant information sheet

Ethics clearance reference number: REC -012714-039 (NHERC)
Research permission reference number: 0539/12
March 2020
Title: Immunisation Safety Surveillance in Asosa Zone, Ethiopia

Dear Prospective Participant

My name is Muluken Asress and I am doing research with Prof TDD Mavis Maja, a professor, in the Department of Health studies towards a Doctor of Philosophy at the University of South Africa. We are inviting you to participate in a study entitled Immunisation Safety Surveillance in Asosa Zone, Ethiopia.

It is known that immunisation safety surveillance is becoming a serious public health issue worldwide including in our country. To enhance service related to it the government is expanding and scaling up awareness creation and training for health care providers. This study is aimed to assess socio-demographic, access, organisational, motivation, knowledge, perception, practice and challenges of health care providers to perform immunisation safety surveillance in respective health systems of Assosa Zone.

You are working under Asosa zone health office and contributing a lot in the progress of immunisation/surveillance/pediatric treatment/data improvement. Because of you are assigning in this department you are purposely selected for this study. Actually, not only you but also others working in other zone and woreda in a similar position are also included. I got your list from the head of the health office.

You will be asked questions related to different factors expected to affect immunisation safety surveillance of HCPs. You are expected to answer from what you are, know, perceive and practice. The interview will last within 35 to 45 minutes and the interview will be recorded as you can see in this audio tape.

Your participation in this study is fully in your own voluntary and also you have the right to withdraw from this study at any time you want but your response will do a lot to our study. So, if you are voluntary, you will be given this sheet to put an agreement signature. Being participate in this study you will not get any payment or other benefit but as I mentioned earlier your contribution is very helpful beyond this study outcome for taking corrective action. On the other hand, there will not be any negative consequences being you participated in this study or following the information you provided.

The information you provide will only be used for this study by the researcher, but it will be reviewed by person responsible making sure that research is done properly, including the transcriber, external coder and members of the Research Ethics Review Committee. We strictly maintain confidentiality unless you allowed seeing others for your record. Data will be recorded using codes and will be kept under the control of the investigators and

will not be used for other purposes other than this study. However, data may be used for other purposes, such as a research report, journal articles and/or conference proceedings.

Hard copies of your answers will be stored by the researcher for a period of five years in a locked cupboard/filing cabinet in the researcher home for future research or academic purposes; electronic information will be stored on a password protected computer. Future use of the stored data will be subject to further Research Ethics Review and approval if applicable.

This study has received written approval from the Research Ethics Review Committee of the College of Human Health Sciences, Unisa. If you need, a copy of the approval letter it is available in the researcher hand.

If you would like to be informed of the final research findings, please contact Muluken Asres. +251920518186, mulukena.cgpp@gmail.com. The findings are accessible for you after approval of the university. If you need any additional information or want to contact the researcher about any aspect of this study, please contact Muluken Asres, +251920518186, mulukena.cgpp@gmail.com. If you have concerns about the way in which the research has been conducted, you may contact Prof Todd Mavis Maja, majatmm@gmail.com. Contact the research ethics chairperson of the HSREC, Prof J E Maritz at HSREC@unisa.ac.za if you have any ethical concerns.

Thank you for taking time to read this information sheet and for participating in this study.

Thank you

Muluken Asres

ANNEXURE E: Consent to participate in this study

I, _____ (participant name), confirm that the person asking my consent to take part in this research has told me about the nature, procedure, potential benefits and anticipated inconvenience of participation.

I have read (or had explained to me) and understood the study as explained in the information sheet.

I have had sufficient opportunity to ask questions and am prepared to participate in the study.

I understand that my participation is voluntary and that I am free to withdraw at any time without penalty (if applicable).

I am aware that the findings of this study will be processed into a research report, journal publications and/or conference proceedings, but that my participation will be kept confidential unless otherwise specified.
I agree to the recording of the in-depth interview using audio tape.

I have received a signed copy of the informed consent agreement.

Participant name and surname _____ (please print)

Participant signature _____ Date _____

Researcher's name and surname _____ (please print)

Researcher's signature _____ Date _____

ANNEXURE F: Global reporting form for AEFI

***Patient name:** _____

***Patient's full address:** _____

Telephone: _____

Sex:

Male ☐

Female ☐

***Date of birth:** ____/___/_____

OR Age of onset ☐☐ Years ☐☐ Months ☐☐ Days

OR Age group at onset ☐ <1 year ☐ 1 to 5 years ☐ >5 years

***Reporter's name:** _____

Institution: _____

Designation and Department:

_____

Address:

_____

_____

Telephone and e-mail:

_____

Date patient notified event to health system: _____

Today's date: _____

Health facility (place or vaccination centre) name and address:

_____

VACCINE					DILUENT (IF APPLICABLE_			
***Name of vaccine**	***Date and time of reconstitution**	***Date of vaccination**	***Time of vaccination**	***Dose (1st, 2nd, etc)**	***Batch/Lot number**	**Expriry date**	**Expiry date of diluent**	***Batch/Lot number**

***Adverse event(s):**

Severe local reaction ☐

Seizures ☐

Abscess ☐

Sepsis ☐

Encephalopathy ☐

Toxic shock syndrome ☐

Thrombocytopenia ☐

Anaphylaxis ☐

Fever>38^{O}C ☐

Other (specify): _____

>3 days ☐

Beyond nearest joint ☐

Febrile ☐

Afebrile ☐

Date AEFI started:
_____

Time:
_____

Describe AEFI (signs and symptoms:

_____

***Seious: Yes/No:**

If Yes

Death ☐

Life threatening ☐

Persistent or significant disability ☐

Hospitalisation ☐

Congenital anomaly ☐

Other important medical event (specify):

_____

***Outcome:**

Recovering ☐

Recovered ☐

Recovered with sequelae ☐

Not recovered ☐

Unknown ☐

Died ☐

If died, date of death: _____

Autopsy done

Yes ☐

No ☐

Unknown ☐

Past medical history (including history of similar reaction or other allergies), concomitant medication and other relevant information (e.g. other cases). Use additional sheets if needed:

First decision-making level to complete:

Investigation needed:

Yes

No

If Yes, date investigation planned: _____

National level to complete: _____

Date report received at national level: _____

AEFI wordwide unique ID: _____

Comments:

***Compulsory field**

ANNEXURE G: Selected associated variables in bivariate binary logistic regression analysis

Variables	Exp (B)	95% C. I. for EXP(B)	
		Lower	Upper
Type of Health facility			
Hospital	1.0		
HCs	0.29	0.07	1.19
HPs	0.55	0.30	1.01
Age of respondents			
Above 30 years	1.00		
25-30 years	0.35	0.15	0.81
19-24 years	0.43	0.22	0.84
Work Experiences			
10 and above years	1.0		
5-9 years	0.29	0.15	0.58
0.3 to 4 years	0.40	0.21	0.78
Location of Health Facilities			
Urban	1.0		
Rural	0.44	0.22	0.88
Status of electricity in the Health Facility			
Availability of electricity	1.0		
Functional electricity	0.43	0.23	0.80
Non-functional electricity	0.95	0.36	2.50
Vehicle road accessibility from HF to district			
Available			
Not available	0.47	0.22	1.009
Bajaj as means of transportation			
Yes			
No	0.51	0.30	0.86
Rate of parents' treatment seeking behaviour			
Very good	1.0		
Good	5.73	0.49	66.31
Fair	5.35	0.47	60.21
Poor	40.0	1.75	914.79
Standard AEFI surveillance reporting form			
Available and seen	1.0		
Available but not seen	0.000	0.000	1.00
Available but not now	0.0001	0.0001	1.00
Never	0.0001	0.0001	1.00
Do not know	0.0001	0.0001	1.00
Other means of surveillance data communication			
Available	1.00		
Not available	0.196	0.05	0.84
Satisfaction with your current position			
Very good	1.0		
Good	8700	0.0001	1.00
Fair	4285	0.0001	1.00
Dissatisfied	3096	0.0001	1.00
Very dissatisfied	2585	0.0001	1.00
Periodically performance self-evaluation			
Yes, document seen	1.0		
Yes, document not seen	5457	0.0001	1.00
Not available	0.000	0.0001	1.00

Nothing done for AEFI case because will relieve by itself			
Yes	1.00		
No	0.515	0.30	0.87
AEFI cases will go to health facility for medical care			
Yes	1.0		
No	0.43	0.21	0.90
Mean knowledge value			
Above the mean value	1.0		
Equal to mean value	0.67	0.39	1.14
Below the mean value	0.16	0.04	0.72
Mean Practice value			
Above the mean value	1.0		
Equal to mean value	24.6	9.89	61.10
Below the mean value	4711	0.0001	1.000

ANNEXURE H: Pearson correlation test for cross-checking multi-collinearity

Variables	Work experience in year	Age	Location of health facility	Status of electricity in the health facility	Bajaj	Parents treatment seeking behaviour	Other means	Nothing done because it will relieve by itself	Will go to health facility for medical care	Mean knowledge value	Practice mean value
Experience in year	1	0.489	0.123	0.094	0.236	-0.082	0.052	0.007	0.045	-0.028	-0.169
Age categorization	0.489	1	0.182	0.130	0.248	-0.029	-0.030	0.002	0.089	-0.087	-0.186
Location of health facility	0.123	0.182	1	0.678	-0.118	-0.026	-0.064	0.264	0.088	-0.013	-0.171
Status of electricity in the Health Facility	0.094	0.130	0.678	1	-0.014	-0.031	-0.020	0.308	0.057	0.004	-0.225
Bajaj	0.236	0.248	-0.118	-0.014	1	-0.057	0.084	-0.017	0.115	0.092	-0.098
Parents treatment seeking behaviour	-0.082	-0.029	-0.026	-0.031	-0.057	1	-0.088	0.022	-0.001	-0.003	-0.057
Other means	0.052	-0.030	-0.064	-0.020	0.084	-0.088	1	-0.082	0.089	0.110	-0.148
Nothing done because it will relieve by it self	0.007	0.002	0.264	0.308	-0.017	0.022	-0.082	1	-0.444	0.213	-0.061
Will go to health facility for medical care	0.045	0.089	0.088	0.057	0.115	-0.001	0.089	-0.444	1	-0.154	-0.126
Mean knowledge value	-0.028	-0.087	-0.013	0.004	0.092	-0.003	0.110	0.213	-0.154	1	-0.091
Practice mean value	-0.169	-0.186	-0.171	-0.225	-0.098	-0.057	-0.148	-0.061	-0.126	-0.091	1

ANNEXURE I: Language approval certificate

Registration No: 2018/578658/07

Certificate

This serves to certify that

Muluken Asres Alemu

Student No: 64095118

Who has written a Thesis titled

IMMUNISATION SAFETTY SURVEILLANCE IN ASOSA ZONE, ETHOPIA

As a requirement for

Degree: Doctor of Literature and Philosophy

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TO WHOM IT MAY CONCERN

I hereby confirm that I have formatted (technical edited) **MULUKEN ASRES ALEMU's** thesis entitled: **IMMUNISATION SAFETY SURVEILLANCE IN ASOSA ZONE, ETHIOPIA**

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