KNOWLEDGE, PERCEPTIONS AND PRACTICE OF NURSES ON SURVEILLANCE OF ADVERSE EVENTS FOLLOWING CHILDHOOD IMMUNIZATION IN NAIROBI COUNTY, KENYA

BY

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REG NO: Q57/CTY/PT/23675/2011

A RESEARCH THESIS SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF PUBLIC HEALTH IN THE SCHOOL OF PUBLIC HEALTH OF KENYATTA UNIVERSITY

SEPTEMBER, 2014
DECLARATION

This thesis is my original work and has not been presented for a degree in any other University

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DEDICATION

I dedicate this thesis to all those who have great zeal and interest in Monitoring and Evaluation of Immunization programs.
ACKNOWLEDGEMENTS

My greatest appreciation goes to my supervisors Dr. Tom Were and Dr. Harrysone Atieli for their dedication, constant availability, patience and thorough guidance. You have been an inspiration to me. Your devotion to seeing me complete this thesis was a huge sacrifice and favor to me. May the Lord bless you in abundance. In addition, I thank the nurses and other staff working at the Nairobi County Health Centers for their immense participation and cooperation during data collection. Last but not least to my Family and friends who constantly encouraged me to give it another trial whenever I felt like giving up.
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OPERATIONAL DEFINITION OF KEY CONCEPTS AND TERMS

For purposes of this study, the following terms are defined as follows:

**Detecting:** process of identifying and linking an AEFI to immunization process based on presenting signs and symptoms without doing an investigation.

**Good knowledge:** a respondent has good knowledge level when his or her total knowledge score is equal to or above the mean of the cumulative knowledge scores of all respondents.

**Good perception:** a respondent has good perception when his or her total score on perception is equal to or above the mean of the cumulative scores on perception towards AEFI surveillance.

**Good practice:** a respondent has good practice level when his or her total practice score is equal to or above the mean of the cumulative practice scores.

**Investigating:** refers to the process of carrying out laboratory tests to confirm causal relationship between an adverse event and immunization process.

**Management of an AEFI:** refers to treating Adverse Events Following Immunization or counseling the affected parents/guardians of the vaccinated child.

**Passive surveillance:** The process relies on immunization providers, health professionals, and consumers voluntarily submitting ad-hoc reports to jurisdictional public health and/or federal regulatory authorities such as the Division of Vaccines and Immunization.

**Poor knowledge:** a respondent has poor knowledge level when his or her total knowledge score is below the mean of the cumulative knowledge scores.

**Poor perception:** a respondent has poor perception level when his or her total perception score is below the mean of the cumulative perception scores towards AEFI surveillance.

**Poor practice:** a respondent has poor practice level when his or her cumulative practice score is below the mean cumulative practice scores.
**Reporting:** is the process of communicating identified adverse event to the supervisor at district level or central office in the Ministry of Health

**Surveillance of adverse event following immunization:** defined as the process of detecting, reporting, investigating and managing Adverse Events after Immunization.
### ABBREVIATIONS AND ACRONYMS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>AEFI</td>
<td>Adverse Event Following Immunization</td>
</tr>
<tr>
<td>BCG</td>
<td>Bacille Calmette-Guerin</td>
</tr>
<tr>
<td>CCN</td>
<td>City Council of Nairobi</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control &amp; Prevention</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence Interval</td>
</tr>
<tr>
<td>DPT</td>
<td>Diphtheria, Pertusis and Tetanus</td>
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<tr>
<td>EPI</td>
<td>Expanded Programme of Immunization</td>
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<tr>
<td>GACVS</td>
<td>Global Advisory Committee on Vaccine Safety</td>
</tr>
<tr>
<td>GOK</td>
<td>Government of Kenya</td>
</tr>
<tr>
<td>GSK</td>
<td>Glaxo SmithKline</td>
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<tr>
<td>KEMRI</td>
<td>Kenya Medical Research Institute</td>
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<tr>
<td>LMICs</td>
<td>Low and Middle Income Countries</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
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<tr>
<td>MOPHS</td>
<td>Ministry of Public Health and Sanitation</td>
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<tr>
<td>UK</td>
<td>United Kingdom</td>
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<tr>
<td>UN</td>
<td>United Nations</td>
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<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<tr>
<td>USA</td>
<td>United States of America</td>
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<td>WHO</td>
<td>World Health Organization</td>
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ABSTRACT

Although vaccines currently approved for routine childhood immunization are safe and effective, frequent Adverse Events Following Immunization often cause ill health and sometimes loss of public trust in immunization programs. Nurses are essential in AEFI surveillance. During the pre-licensure clinical trials, serious adverse events with low occurrence frequency go undetected due to limited number of enrolled subjects. In Nairobi County, only one Adverse Event Following Immunization has been reported since inception of Expanded Programme of Immunization. This study sought to assess nurses’ knowledge level, to establish their perception and to examine their practices towards surveillance of post-immunization adverse events within City Council of Nairobi Health Centers. A cross-sectional hospital-based survey study, using proportionate random sample from all the health facilities, involving nurses (n=274) working at city council of Nairobi health centers was done. Data was collected using self administered questionnaire. Data analysis was performed using SPSS version 20 (SPSS Inc, USA). Chi-square test was used to establish comparisons between categorical variables. Associations between knowledge, perception and practice levels were analyzed using correlation. Binary logistic regression was computed appropriately. 29.2% of the respondents had good knowledge on AEFI surveillance, while 32.1% of the respondents had good practice towards AEFI surveillance. 45.3% of the respondents had good perception towards AEFI surveillance. Respondents aged more than 49 years (43.3%, P=0.010) and those with at least 30 years of experience in nursing (41.3%, P=0.019) had good knowledge on AEFI surveillance. Respondents having Bachelors nursing degree (83.7%, P<0.0001) and those trained in AEFI surveillance (44.4%, P<0.0001) had good knowledge on AEFI surveillance. In addition, respondents having Bachelors nursing degree (88.6%, P<0.0001) and those with previous AEFI training (61.6%, P<0.0001) had good perception on AEFI surveillance. Respondents with Bachelors degree in nursing (85.7%, P<0.0001) and those trained in AEFI (51.2%, P<0.0001) had good practices on AEFI surveillance. In addition, respondents trained in AEFI (51.2%, P<0.0001) had good practices. Respondents trained in nursing at Bachelors degree level were 13.9 times more likely to have good knowledge (OR, 13.85; 95% CI, 4.39-46.66; P<0.0001), whereas those with previous AEFI training were 4.4 times more likely (OR, 4.38; 95% CI, 2.35-8.17; P<0.0001) to possess good knowledge on AEFI surveillance. Respondents having Bachelors degree nursing and those with training in AEFI were 8.9 (OR, 8.87; 95% CI, 2.82-27.69; P<0.0001) times and 3.7(OR, 2.18; 95% CI, 2.18-6.36; P<0.0001) times, respectively more likely to have good perception towards AEFI surveillance. Furthermore, those trained in AEFI were 5.7 (OR, 5.67; 95% CI, 3.68-10.43; P<0.0001) times more likely to have good practice on AEFI surveillance. Therefore, findings of this study demonstrated low knowledge, poor perception and poor practice level towards AEFI surveillance among nurses working at City Council of Nairobi Health Centers. This study illustrated knowledge and perceptions influence practice towards AEFI surveillance. Thus, information generated from this study might be valuable in informing policy review on immunization programs at the city council of Nairobi health Centers and enhance AEFI surveillance and consolidate the gains made in immunization coverage.
CHAPTER I: INTRODUCTION

1.1 Background

Immunization of infants and young children against serious infectious diseases is the most successful and cost-effective intervention in preventative health care (Cunha et al., 2013; Waldman et al., 2010). Vaccines have enhanced control of epidemics and eradication of infectious diseases significantly reducing morbidity and mortality globally (Buttery et al., 2012). However, vaccination occasionally leads to deleterious effects including adverse reactions (WHO, 2013). These adverse reactions are referred to as Adverse Events Following Immunization (AEFI). An Adverse Event Following Immunization is defined as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine (WHO, 2013). The commonly encountered adverse events that follow vaccination include pain at the injection site, swelling, and redness at the site of injection. Others are fever, rash, excessive crying, convulsions, anaphylaxis, encephalitis, drowsiness or irritability (WHO, 2010). Although studies in China have studied the frequency of adverse events and classified them as 1) very common (>10%); 2) common (1–10%); 3) uncommon (0.1–1%); 4) rare (0.01–0.1%), and 5) very rare (<0.01%) (Verma et al., 2011; Nokleby et al., 2006), no studies in Kenya have attempted to identify and classify AEFI.

The key elements of an effective surveillance system include rapid notification and effective evaluation of basic information; rapid and effective response, ensuring appropriate outcome of action and focused responsibility to avoid duplication of efforts (Verma et al., 2011). According to Verma et al., (2011), an AEFI surveillance system should include two key
components: at the site of the adverse event and front line health worker, the initial report is generated, either verbally or by using adverse events reporting form. Serious adverse events should be reported to the next line within six hours. Secondly, at the peripheral district level, adverse events reports should be reviewed as they come in and analyzed monthly. Feedback should be provided to the health workers involved in immunization.

Globally, a range of AEFI surveillance systems have been put in place (Netterlid et al., 2009). For instance, the Global Advisory Committee on Vaccine Safety (GACVS) was established in 1999 to advise WHO on vaccine related safety issues and enable WHO to respond promptly, efficiently and with scientific rigor to issues of vaccine safety with potential global importance (Folb et al., 2004). Many countries have established national monitoring system to carry out surveillance of adverse events following immunization. According to Awaidy et al., (2010), fifty three percent of all WHO member countries reported having a national AEFI monitoring system. The United States established Vaccine Adverse Event Reporting System (VAERS) whereas Canada has the Canadian Adverse Event Following Immunization System (CAEFISS) established in 2005. In Africa, few countries have put in place AEFI surveillance systems. Ghana has made strides towards training its nurses on AEFI surveillance with significant results in AEFI reporting and investigation (Dodoo et al., 2006).

In Kenya, a passive surveillance of adverse events following immunization is carried out. Nurses at immunization centers have the responsibility of identifying and reporting adverse events to the district, provincial or national level. These reports are then investigated with assistance from the Division of Vaccines and Immunization at the national level. Nurses are
directly involved in AEFI detection, investigation, reporting and management. Therefore, this study focused on examining the knowledge, perception and current practices of nurses towards AEFI surveillance.

1.2 Problem statement

Even though vaccines produced and regulated in keeping with WHO standards are safe, no vaccine is without risk of potential adverse reaction. In addition to the vaccines themselves, the process of immunization is a potential source of adverse events (WHO, 2012). When an adverse event following immunization (AEFI) raises concerns among the public to the extent that they refuse further immunizations for their children, the children are more likely to get a vaccine preventable disease and suffer the consequences (MOH, Ethiopia, 2011). Poor AEFI surveillance impacts negatively on immunization coverage. For instance, the hypothetical association between Measles-Mumps-Rubella (MMR) vaccines with autism in the UK led to a drop in MMR coverage from ninety two percent in 1995-1996 to eighty percent in 2003-2004 (Burgess et al., 2006). In Africa, poliomyelitis vaccine was suspended in Nigeria for one year following quality and safety issues alleged by religious leaders. This led to massive rebound of polio cases (Clements et al., 2006).

Vaccine safety surveillance and follow up are, therefore, central to address both actual and perceived AEFI related issues. However, such surveillance and follow up infrastructure lags behind vaccine development in industrialized countries and is absent in most developing countries (Cunha et al., 2013). Although the Kenya Expanded Programme of Immunization (KEPI) was established in 1980, only three AEFI reports have been submitted to the Division
of Vaccines and Immunization (DVI, 2013) to-date. The latest AEFI report was documented in August 2011. An infant death was suspected to be related to Synflorix (a 10–valent pneumococcal conjugate vaccine) vaccine administered to a fourteen week infant at Gertrude’s Children hospital. It was unknown whether such numerous AEFI reported in other countries also happened in City Council of Nairobi Health Centers, Kenya. These low AEFI reporting rates could be attributed to the fear that reports might be used against the nurses themselves. According to WHO (2011), most countries detect serious AEFI with deaths and hospitalizations. In Ghana, for instance, hundreds of AEFI reports are detected, investigated and reported on a yearly basis (Dodoo et al., 2006). Bangladesh on the other hand reports over 2000 AEFI cases per year (WHO, 2011). In Australia, ninety three percent of the nurses had reported seeing or being involved in care of children with AEFI. All the Australian nurses were aware of the reporting procedure with at least Sixty six percent of them having reported AEFI (Parella et al., 2013). In the United States, 37% of the health care providers had identified at least one AEFI with seventeen percent indicating to have reported the AEFI (McNeil et al., 2013). On the contrary, fewer published studies have been done in Kenya to investigate surveillance of AEFI by nurses. Owino et al., (2009) cited post-immunization adverse events following immunization as one of the factors influencing immunization coverage in Mathare slums, Nairobi. It was unknown whether nurses in Kenya were knowledgeable and trained in AEFI surveillance. Their perception and practices towards AEFI surveillance also remained largely unknown. This study sought to fill this knowledge gap.
1.3 Justification of the study

To reduce the occurrence of vaccine adverse events and maintain public confidence in vaccines, it is important to improve understanding of vaccine safety and thereby foster the development and use of safer vaccines. One of the best ways to enhance our understanding of vaccine safety is to improve surveillance of vaccine adverse events (Cunha et al., 2013; WHO, 2009; Elaine et al., 2008). During pre-licensure testing, detection of uncommon adverse events with delayed onset is not highly sensitive. Post-licensure or post-marketing surveillance, the continuous monitoring of vaccine safety in the general population after licensure, is needed to identify and evaluate such adverse events (Elaine et al., 2008). With the recent introduction of newly developed vaccines in sub-Saharan Africa (e.g. Pneumococcal conjugate and rotavirus vaccines), and the extensive use of established vaccines in preventable mass vaccination campaigns (e.g. measles), there is an increased need for effective surveillance of serious adverse events following immunization (Breugelmans and Gessner, 2010). According to Gahunia et al., (2013) and Verma et al., (2011), surveillance of adverse events following immunization is an important process for maintaining vaccine safety. Efforts need to be made to increase understanding by health practitioners about how vaccine safety issues are investigated and about what constitutes evidence for causal relationships (Halsey, 2002). In addition, efforts to monitor closely vaccines for safety before and after licensure must continue and expand as needed to ensure that the vaccines used to protect against disease are as safe as possible. Monitoring and evaluation of vaccine safety is therefore an integral part of the EPI (Hu et al., 2013). However, nurses’ knowledge, perception of and practices regarding surveillance of adverse events following immunization (AEFI) is understudied (McNeil et al., 2013) with few studies conducted elsewhere and
published to-date (Meranus et al., 2012). Nurses have essential and pivotal role to play in gaining and maintaining public confidence in the safety of vaccines through operational AEFI surveillance (Gahunia et al., 2013; Netterlid et al., 2009). These roles include providing evidence-based information on the benefits and risks of vaccines; identifying and reporting adverse events following immunization (Gahunia et al., 2013).

The City Council of Nairobi has jurisdiction over most Health Centers in Nairobi which offer large quantities of routine vaccines in the national immunization programme. The large number of vaccine doses administered increases the likelihood of vaccine recipients experiencing diverse adverse events after immunization. It was not known whether nurses in Nairobi, Kenya, understood vaccine safety and its potential impact on vaccine coverage. This study therefore sought to generate credible information that would fill this knowledge gap. Furthermore, knowledge gained from this study may help improve monitoring of the vaccine safety and the vaccination process.

1.4 Research questions

1. What is the knowledge level of nurses working at the City Council of Nairobi Health Centers towards AEFI surveillance?

2. What are the nurses’ perceptions towards AEFI surveillance within Health Centers in Nairobi County?

3. What is the nurses’ practice towards surveillance of Adverse Events Following Childhood immunization within Health Centers in Nairobi County?
4. What is the relationship between nurses’ socio-demographic factors and surveillance of Adverse Events Following childhood Immunization within Health Centers in Nairobi County?

1.5 Null Hypotheses

1. Ho. Nurses working at the City Council of Nairobi Health Centers have poor knowledge on AEFI surveillance.

2. Ho. Nurses working at City Council of Nairobi Health Centers have poor perception towards AEFI surveillance.

3. Ho. Nurses working in Nairobi City Council Health Centers have poor practices towards surveillance of adverse events following childhood immunization.

4. Ho. Nurses’ socio-demographic factors do not determine the relationship between nurses’ characteristics and surveillance of Adverse Events Following childhood Immunization within City Council of Nairobi Health Centers.

1.6 Research objectives

1.6.1 General objective

To determine the knowledge, perception and practice of nurses towards surveillance of Adverse Events Following childhood Immunization within City Council of Nairobi Health Centers.
1.6.2 Specific objectives

1. To assess the knowledge level of nurses working at the City Council of Nairobi Health Centers on AEFI surveillance.

2. To establish the nurses’ perception towards AEFI surveillance within City Council of Nairobi Health Centers.

3. To examine the nurses’ practice towards surveillance of Adverse Events Following childhood Immunization within Health Centers in Nairobi County.

4. To determine the relationship between nurses’ socio-demographic characteristics and surveillance of Adverse Events Following childhood Immunization within Health Centers in Nairobi County.

1.7 Significance and anticipated output

The findings of this study will be significant in deducing current knowledge, perception and practices of nurses towards AEFI surveillance. This information may be used by different immunization programme stakeholders (e.g. donors, vaccinators, immunization coordinators and managers) to develop and redesign policies, guidelines and standard operating procedures on AEFI surveillance. In addition, determining the current knowledge, perception and practice of nurses on surveillance of AEFI might enable immunization managers strengthen the immunization programmes, build public confidence and increase immunization coverage. Strategies to inform and ensure nurses carrying out vaccination are knowledgeable will be put in place based on practical evidence-based information generated. This may ultimately help in consolidating the gains made in the immunization programme. Eventually, the levels of vaccine coverage and control of vaccine preventable diseases may increase.
1.8 Conceptual framework

Independent Variables

- Age
- **Years of experience**: 0-9 yrs; 10-19 yrs; 20-29 yrs; >30 yrs
- Gender: Male, Female
- Education: Degree, Diploma, Certificate
- Employer: GoK, CCN, NGO
- AEFI Training: Yes, No

Dependent Variables

- Knowledge on AEFI
- Perception towards AEFI
- Practices on AEFI

Constructed using information from: WHO, 2013; Zanoni et al., 2009; Zuber, 2009; Bedford et al., 2005; Miller et al., 2002

Figure 1.1: Conceptual framework
CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

The development of vaccines is one of the most important public health achievements. However, as the incidence of vaccine preventable diseases decreases, the general public has become increasingly concerned about vaccine safety. An Adverse Event Following Immunization is defined as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine (WHO, 2013). The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease (WHO, 2013; Verma, 2011). The major goal of immunization safety surveillance is early detection and appropriate quick response to adverse events in order to lessen the negative impact on the health of individuals and on the immunization programme. Furthermore, AEFI surveillance is a key indicator of programme quality and enhances programme credibility by providing actual country data on vaccine risks (MOPHS Kenya, 2011). Reported adverse events can either be true adverse events i.e. really a result of the vaccine or immunization process, or coincidental events that are not due to the vaccine or immunization process but are temporarily associated with immunization.

2.2 Classification of adverse events following immunization

Adverse events following immunization are classified into four categories based on causality as follows (WHO, 2013).
2.2.1 Vaccine product-related reaction

These adverse events are caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product. In addition to the specific infectious disease-related antigens, other components of the vaccine may theoretically cause adverse effects, including adjuvants added to enhance vaccine potency (Vogel & Hems, 2004), preservatives included in inactivated vaccine formulations that are presented in multi-dose vials (Finn & Egan, 2004) or components incompletely removed during the purification stages after the antigen production process. Vaccine quality defect-related reaction are caused or precipitated by a vaccine due to one or more quality defects of the vaccine product, including the administration device, as provided by the manufacturer (WHO, 2013).

2.2.2 Immunization error-related reaction

These adverse events are caused by an error in vaccine preparation, handling or administration (WHO, 2013). According to MOPHS, Kenya (2011), most of the reported AEFI are related to programme errors than any other cause. The most common immunization-error related reactions include: too much vaccine given in one dose; inadequate shaking of vaccines before use; immunization injected in wrong place or plane; failure to use re-use prevention needle and syringe; used needles handled carelessly; vaccine reconstituted with the wrong diluents; wrong amount of diluents used; vaccine prepared incorrectly; vaccine or diluents contaminated due to poor technique; vaccine stored incorrectly; using vaccines beyond their discard point; and contraindications ignored e.g. when a child who has had severe reaction after a previous dose of DPT is immunized with the same vaccine. According to Verma et al., (2011), adverse events caused by an error or accident in vaccination program
relating to manufacturing, handling, cold chain maintenance, vaccination schedule or administration are considered arising from immunization errors. They should generally be preventable and detract from the overall benefit of the vaccination program. A program error may lead to a cluster of events associated with immunization. The most common immunization error related reaction is an infection (including blood-borne virus) as a result of non-sterile injection. The infection can manifest as a local reaction (e.g. suppuration, abscess), systemic effect (e.g. sepsis or toxic shock syndrome), or blood-borne virus infection (e.g. HIV, hepatitis B or hepatitis C) (Verma, 2011). According to Petousis-Harris (2008), most vaccines are given by injection and despite the ambiguity of this method of administration, there is little consensus about administration techniques. In addition, these inconsistencies may cause anxiety if parents observe differences in practice (Halsey, 2002). Possible consequences of these inconsistencies in injection technique include pain, fainting and tissue injury. These occur as a result of the injection rather than the vaccine.

2.2.3 Coincidental events

These adverse events are caused by something other than the vaccine product, immunization error or immunization anxiety. Coincidental events are unrelated to immunizations or vaccines in any way except for the time that they occur (WHO, 2013).

2.2.4 Immunization anxiety-related reaction

Some adverse events arise from anxiety about or pain from the injection itself rather than the vaccine (WHO, 2013).
2.3 Detection and Reporting of AEFI

Detection of adverse events following immunization should involve several groups of people: i) health workers (mostly nurses) providing immunization services; ii) health workers providing clinical treatment of AEFI in health centers, hospitals or special treatment facilities; iii) parents who report AEFI affecting their children; researchers conducting clinical studies or field trials (WHO, 2012).

Reportable Adverse Events Following Immunization (AEFI) include all injection site abscesses, anaphylaxis, convulsions, Toxic shock syndrome, acute flaccid paralysis, all cases of BCG lymphadenitis and all deaths occurring within a month after immunization and are thought by health workers to be related to immunization (WHO, 2013; WHO, 2010). Furthermore, all cases requiring hospitalization that occur within one month of immunization and severe local reactions (e.g. swelling beyond the nearest joint; pain, redness and swelling of more than three days duration) should be reported especially if they occur in clusters. This can be an early indication of immunization-error related reactions or problems with specific vaccine lots (MOPHS-Kenya, 2011). AEFI reports should be submitted to supervisors at district level and also the pharmaceutical companies responsible for the specific vaccine (WHO, 2010).

According to Guo et al., (2013), in their review of the reporting rates of adverse events following immunization, noted that due to differing reporting rates between different countries and regions, differences in surveillance practices required further exploration.
2.4 Investigation of AEFI

Immunization programs face the responsibility of continuously monitoring the occurrence of AEFI in order to identify possible deviation from the known safety profile of the vaccine used (Ball, 2004). It further enables rapid detection and rigorous investigation of potential new adverse events so that appropriate corrective action can be implemented as necessary (Ball, 2004). According to Zuber (2009), regardless of their source, signals require investigation, initially for validation and subsequently for hypothesis testing to assess the likelihood that there is a causal link between vaccine administration and the adverse events. The case investigation is commenced by the primary health care provider (nurse) or the supervisor who detects the AEFI. The aim is to find the cause of AEFI or cluster of AEFI and correct it. Investigations need to be started within 24 hours. If no further investigations are to be done, the nurse will fill the case investigation form and forward it to the supervisor. Serious AEFI or clusters should be investigated by specially trained health care providers from the district or central level (WHO, 2010). Data collected during investigation include patient demographics, immunization history, lab results and data on vaccine administered and programme related data. Programme related data include vaccine storage, reconstitution and handling practices (WHO, 2010).

2.5 Knowledge of nurses on AEFI surveillance

According to WHO (2010), immunization safety surveillance needs to include training that will enable appropriate response at all levels in the system. The person responsible for immunization safety surveillance needs to keep informed about the latest developments in safety, monitoring and current concerns regarding immunization. One also needs to know any
allegations, about vaccine safety, that might be circulating (WHO, 2010). According to Bedford et al., (2005), health professionals engaged in vaccination need to be trained so that they are able to provide accurate and up to date information about the diseases and vaccines to their patients, ensure that their practice is safe and effective and also give a high standard of care. Besides, they should be able to demonstrate competence, current evidence-based knowledge and understanding of Adverse Events Following Immunization. In trying to establish the familiarity of health workers in the United States of America with VAERS, Hutchinson et al., (2007) found that such familiarity was dependent on training in AEFI. Training was associated with higher reporting rates amongst health workers, especially nurses.

Although training is essential for health care providers, only a minority of countries have established systems to inform and update personnel on AEFI surveillance. Thirty five percent of 26 studied European Union countries had developed a training program or manual for nurses on prevention, identification and treatment of AEFI (Zanoni et al., 2009). This is an indication that health staff training programmes are practically neglected not only in European Union countries but also in most parts of the world. Zanoni et al., (2009) further asserts that taking into consideration the current knowledge of vaccines and the rate of growing information and disinformation in the immunization field, continuous education and updating of personnel is recommended. The ministry of Health in Ethiopia (2011) emphasizes that solving operational problems through training will deal with lack of skills and knowledge and with poor attitude. In a survey done in Sri-Lanka on AEFI surveillance, the knowledge of nurses on AEFI was examined. The findings indicated that the knowledge levels varied on
different aspects of AEFI surveillance under investigation (MOH, Sri-Lanka, 2012). For instance, nurses were more knowledgeable (92%) on how to use adrenaline in managing anaphylaxis despite their low ability to detect an anaphylaxis (52%) and to identify contraindication for immunization (42%). This survey did not establish essential knowledge indicators on AEFI surveillance such as nurses’ knowledge on causes, classification and management of AEFI.

Human capacity development in low medium countries is an important priority in order to address multiple vaccine safety issues that can affect the performance of immunization programs. Improved capacity in terms of know-how should also be accompanied by the development of an infrastructure that supports ongoing monitoring of the safe use of vaccines (Zuber, 2009). A cross-sectional descriptive study carried out by LI et al., (2012) to assess staff knowledge, attitude and practices on AEFI at Shadong province in China recruited a sample size of one hundred and ninety staff. The findings indicated that most staff had general but not detailed knowledge about AEFI. However, this study focused on all cadres of clinical staff working in the province instead of focusing on nurses only, who are the main cadre that administers vaccines, diagnose, manage and report AEFI. A different cross-sectional study on nurses’ knowledge, attitude and practices towards reporting of adverse drug reactions was done in United Emirates (Lisha et al., 2012). Results indicated higher knowledge levels among nurses with degree education and those less than thirty years of age. This study however, had only two categories of nurses’ years of experience; those with less than seven years and those with more than seven years. This categorization is misleading since most nurses work for many years. A separate study in the United States of America on vaccine
safety among 293 recruited Health Care Providers indicated that sixty percent of them knew how to report a suspected AEFI using the reporting system (Meranus et al., 2012). Like most of the studies reviewed above, this study did not examine key knowledge aspects of AEFI surveillance such as knowledge on how to diagnose AEFI, how to investigate and manage AEFI cases.

2.6 Perception of nurses towards AEFI surveillance

The influence of nurses’ perception towards AEFI surveillance is not well studied and documented. According to MOH, Ethiopia (2011), lack of motivation and staff anxiety about implications of programmatic errors negatively contribute to AEFI surveillance, especially on reporting of adverse events. According to Dodoo et al., (2006), motivation combined with training and supervision, contributed significantly to improving AEFI reporting rates in Ghana. 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 a hindrance to their participation in AEFI surveillance (Parella et al., 2013). Kenya Medical Research Institute (KEMRI) and the Center for Disease Control (CDC) in 2011 commenced a study to evaluate the risk for AEFIs following administration of pneumococcal conjugate vaccine 10. Among AEFI detected included injection site abscesses and swelling. This study, however, did not examine the nurses’ knowledge and perceptions towards AEFI surveillance following administration of pneumococcal conjugate vaccine 10. Owino et al., (2009) identified fear of adverse effects following immunization (AEFIs) to be playing a role in contributing to the high vaccination drop-out rates. However, this study did not interrogate other perceptual aspects among nurses that can hinder AEFI surveillance such as not being
sure of one’s responsibilities aside from being unsure about the diagnosis. Other aspects that were not studied included perception of nurses on the aim of AEFI surveillance, one’s interest in AEFI surveillance, effects of poor AEFI monitoring and fear for personal consequences among reporting nurses. Furthermore, the effect of nurses’ socio-demographic characteristics, such as qualification and years of experience, on perception towards AEFI surveillance had not been established.

### 2.7 Practice of nurses regarding AEFI surveillance

AEFI reporting rates vary worldwide. In Sri-Lanka, both over-reporting and under-reporting were observed during the 2012 survey on AEFI surveillance. Despite the good reporting rates, investigation of AEFI was still a major problem with most of the cases not being investigated (MOH Sri-Lanka, 2012). Reporting AEFI cases must always be encouraged. WHO (2011) asserts that as the AEFI cases are not reported for a long period of time, health workers lose interest or forget about appropriate procedures to manage AEFI cases. According to the Ethiopian guidelines on AEFI surveillance (2011), improving logistics is an appropriate response if programme errors can be traced to the lack of supplies or equipment or to a failure in the cold chain. Managers should investigate suspected breaks in the cold chain to find the cause and take appropriate measures.

Availability of AEFI reporting forms at the immunization centers significantly influences the reporting. In their ten month prospective study in Ghana, Dodoo et al., (2006) noted a six hundred percent increase in AEFI reporting rate following training, monitory visits and provision of AEFI reporting forms. However, this study failed to indicate the influence of
other logistical factors such as availability of AEFI investigation forms, surveillance guideline protocols, specimen transport logistics and perception towards AEFI investigation.

A study on knowledge, attitude and beliefs towards reporting of AEFI amongst military health system was conducted in United States of America (Hutchinson et al., 2007). A convenience sample of 547 respondents was studied. Fifty four percent of the respondents reported familiarity with the Vaccine Adverse Events Reporting System. The proportion of respondents who acknowledged reporting an AEFI was seventy one percent. Ninety percent of the respondents identified three factors deemed to facilitate AEFI reporting: training in identifying AEFI, information on when to report AEFI and information on how to report to the surveillance system. However, this study did not solely examine the practice of nurses, who are the key stakeholders in AEFI surveillance. In addition, this study failed to investigate on nurse’s knowledge and perception towards investigation and management of AEFI. A study on knowledge, attitude and beliefs of health care providers towards AEFI was conducted in Atlanta (USA) using Dilman design methodology (McNeil et al., 2013). It involved one thousand, six hundred and seven participants. Results revealed that forty percent of health care providers diagnosed at least one AEFI. The proportion of healthcare providers who had ever reported an AEFI to Vaccine Adverse Events Reporting System (VAERS) amounted to nineteen percent. This study was however different from that in the United States of America which recruited a sample size of five hundred and forty seven health care providers in assessing their knowledge, attitude and beliefs on reporting AEFI (Hutchinson et al., 2007). Seventy one percent of the respondents in this study acknowledged reporting in some fashion the last identified AEFI. More than half of the respondents were familiar with
the VAERS. In addition, ninety percent of the respondents identified three factors deemed to facilitate AEFI reporting: having training in identifying AEFI; information on when to report AEFI and information on how to report to the surveillance system. These two studies, however, failed to focus on the magnitude of nurses’ knowledge and practices towards AEFI surveillance.

A different study was conducted in the United States of America on health professionals’ AEFI reporting (Meranus et al., 2012). This study included nurses, physicians and pharmacists. It examined the frequency of reporting AEFI to the Vaccine Adverse Event Reporting System (VAERS), beliefs and awareness of AEFI reporting, barriers to reporting and strategies to increase reporting rates. Although nineteen percent of the respondents had ever diagnosed a patient with AEFI, 71% of the total respondents had never come across a patient with reportable AEFI. Eighteen percent of the nurses indicated that they did not know whose responsibility it was to report AEFI. In addition, lack of clear definition of reportable AEFI was cited by 61% of the respondents as a barrier to AEFI reporting. This study demonstrated significant differences in having ever reported an AEFI by health professional type. Other barriers to reporting cited by respondents included time pressures in completing a report (60%) and problems accessing reporting system or lack of access to computer when needed (28%). In a study carried out in Australia amongst health care workers, ninety three percent reported seeing or being involved in the care of children with a suspected AEFI (Parella et al., 2013). Majority of these Australian nurses (65.5%) had reported such AEFI although some respondents were not sure of reportable post immunization adverse events (Parella et al., 2013).
2.8 Summary of Literature Review

Although nurses offering immunization services ought to demonstrate competence in AEFI surveillance, it was unknown whether nurses offering immunization services in Kenya had adequate knowledge in AEFI surveillance. More importantly, the scope of understanding on various aspects of AEFI surveillance was unexplored in previous studies. One of the important determinants of this is training in AEFI. It was not known whether nurses offering immunization services in Nairobi County had undergone AEFI training.

Similar gaps in literature were evident on the scope on nurses’ believes towards AEFI surveillance. Most reviewed studies did not examine nurses’ views on various aspects of AEFI surveillance. For instance, nurses’ opinions on aspects such as fear of personal consequences upon reporting and reporting processes being long and tedious. Others included lack of interest and insight on the importance of AEFI surveillance. In as much as some previous studies cited various factors influencing practices towards AEFI surveillance, they were inadequate in exploring the scope of aspects that constitute practices towards AEFI surveillance. Availability of equipments and materials used in AEFI surveillance also constitute AEFI surveillance practices.
CHAPTER 3: METHODOLOGY

3.1 Location of the study

The study was conducted at City Council of Nairobi Health Centers where immunization services were offered. The seventy eight health facilities are spread across the nine districts within Nairobi County (Kamukunj, Starehe, Kasarani, Westlands, Dagoreti, Langata, Embakasi, Njiru and Makadara). There are 50 health centers, 11 dispensaries and 17 clinics. Vaccines offered are those in the routine national immunization programme: BCG, Pentavalent, Pneumococcal conjugate, Polio, and Rotavirus vaccines. In addition, various travel vaccines, anti-rabies and Tetanus Toxoid vaccines are also offered. The vaccines are sourced from the government of Kenya. Nurses administer vaccines and are supposed to detect, report and manage any vaccine adverse reactions following immunization. The City Council of Nairobi health facilities were selected since they serve a larger population of babies and subsequently offer more vaccine doses compared to private facilities. The wide range of antigens administered poses an increased probability of post-immunization adverse events occurring.

3.2 Study design

A cross-sectional hospital-based study design was used. This design enabled description of the AEFI surveillance amongst health care providers, at one point in time, without influencing their behavior in any way.
3.3 Study variables

3.3.1 Dependent variables

These were nurse’s knowledge, perceptions and practices towards surveillance of adverse events following childhood immunization.

3.3.2 Independent variables

These include nurses’ socio-demographic factors: gender, age, employer, years of experience, training in AEFI, and qualification.

3.4 Target population

The study population comprised nurses working at City Council of Nairobi health facilities (N=960). The nurses provide healthcare services including vaccination. Only nurses working in Maternal and child health units were targeted.

3.5 Selection criteria

3.5.1 Inclusion criteria

1. Nurses working within Maternal and Child Health (MCH) units in City Council of Nairobi health centers.
2. Nurses In-charge or Matrons working at City Council of Nairobi health centers.
3. Having worked at the above facilities for at least three consecutive months since one would have gone through the induction process and was able to function optimally.
3.5.2 Exclusion criteria

1. Nurses working at City Council of Nairobi dispensaries and clinics.
2. Eligible nurses working at City Council of Nairobi who were on leave at the time of the study
3. Those who declined to take part in the study.

3.6 Sampling technique

The study was conducted in all the health centers within the nine districts. The number of respondents included in this study was distributed proportionally in each of the health centers within the nine districts in the Nairobi County. Eligible members from each facility were randomly selected until the required sample size was obtained for that facility (Table 3.1).

Table 3.1: Sampling technique used to derive desired sample size

<table>
<thead>
<tr>
<th>District</th>
<th>Total number of health centers</th>
<th>Total number of nurses</th>
<th>Probability proportionate sample</th>
<th>Sample size (Nurses)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kamukunji</td>
<td>3</td>
<td>58</td>
<td>16.6</td>
<td>17</td>
</tr>
<tr>
<td>Starehe</td>
<td>4</td>
<td>79</td>
<td>22.6</td>
<td>23</td>
</tr>
<tr>
<td>Kasarani</td>
<td>8</td>
<td>151</td>
<td>43.1</td>
<td>43</td>
</tr>
<tr>
<td>Westlands</td>
<td>7</td>
<td>136</td>
<td>38.8</td>
<td>39</td>
</tr>
<tr>
<td>Dagoreti</td>
<td>4</td>
<td>78</td>
<td>22.3</td>
<td>22</td>
</tr>
<tr>
<td>Langata</td>
<td>9</td>
<td>172</td>
<td>49.1</td>
<td>49</td>
</tr>
<tr>
<td>Embakasi</td>
<td>6</td>
<td>113</td>
<td>32.3</td>
<td>32</td>
</tr>
<tr>
<td>Njiru</td>
<td>4</td>
<td>77</td>
<td>22.0</td>
<td>22</td>
</tr>
<tr>
<td>Makadara</td>
<td>5</td>
<td>96</td>
<td>27.4</td>
<td>27</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>50</strong></td>
<td><strong>960</strong></td>
<td></td>
<td><strong>274</strong></td>
</tr>
</tbody>
</table>
3.7 Sample size determination

Sample size was determined according to Fisher’s formula (1998) as follows:

\[ n = \frac{Z^2pq}{d^2} \]

where:

- \( n \) = desired sample size,
- \( Z \) = standard normal deviate (set at 1.96 which corresponds to the 95% confidence level)
- \( P \) = proportion in the target population estimated to have knowledge on Adverse Events Following Immunization. Since there is no reasonable estimate, 50% (0.5) will be used
- \( q \) = 1.0 - \( p \)
- \( d \) = degree of accuracy desired (0.05 level)

\( p = 0.5 \)
\( q = 1.0 - p \)
\( d = 0.05 \)
\( n = 384 \)

Since the estimated total population (N) is less than 10,000 (960), then the desired sample size, \( n_f = \frac{n}{1+ \left( \frac{n}{N} \right)} \) where N is the total population of providers i.e., 960

\( n_f = 274 \) nurses.

3.8 Construction of research instruments

Self-administered questionnaires (Appendix II) were used to collect data from respondents (nurses). Questions on AEFI surveillance were used to assess nurses’ knowledge, perception and practices towards AEFI. Specific questions addressed causes of AEFI, types of AEFI, detection of AEFI, reporting, investigating and managing of AEFI.
3.9 Pretest
The study tool was pretested at one of the City Council of Nairobi health facilities (Embakasi health center) since the facility had unique characteristics similar to those used in full scale study. However, this health centre was excluded from the full scale study. Nurses were identified and 27 questionnaires pre-tested. This helped establish the effectiveness of the data collection tool. Corrections and amendments on the questions found ineffective were then be made before conducting full scale study.

3.10 Data management and analysis
Data collected was entered, coded and cleaned in the excel software, Microsoft office Excel 2010 and then exported into IBM® SPSS version 20.0 (SPSS Inc, USA). All statistical analyses were performed using the statistical package for social sciences (SPSS) software. Descriptive statistics was computed to generate frequencies, mean, median and standard deviation. Knowledge levels were determined using a series of 14 questions on AEFI, on its causes, management of AEFI, diagnosis of AEFI, prevention and reporting of AEFI. Perception towards AEFI surveillance was assessed using 14 statements on a 5-point Likert scale (Agree, Neutral and Disagree). On the other hand, practice of respondents on AEFI surveillance was examined using 10 questions.

Chi-square test was used to establish comparisons between categorical variables. Pearson’s correlation test was used to measure the strength and direction of relationships between the dependent variables (knowledge, perception and practices) and the independent variables to establish the predictions of knowledge, perceptions and practices. Binary logistic regression
tests were used to determine associations between the dependent variables (knowledge, perception and practice) and independent variables (education, years of experience, AEFI training and AEFI training modality used). Age, gender and type of employer of the respondents were confounders and were therefore controlled for in the regression. More females opt for nursing career than males (Lisha et al., 2012). All variables significant in the Chi-square with $P<0.05$ were included in the regression models. All tests were two-tailed with a $P$-value of less than 0.05 being considered significant for all statistical analyses. Data was summarized using frequency tables and pie-charts.

### 3.11 Ethical considerations

This research thesis was approved by Kenyatta University Graduate School. Ethical approval was obtained from the Kenyatta University Ethics Review Committee (KU-ERC), Ref No. KU/R/COMM/51/204. Thereafter, research permit was obtained from the National Council for Science and Technology (Ref No.: NCST/RCD/12A/013/43) prior to the study. Administrative authorization to carry out the study was sought from the city council of Nairobi administration (Chief Administrative officer and County Medical officer of health). District medical officers of health or District public health nurses were furnished with approval letter from the City Council of Nairobi administration prior to the study. Informed consent was obtained from study participants prior to their enrollment into the study. Participation in the study was voluntary. Confidentiality of the information from the study participants was maintained throughout the study. In addition, codes were used to maintain anonymity of all participants and keep their information confidential.
CHAPTER 4: RESULTS

4.1 Socio-demographic characteristics of study respondents

A total of two hundred and seventy four nurses were recruited in the study with a response rate of one hundred percent. The socio-demographic characteristics of the study participants are summarized in Table 4.1. The median (range) age of the nurses was 40 (23-58) years. Age distribution of the respondents was as follows: 20-29 years, 57 (20.8%); 30 – 39 years, 67 (24.5%); 40 – 49 years, 83 (30.3%); 50 – 59 years, 67 (24.5%). Many of the respondents were female 229 (83.6%). Most of the respondents 156 (56.9%) had a diploma level of training in nursing. Those with Certificate level were 83 (30.3%), and those with BSC in nursing were 35 (12.8%). 143 (52.2%) of the respondents were employed by the City Council Nairobi. This was closely followed by Government of Kenya, GoK, having employed 124 (45.3%). The rest 7 (2.6%) were employed on capacity building basis by Non-governmental organizations, NGO, University of Maryland and KEMRI/WALTER Reed project.

The mean number of years of experience by the respondents was 15.6 (±9.2) years. Most of respondents had between 20-29 years of experience, 107 (39.1%). Those with 10-19 years were 42 (15.3%); 30-39 years were 75 (27.4%) and those with below 10 years experience were 50 (18.2%). Many of the respondents [149, (54.4%)] had no prior training in AEFI. For those with previous AEFI training, 47 (37.6%) of them received both on job training and seminar or workshop. 12 (9.6%) of the respondents had learned of AEFI at college/University. Those who had been trained through seminar or workshop alone were 16 (12.8%). 21 (16.8%) respondents had learnt of AEFI through on-job training.
Table 4.1. Characteristics of study respondents

<table>
<thead>
<tr>
<th>Variable</th>
<th>n=274</th>
<th>Frequencies (n)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (Years)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>40.3 (±9.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 -29</td>
<td>57</td>
<td>20.8</td>
<td></td>
</tr>
<tr>
<td>30 -39</td>
<td>67</td>
<td>24.5</td>
<td></td>
</tr>
<tr>
<td>40 -49</td>
<td>83</td>
<td>30.3</td>
<td></td>
</tr>
<tr>
<td>50 – 59</td>
<td>67</td>
<td>24.5</td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>45</td>
<td>16.4</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>229</td>
<td>83.6</td>
<td></td>
</tr>
<tr>
<td><strong>Level of Education</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BSc Nursing Degree</td>
<td>35</td>
<td>12.8</td>
<td></td>
</tr>
<tr>
<td>Diploma Nursing</td>
<td>156</td>
<td>56.9</td>
<td></td>
</tr>
<tr>
<td>Certificate</td>
<td>83</td>
<td>30.3</td>
<td></td>
</tr>
<tr>
<td><strong>Employer</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>City council of Nairobi</td>
<td>143</td>
<td>52.2</td>
<td></td>
</tr>
<tr>
<td>GoK</td>
<td>124</td>
<td>45.3</td>
<td></td>
</tr>
<tr>
<td>NGO</td>
<td>7</td>
<td>2.6</td>
<td></td>
</tr>
<tr>
<td><strong>Years of experience</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>15.6 (±9.2)</td>
<td>years</td>
<td></td>
</tr>
<tr>
<td>0 -9</td>
<td>50</td>
<td>18.2</td>
<td></td>
</tr>
<tr>
<td>10 – 19</td>
<td>42</td>
<td>15.3</td>
<td></td>
</tr>
<tr>
<td>20 – 29</td>
<td>107</td>
<td>39.1</td>
<td></td>
</tr>
<tr>
<td>30 – 39</td>
<td>75</td>
<td>27.4</td>
<td></td>
</tr>
<tr>
<td><strong>Training in AEFI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>125</td>
<td>45.6</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>149</td>
<td>54.4</td>
<td></td>
</tr>
<tr>
<td><strong>Type of Training</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>On job training</td>
<td>21</td>
<td>16.8</td>
<td></td>
</tr>
<tr>
<td>On job training &amp; Seminar/Workshop</td>
<td>47</td>
<td>37.6</td>
<td></td>
</tr>
<tr>
<td>Seminar/Workshop</td>
<td>16</td>
<td>12.8</td>
<td></td>
</tr>
<tr>
<td>College / University class</td>
<td>12</td>
<td>9.6</td>
<td></td>
</tr>
<tr>
<td>College / University class and Seminar/Workshop</td>
<td>29</td>
<td>23.2</td>
<td></td>
</tr>
</tbody>
</table>

Data are represented as the frequency and proportions (%) of respondents. n = 274. BSc, Bachelor of Science; GoK, Government of Kenya; NGO, Non-Governmental Organization; SD, Standard deviation
4.2 Knowledge levels of respondents towards AEFI surveillance

Most respondents (62.4%) did not know the causes of AEFI. Only up to 10% of the respondents knew AEFI cases which should be reported. Less than 40% of the respondents knew how to manage a child with AEFI. Few respondents (36.4%) knew AEFI investigation examines operational aspects of the programme. Similarly, 36.5% of the respondents knew vaccine IM injections technique as shown in Table 4.2 below.

Table 4.2. Knowledge levels of respondents on AEFI surveillance

<table>
<thead>
<tr>
<th>Aspects of knowledge on AEFI surveillance</th>
<th>n=274</th>
<th>Freq (n)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>AEFI as a medical condition is not limited to vaccination only</td>
<td></td>
<td>73</td>
<td>27.8</td>
</tr>
<tr>
<td>AEFI can be caused by reconstituted vaccine stored longer than recommended period; vaccine reaction; inappropriate route or injection technique; vaccines stored beyond expiry date or contaminated vaccine diluents.</td>
<td></td>
<td>102</td>
<td>37.6</td>
</tr>
<tr>
<td>Skin at injection site should be stretched during IM injections</td>
<td></td>
<td>99</td>
<td>36.5</td>
</tr>
<tr>
<td>Paracetamol and Ibuprufen is not used routinely to prevent immunization fever</td>
<td></td>
<td>136</td>
<td>49.6</td>
</tr>
<tr>
<td>DHMT is responsible for supervising facilities on AEFI</td>
<td></td>
<td>129</td>
<td>37.8</td>
</tr>
<tr>
<td>Adrenaline should not be administered subcutaneously during anaphylaxis</td>
<td></td>
<td>61</td>
<td>22.5</td>
</tr>
<tr>
<td>During anaphylaxis patient’s legs are raised above trunk and given oxygen</td>
<td></td>
<td>108</td>
<td>39.4</td>
</tr>
<tr>
<td>DPHN receives AEFI reports from facility nurse</td>
<td></td>
<td>163</td>
<td>60.1</td>
</tr>
<tr>
<td>AEFI investigation examines operational aspects of the programme</td>
<td></td>
<td>99</td>
<td>36.4</td>
</tr>
<tr>
<td>Investigation of an AEFI should be commenced within 24 hrs</td>
<td></td>
<td>69</td>
<td>25.5</td>
</tr>
<tr>
<td>All injection site abscesses should be reported</td>
<td></td>
<td>28</td>
<td>10.3</td>
</tr>
<tr>
<td>Injection site swelling and redness should be reported</td>
<td></td>
<td>22</td>
<td>8.3</td>
</tr>
<tr>
<td>Treatment of a coincidental illness falsely attributed as a vaccine reaction should not be delayed until investigations are confirmed</td>
<td></td>
<td>69</td>
<td>25.7</td>
</tr>
<tr>
<td>Immunization surveillance aims at early detection and response to AEFI</td>
<td></td>
<td>102</td>
<td>37.2</td>
</tr>
</tbody>
</table>

Total sample size, n = 274. Data are presented as number (No.) of subjects and proportions (%). IM, intramuscular injection. AEFI, Adverse Events Following Immunization. DHMT, District Health Management Team. DPHN, District Public Health Nurse.
Each correct response was assigned a score of 1.0 and each incorrect response was allocated a score of 0.0, then the overall score was calculated for all the 14 knowledge responses for each individual. The maximum expected score was 14. The overall mean knowledge score on causes of AEFI, identification, investigating, managing and reporting of AEFI was 7.62 (±2.2) out of a maximum 14. Since data was normally distributed, the mean was used as a cut-off for those with good knowledge (values ≥ mean) and those with poor knowledge (values < mean). Thus, 194 (70.8%) of the respondents had poor knowledge whereas 80 (29.2%) had good knowledge as shown in figure 4.2 below.

![Pie chart showing 70.8% with poor knowledge and 29.2% with good knowledge.]

**Figure 4.1. Overall proportion of nurses with Good and Poor knowledge on AEFI surveillance**

### 4.3 Perception of respondents towards AEFI surveillance

Forty nine point three percent of the respondents believed reporting an AEFI could not lead to personal consequences. 41.3% of the nurses felt that reporting an AEFI would make them feel guilty about having caused harm and be responsible for the event. Some respondents (25.2%)
felt that the process of reporting an AEFI is long and tedious. However, 97.8% of them acknowledged that nurses play a vital role in diagnosing, reporting, investigating and managing AEFI. A majority of the respondents (97.4%) were ready to learn more about AEFI surveillance whereas less than 10% were not interested in investigating an AEFI as shown in table 4.3.

**Table 4.3. Perception of respondents towards AEFI surveillance**

<table>
<thead>
<tr>
<th>Perceptions on AEFI Surveillance</th>
<th>n=274</th>
<th>Agree N (%)</th>
<th>Neutral N (%)</th>
<th>Disagree N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Believe reporting an AEFI cannot lead to personal consequences</td>
<td></td>
<td>115 (41.9)</td>
<td>24 (8.8)</td>
<td>135 (49.3)</td>
</tr>
<tr>
<td>Believe reporting an AEFI, such as injection abscess, will make him/her feel guilty about having caused harm and be responsible for the event.</td>
<td></td>
<td>116 (42.3)</td>
<td>32 (11.7)</td>
<td>126 (46.0)</td>
</tr>
<tr>
<td>Believe nurses are reluctant to report an AEFI when they are not confident about the diagnosis</td>
<td></td>
<td>173 (63.1)</td>
<td>40 (14.6)</td>
<td>61 (22.3)</td>
</tr>
<tr>
<td>Believe that investigation of AEFI should be done by clinical officers or doctors and not nurses</td>
<td></td>
<td>102 (37.2)</td>
<td>63 (23.0)</td>
<td>109 (39.8)</td>
</tr>
<tr>
<td>Believe that poor monitoring of adverse events can cause reduction of immunization coverage</td>
<td></td>
<td>110 (65.1)</td>
<td>24 (9.2)</td>
<td>140 (25.7)</td>
</tr>
<tr>
<td>Believe that the process of reporting an AEFI is long and tedious</td>
<td></td>
<td>69 (25.2)</td>
<td>56 (20.4)</td>
<td>149 (54.4)</td>
</tr>
<tr>
<td>Believe reporting and investigating AEFI is none of his/her business</td>
<td></td>
<td>58 (21.2)</td>
<td>11 (4.0)</td>
<td>205 (74.8)</td>
</tr>
<tr>
<td>Believe that even if adverse events are reported to DVI/DPHN, no feedback is sent back</td>
<td></td>
<td>32 (11.7)</td>
<td>76 (27.7)</td>
<td>166 (60.6)</td>
</tr>
<tr>
<td>Believe that enhancing surveillance of AEFI can help build public trust in immunisation programme</td>
<td></td>
<td>200 (73.0)</td>
<td>14 (5.1)</td>
<td>60 (21.9)</td>
</tr>
<tr>
<td>Believe that nurses play a vital role in diagnosing, reporting, investigating and managing AEFI</td>
<td></td>
<td>212 (77.4)</td>
<td>0 (0.0)</td>
<td>62 (22.6)</td>
</tr>
<tr>
<td>Desires to learn more about how to diagnose, report, investigate and manage AEFI</td>
<td></td>
<td>257 (93.8)</td>
<td>0 (0.0)</td>
<td>17 (6.2)</td>
</tr>
<tr>
<td>Believe every nurse working at a health facility should know AEFI</td>
<td></td>
<td>207 (75.5)</td>
<td>6 (2.2)</td>
<td>61 (22.3)</td>
</tr>
<tr>
<td>Believe he/she is always busy and there is no time to report AEFI</td>
<td></td>
<td>136 (49.7)</td>
<td>10 (3.6)</td>
<td>128 (46.7)</td>
</tr>
<tr>
<td>Believe he/she is not interested in investigating or reporting AEFI to DPHN/DVI</td>
<td></td>
<td>27 (9.9)</td>
<td>22 (8.0)</td>
<td>225 (82.1)</td>
</tr>
</tbody>
</table>

Total sample size, n = 274. Data are presented as number (N) of subjects and proportions (%). AEFI, Adverse Events Following Immunization. DVI, Division of Vaccines and Immunization. DPHN, District Public Health Nurse.
Perception towards AEFI surveillance was assessed using 14 statements on a 5-point Likert scale (Agree, Neutral and Disagree). Positive statements were scored as: +5 (Agree); +3 (Neutral); +1 (Disagree). Negative statements were scored as: +1 (Agree); +3 (Neutral); +5 (Disagree). The cumulative mean score on perception was calculated and those who scored above the mean were deemed to have good perception whereas those with scores below the mean were deemed to have poor perception towards AEFI surveillance. The highest possible score was 70 and the lowest possible score was 14. Since data was normally distributed (Skewness=0.62; Kurtosis=2.48), the mean (±standard deviation) of the cumulative likert scores on the perception scores for beliefs on detection, reporting, investigating and managing AEFI was 59.12 (±9.36). Since data was normally distributed (Skewness=0.24; Kurtosis=0.48), the mean was therefore as the cut-off for good (values≥mean) and poor (values<mean) perception towards AEFI surveillance. Thus, 124 (45.3%) of the respondents had good perception and 150 (54.7%) of the respondents had poor perception as shown in figure 4.3 below.

Figure 4.2. Overall proportion of respondents with good and poor perception towards AEFI surveillance
4.4 Practice of respondents towards AEFI surveillance

The practice of respondents towards AEFI surveillance was assessed using questions addressing their activities towards diagnosing, reporting, investigating and managing AEFI. Majority of the respondents (56.5%) informed the caretakers about possible vaccine adverse reactions and how to manage them. Eighty three point nine percent of the respondents rule out contraindications to vaccine(s) in a child prior to administration. Fewer respondents (44.5%) had ever seen an AEFI reporting and investigation form. Barely fourteen point two respondents had an anaphylactic pack within their immunization rooms as shown in table 4.4 below.

<table>
<thead>
<tr>
<th>Practice aspects</th>
<th>n=274</th>
<th>Yes, n (%)</th>
<th>No, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rules out contraindications to vaccine(s) in a child prior to administration</td>
<td>230 (83.9)</td>
<td>44 (16.1)</td>
<td></td>
</tr>
<tr>
<td>Have an anaphylactic pack with adrenaline in the immunization room</td>
<td>39 (14.2)</td>
<td>224 (85.8)</td>
<td></td>
</tr>
<tr>
<td>Informs the caretaker of possible vaccine adverse reactions and how to treat them</td>
<td>155 (56.5)</td>
<td>119 (43.5)</td>
<td></td>
</tr>
<tr>
<td>Has ever come across a child with injection site swelling, redness, abscesses, BCG lymphadenitis, convulsion, shock, AFP or fever &gt;40°C and diagnosed as an AEFI</td>
<td>88 (32.1)</td>
<td>186 (67.9)</td>
<td></td>
</tr>
<tr>
<td>Reported detected adverse event following immunization</td>
<td>2 (2.3)</td>
<td>86 (97.7)</td>
<td></td>
</tr>
<tr>
<td>Participated in AEFI investigation for detected AEFI cases</td>
<td>2 (2.3)</td>
<td>86 (97.7)</td>
<td></td>
</tr>
<tr>
<td>Records vaccine batch number and expiry date during vaccination</td>
<td>209 (76.3)</td>
<td>65 (23.7)</td>
<td></td>
</tr>
<tr>
<td>Have ever seen an AEFI reporting and investigation form</td>
<td>122 (44.5)</td>
<td>152 (55.5)</td>
<td></td>
</tr>
<tr>
<td>Have AEFI reference guidelines materials at work station</td>
<td>106 (38.7)</td>
<td>168 (61.3)</td>
<td></td>
</tr>
<tr>
<td>Have relevant AEFI specimen transportation containers</td>
<td>69 (25.2)</td>
<td>205 (74.8)</td>
<td></td>
</tr>
</tbody>
</table>

Total sample size, n = 274. Data are presented as number (No.) of subjects and proportions (%). AEFI, Adverse Event Following Immunization; BCG, Bacillus Calmette–Guérin.
The practice towards AEFI surveillance was assessed using 10 questions. The mean (±standard deviation) of the cumulative practice scores on practice towards detection, reporting, investigating and managing AEFI was 28.45±5.65 out of a maximum of 50. Since data was normally distributed (Skewness=0.13; Kurtosis=0.41), the mean was therefore used as the cut-off for good (values≥mean) and poor (values<mean) practice towards AEFI surveillance. Thus, 88 (32.1%) of the respondents had good practice and 186 (67.9%) of the respondents had poor practice towards AEFI as shown in figure 4.4 below.

**Figure 4.3: Overall proportion of respondents with good and poor practice towards AEFI surveillance**
4.5 Association between the respondents’ knowledge and their characteristics

The association between nurses’ knowledge levels and their characteristics is summarized in Table 4.5. Older respondents (more than 49 years) were significantly more likely to have good knowledge on AEFI $\chi^2$ 8.73 (3, N=274), $P=0.01$. The proportion of respondents with good knowledge was higher among female respondents (32.3%) compared to male respondents (13.3%) with good knowledge, $\chi^2$ 6.55 (1, N=274), $P=0.006$. Respondents with BSc Nursing degree (85.7%) education were more likely to have good AEFI knowledge compared to those having a diploma (16.0%) or certificate (30.1%) education, $\chi^2$ 67.21 (2, N=274), $P=<0.0001$. Knowledge of the respondents on AEFI surveillance increased with their years of experience. Majority of respondents with at least 30 years of experience (41.3%) had good knowledge on AEFI surveillance. This is slightly higher compared to those with 20 – 29 years of experience (24.3%), 10 – 19 (33.3%) and less than 10 years of experience (18.0%), $\chi^2$ 9.97 (3, N=274), $P=0.019$. In addition, respondents with previous training in AEFI surveillance were more likely to have good knowledge on AEFI surveillance, $\chi^2$ 23.37 (1, N=274), $P<0.0001$. 
Table 4.5 Association between knowledge and Respondents’ characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Good knowledge n (%)</th>
<th>Poor knowledge n (%)</th>
<th>df</th>
<th>$\chi^2$</th>
<th>$P$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (Years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 -29</td>
<td>15 (26.3)</td>
<td>42 (73.7)</td>
<td>3</td>
<td>8.73</td>
<td>0.010</td>
</tr>
<tr>
<td>30 -39</td>
<td>17 (25.4)</td>
<td>50 (74.6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40 -49</td>
<td>19 (22.9)</td>
<td>64 (77.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥50</td>
<td>29 (43.3)</td>
<td>38 (56.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>74 (32.3)</td>
<td>155 (67.7)</td>
<td>1</td>
<td>6.55</td>
<td>0.006</td>
</tr>
<tr>
<td>Male</td>
<td>6 (13.3)</td>
<td>39 (86.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Degree</td>
<td>30 (85.7)</td>
<td>5 (14.3)</td>
<td>2</td>
<td>67.21</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Diploma</td>
<td>25 (16.0)</td>
<td>131 (84.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Certificate</td>
<td>25 (30.1)</td>
<td>58 (69.9)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Employer</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>City council of Nairobi</td>
<td>27 (18.9)</td>
<td>116 (81.1)</td>
<td>1</td>
<td>15.418</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>GoK</td>
<td>50 (40.3)</td>
<td>74 (59.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NGO*</td>
<td>3 (42.9)</td>
<td>4 (57.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Years of experience</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 -9</td>
<td>9 (18.0)</td>
<td>41 (82.0)</td>
<td>3</td>
<td>9.965</td>
<td>0.019</td>
</tr>
<tr>
<td>10 – 19</td>
<td>14 (33.3)</td>
<td>28 (66.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 – 29</td>
<td>26 (24.3)</td>
<td>81 (75.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥30</td>
<td>31 (41.3)</td>
<td>44 (58.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Training</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>55 (44.0)</td>
<td>70 (56.0)</td>
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<td>24.366</td>
<td>&lt;0.0001</td>
</tr>
<tr>
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<td>25 (16.8)</td>
<td>124 (83.2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Type of Training</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>On job training &amp; Seminar</td>
<td>28 (59.6)</td>
<td>19 (40.4)</td>
<td>3</td>
<td>9.955</td>
<td>0.041</td>
</tr>
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<td>8 (50.0)</td>
<td>8 (50.0)</td>
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<td></td>
</tr>
<tr>
<td>On job training</td>
<td>5 (23.8)</td>
<td>16 (76.2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>College / University class</td>
<td>10 (34.5)</td>
<td>19 (65.5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>College / University class*</td>
<td>4 (33.3)</td>
<td>8 (66.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data shown are frequencies (n) of subjects and proportions (%). df, degrees of freedom $\chi^2$, Pearson’s chi-square. Variables with an * had cell counts less than 5 and were not included in the analysis. Values in bold are significant $P$-values.
4.6 Association between Perception and Respondents’ characteristics

The association between perception and socio-demographic characteristics of respondents is summarized in Table 4.6. Respondents with a previous training in AEFI were more likely to have good perception towards AEFI surveillance (61.6%) compared to those who did not, $\chi^2$ 24.79 (1, N=274), $P<0.0001$. Majority of the respondents with diploma education had poor perception towards AEFI surveillance (63.5%). This is significantly higher compared to those with certificate (56.6%) education, $\chi^2$ 31.40, (2, N=274), $P<0.0001$. 
Table 4.6. Association between Perception of nurses and their characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Good perception n (%)</th>
<th>Poor perception n (%)</th>
<th>df</th>
<th>$\chi^2$</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (Years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 - 29</td>
<td>22 (38.6)</td>
<td>35 (61.4)</td>
<td>3</td>
<td>3.293</td>
<td>0.349</td>
</tr>
<tr>
<td>30 - 39</td>
<td>27 (40.3)</td>
<td>40 (59.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40 - 49</td>
<td>43 (51.8)</td>
<td>40 (48.2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥50</td>
<td>32 (47.8)</td>
<td>35 (52.2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>108 (47.2)</td>
<td>121 (52.8)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>16 (35.6)</td>
<td>29 (64.4)</td>
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<td>2.045</td>
<td>0.153</td>
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<td><strong>Qualification</strong></td>
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<tr>
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<td>4 (11.4)</td>
<td>2</td>
<td>31.410</td>
<td>&lt;0.0001</td>
</tr>
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<td>99 (63.5)</td>
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<td></td>
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</tr>
<tr>
<td>Certificate</td>
<td>36 (43.4)</td>
<td>47 (56.6)</td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Employer</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>City council of Nairobi</td>
<td>52 (36.4)</td>
<td>91 (63.6)</td>
<td>1</td>
<td>9.983</td>
<td>0.007</td>
</tr>
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<td>GoK</td>
<td>69 (55.6)</td>
<td>55 (44.4)</td>
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</tr>
<tr>
<td>NGO*</td>
<td>3 (42.9)</td>
<td>4 (57.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Years of experience</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 - 9</td>
<td>20 (40.0)</td>
<td>30 (60.0)</td>
<td>3</td>
<td>6.530</td>
<td>0.088</td>
</tr>
<tr>
<td>10 – 19</td>
<td>19 (45.2)</td>
<td>23 (54.8)</td>
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</tr>
<tr>
<td>20 – 29</td>
<td>42 (39.3)</td>
<td>65 (60.7)</td>
<td></td>
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</tr>
<tr>
<td>≥30</td>
<td>43 (57.3)</td>
<td>32 (42.7)</td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Training</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>77 (66.6)</td>
<td>48 (38.4)</td>
<td>1</td>
<td>24.786</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>No</td>
<td>47 (31.5)</td>
<td>102 (68.5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Type of Training</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>On job training &amp; Seminar/Workshop</td>
<td>30 (63.8)</td>
<td>17 (36.2)</td>
<td>3</td>
<td>2.099</td>
<td>0.718</td>
</tr>
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<td>Seminar/Workshop</td>
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<td>8 (50.0)</td>
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<td></td>
</tr>
<tr>
<td>On job training</td>
<td>12 (57.1)</td>
<td>9 (42.9)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>College / University class &amp; Seminar/Workshop</td>
<td>18 (62.1)</td>
<td>11 (37.9)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>College / University class*</td>
<td>9 (75.0)</td>
<td>3 (25.0)</td>
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</tr>
</tbody>
</table>

Data shown are frequencies (n) of subjects and proportions (%). df, degrees of freedom. $\chi^2$, Pearson’s chi-square. Variables with an * had cell counts less than 5 and were not included in the analysis. Values in bold are significant P-values.
4.7 Association between practice and Respondents’ characteristics

The association between practice and socio-demographic characteristics of respondents is summarized in Table 4.7. Respondents with BSc nursing degree education (85.7%) were more likely to have good practice towards AEFI surveillance compared to those with diploma (16.7%) and certificate (38.6%) education, $\chi^2$ 64.78 ($2, N=274$), $P<0.0001$. Good practice of nurses towards AEFI surveillance also increased with their years of experience i.e. respondents with at least 30 years of experience (45.3%) had good AEFI surveillance practice. This is slightly higher compared to those with an experience of 20 -29 years (26.2%), 10 – 19 years (33.3%) and less than 10 years (24.0%) of experience, $\chi^2$ 9.29 ($3, N=274$), $P<0.026$). Respondents with previous training in AEFI (51.2%) were more likely to have good AEFI surveillance practice compared to those who had never undergone AEFI training (16.1%), $\chi^2$ 38.40, ($1, N=274$), $P<0.0001$. 
## Table 4.7: Association between practice and Respondents’ characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Good practice (%)</th>
<th>Poor practice n (%)</th>
<th>df</th>
<th>$\chi^2$</th>
<th>$P$-value</th>
</tr>
</thead>
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<td>Age (Years)</td>
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<td>20 -29</td>
<td>20 (35.1)</td>
<td>37 (64.9)</td>
<td>3</td>
<td>2.843</td>
<td>0.416</td>
</tr>
<tr>
<td>30 -39</td>
<td>18 (26.9)</td>
<td>49 (73.1)</td>
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</tr>
<tr>
<td>40 -49</td>
<td>24 (28.9)</td>
<td>59 (71.1)</td>
<td>3</td>
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<td></td>
</tr>
<tr>
<td>≥50</td>
<td>26 (38.8)</td>
<td>41 (61.2)</td>
<td>3</td>
<td></td>
<td></td>
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<tr>
<td>Gender</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Female</td>
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<td>150 (65.5)</td>
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<td>3.626</td>
<td>0.057</td>
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<tr>
<td>Male</td>
<td>9 (20.0)</td>
<td>36 (80.0)</td>
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<tr>
<td>Education</td>
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<td></td>
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<td></td>
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</tr>
<tr>
<td>Degree</td>
<td>30 (85.7)</td>
<td>5 (14.3)</td>
<td>2</td>
<td>64.775</td>
<td>&lt;0.0001</td>
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<tr>
<td>Diploma</td>
<td>26 (16.7)</td>
<td>130 (83.3)</td>
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<tr>
<td>Certificate</td>
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<td>51 (61.4)</td>
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<tr>
<td>Employer</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>City council of Nairobi</td>
<td>32 (22.4)</td>
<td>111 (77.6)</td>
<td>1</td>
<td>13.013</td>
<td>0.001</td>
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<tr>
<td>GoK</td>
<td>53 (42.7)</td>
<td>71 (57.3)</td>
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<td>NGO*</td>
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<td>28 (66.7)</td>
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<td>28 (26.2)</td>
<td>79 (73.8)</td>
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<tr>
<td>≥30</td>
<td>34 (45.3)</td>
<td>41 (54.7)</td>
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<td>Training</td>
<td></td>
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</tr>
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<td>Yes</td>
<td>64 (51.2)</td>
<td>61 (48.8)</td>
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<td>38.396</td>
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</tr>
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<td>24 (16.1)</td>
<td>125 (83.9)</td>
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<tr>
<td>Type of Training</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>On job training &amp; Seminar/Workshop</td>
<td>29 (61.7)</td>
<td>18 (38.3)</td>
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<td>0.441</td>
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<td>Seminar/Workshop</td>
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<td>8 (50.0)</td>
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<tr>
<td>On job training</td>
<td>10 (47.6)</td>
<td>11 (52.4)</td>
<td>4</td>
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<tr>
<td>College / University class &amp; Seminar/Workshop</td>
<td>12 (41.4)</td>
<td>17 (58.6)</td>
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</tr>
<tr>
<td>College / University class</td>
<td>5 (41.7)</td>
<td>7 (58.3)</td>
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</tbody>
</table>

Data shown are frequencies (n) of subjects and proportions (%). df, degrees of freedom. $\chi^2$, Pearson’s chi-square. Variables with an * had cell counts less than 5 and were not included in the analysis. Values in bold are significant $P$-values.
4.8 Correlation between Respondents’ knowledge, perception and practices on AEFI surveillance

Since cumulative indices for knowledge (Skewness = 0.92; Kurtosis = -1.16); perception (Skewness = 0.19; Kurtosis = -1.98); and practice (Skewness = 0.77; Kurtosis = -1.42) were normally distributed, the parametric Pearson’s correlation test was used to determine the strength and direction of association. Proportion of respondents with good knowledge versus poor knowledge on AEFI surveillance was positively correlated with their AEFI surveillance practices (r=0.847; P<0.0001). Proportions of good versus poor knowledge was positively correlated with perception (r= 0.588; P<0.0001). Proportions of good versus poor perception was also positively correlated with practice (r= 0.581; P<0.0001). These significant variables were then entered into binary logistic regression analysis based on the magnitude of the chi-square values. This yielded figures shown in table 4.8.

4.9 Logistic regression analysis of knowledge levels and perception towards AEFI surveillance with Respondents’ characteristics

Variables that were significant in the Chi-square test analyses were entered into binary logistic regression controlling for age, gender and employer of the respondents. Respondents with a BSC nursing degree education were 13.9 times more likely to be knowledgeable on AEFI surveillance [OR, 13.85, 95% CI, 4.39 – 43.66; P<0.0001]. Respondents with AEFI training were 4.4 times more likely to be knowledgeable [OR, 4.38, 95% CI, 2.35 – 8.17; P=0.002]. Respondents with previous AEFI training were 3.7 times more likely to have good perception towards AEFI surveillance [OR, 3.70, 95% CI, 2.18 – 6.36; P<0.0001]. Similarly, those with degree education were 8.9 times more likely to have good perception towards
AEFI surveillance [OR, 8.87, 95% CI, 2.82 – 27.69; P<0.0001]. Furthermore, respondents trained in AEFI surveillance were 5.7 times more likely to have good AEFI practices [OR, 5.67, 95% CI, 3.68 – 10.43; P<0.0001]. Degree education was also 9.5 times likely to increase respondents likelihood of having good AEFI surveillance practices [OR, 9.52, 95% CI, 3.14 – 28.89; P<0.0001] as shown in Table 4.8 below.
Table 4.8: Logistic regression of knowledge, perception and practice with nurses’
characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Wald</th>
<th>OR (95% CI)</th>
<th>P-value</th>
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</thead>
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<tr>
<td></td>
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<td></td>
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</tr>
<tr>
<td><strong>Good Knowledge</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Certificate</td>
<td></td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Degree</td>
<td>20.13</td>
<td>13.85 (4.39 – 43.66)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Diploma</td>
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<td>0 -9</td>
<td></td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>10 -19</td>
<td>3.08</td>
<td>2.50 (0.90 – 6.93)</td>
<td>0.079</td>
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<tr>
<td>20 - 29</td>
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<td>1.11 (0.41 – 3.00)</td>
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<tr>
<td>≥30</td>
<td>5.98</td>
<td>3.26 (1.26 – 8.41)</td>
<td>0.012</td>
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</tr>
<tr>
<td>No</td>
<td></td>
<td>Reference</td>
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<td>Yes</td>
<td>21.56</td>
<td>4.38 (2.35 – 8.17)</td>
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<td>Reference</td>
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<td>0.68 (0.13 – 3.53)</td>
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<td>and Seminar/Workshop</td>
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<tr>
<td><strong>Good Perception</strong></td>
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<td>Degree</td>
<td>13.94</td>
<td>8.87 (2.82 – 27.69)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Diploma</td>
<td>1.83</td>
<td>0.68 (0.39 – 1.19)</td>
<td>0.176</td>
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<td></td>
</tr>
<tr>
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<td></td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>23.33</td>
<td>3.70 (2.18 – 6.36)</td>
<td>&lt;0.0001</td>
</tr>
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<td><strong>Good practice</strong></td>
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<td></td>
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<tr>
<td>Education</td>
<td></td>
<td>Certificate Reference</td>
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</tr>
<tr>
<td>Degree</td>
<td>15.83</td>
<td>9.52 (3.14 – 28.89)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Diploma</td>
<td>17.45</td>
<td>0.25 (0.13 – 0.45)</td>
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<td>Reference</td>
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</tr>
<tr>
<td>10 -19</td>
<td>1.40</td>
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<td>3.09 (1.28 – 7.45)</td>
<td>0.012</td>
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</tr>
<tr>
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<td></td>
<td>Reference</td>
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</tr>
<tr>
<td>Yes</td>
<td>31.08</td>
<td>5.67 (3.68 – 10.43)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Data shown are OR, odds ratio with 95% CI, confidence intervals. Values in bold with are significant P-values. Variables controlled for were age, gender and employer of the respondents (Lisha et al., 2012).
CHAPTER 5: DISCUSSION

5.1 Introduction

Little is known about surveillance of adverse events following childhood immunization in Kenya. Only three AEFI cases have previously been reported since the inception of the Expanded Programme of Immunization in the country (DVI, 2013). Nurses are key players in the immunization programmes and their knowledge, perceptions and practices towards surveillance of AEFI influences the quality and safety of the vaccination services besides monitoring and surveillance of AEFI (Chopra et al., 2012). Despite the important role of nurses in the immunization programmes, no information exists to date regarding the contribution of nurses in monitoring and surveillance of AEFI in Nairobi County. Therefore, this study investigated the nurse’s knowledge, perception and practices towards surveillance of adverse events following childhood immunization in Nairobi County.

5.2 Knowledge of respondents on AEFI surveillance

The overall low knowledge levels on AEFI surveillance recorded by the respondents in this study indicates that nurses in Nairobi County poorly understood AEFI surveillance. The findings of this study are consistent with previous studies reporting low knowledge levels on AEFI surveillance in China (Li et al., 2012). These findings, however, differ from the high knowledge levels on AEFI surveillance recorded for nurses in USA (McNeil et al., 2013). The low overall knowledge on AEFI recorded in this study can be attributed to the consistently low knowledge responses recorded on most of the aspects of AEFI knowledge. Most respondents in this study were knowledgeable about AEFI reporting system. This finding is similar to previous studies in the USA showing that most of the nurses knew about
the AEFI reporting system (Hutchinson et al., 2007). However, other important aspects of AEFI knowledge including immunization error-related reactions that occur during vaccine storage, preparation, handling and administration were poorly understood in spite of their contribution to the occurrence of AEFI. Moreover, only a small proportion of respondents (37.6%) in this study knew the causes of AEFI. This is unacceptable since management of AEFI often relies on knowing the cause(s) for appropriate treatment. For instance, only a small portion of the respondents knew of the utility of adrenaline in the emergency management of anaphylaxis following vaccination. This observation contrasts with previous studies in Sri-Lanka indicating that a majority of respondents in an AEFI survey knew of adrenaline usage in the management of vaccine-induced anaphylactic reactions (MOH, Sri-Lanka, 2012). Taken together, these findings on the generally low AEFI surveillance knowledge among nurses working at Nairobi County Council health Centers suggest a need for refresher training on the various aspects of AEFI surveillance.

The finding indicating that knowledge level of the respondents in this study on AEFI increased with their age and experience can be explained in part by accumulation of knowledge with increasing years of working experience. These findings are similar to previous studies in India showing that increasing age and work-related experience determine knowledge levels on drug-associated adverse events (Chopra et al., 2012). However, this result are different from previous studies in Arab Emirates illustrating that age does not influence knowledge levels on vaccine-induced adverse reactions (Lisha et al., 2012). Consistent with the fact that most nurses in the Kenyan health supply chain are of the female gender (MOH, 2011), female nurses were more knowledgeable than their male counterparts.
This observation is probably linked to the dominance of female students in nursing schools and the nursing profession (MOH, 2011).

Academic qualifications also influenced knowledge of the nurse towards AEFI surveillance with nursing degree holders being more knowledgeable than the diploma and certificate holders. This oblivious difference is mainly due to the scope of training of degree nurses with in depth understanding of the basic sciences including vaccine safety monitoring, vaccino-surveillance and adverse reactions. This premise is supported by previous studies showing that degree trained nurses were more competent and knowledgeable in clinical practice than non-degree holders in United Arab Emirates (Lisha et al., 2012). Having a past training in AEFI surveillance was found to be an essential predictor of good knowledge on AEFI surveillance. However, only less than half of the respondents in this study had a previous formal training in AEFI surveillance. The findings of this study are dissimilar to those of Parrella et al., (2013) in United States, where all nurses had received some formal training in vaccine safety and AEFI reporting. While only less than ten percent of respondents indicated having gotten AEFI training while in University or College in this study, previous studies in Australia reported low levels of vaccine safety education during medical training years (Vorsters et al., 2010; Letourneau et al., 2008). Of great significance are the observations showing that the modality of training of the nurses on AEFI seems influences AEFI knowledge. Nurses reporting both on-job training and workshop or seminar trainings had better knowledge levels than those trained through other modalities. This difference could be explained in part by the incentives given during seminars and the subsequent practices and follow-up on the implementation of AEFI surveillance. This study confirms the need to
provide adequate education to nurses, both pre-and in-service. One of the best ways to do this would be to incorporate AEFI Surveillance into continuing medical education programs.

5.3 Perception of respondents towards AEFI surveillance

The overall proportion of respondents with good perception towards AEFI surveillance in this study constitutes a fair proportion of nurses willing to carry out AEFI surveillance. However, more efforts ought to be done to increase the proportion of those with positive perception towards AEFI surveillance. Majority of the respondents believed that enhancing AEFI surveillance could help build public trust in immunization programme. In addition, a high proportion of respondents were ready to learn more about AEFI surveillance. This will be essential to immunization managers, especially at health center level, to seize this positivity and offer AEFI training opportunities. Although three quarters of the respondents believed that nurses play a vital role in AEFI surveillance, more than one third thought it was the responsibility of doctors and clinical officers. This finding is similar to a study in United States where eighteen percent of the respondents believed that reporting of AEFI was not part of their clinical responsibilities (Meranus et al., 2012). This scenario emphasizes the need for immunization managers to sensitize nurses on their role in AEFI surveillance. There is need to reassure nurses that reporting is not meant to be punitive or to apportion blame since half of the respondents believed that reporting AEFI could lead to personal consequences. Although fewer respondents believed that they did not have sufficient time to participate in AEFI surveillance, there is need to allocate time for specific nurses to report suspected AEFI cases. This is consistent with findings in United States of America where more than half of
the respondents thought inadequate time contributed to lack of AEFI reporting (Meranus et al., 2012).

The findings of this study showed a strong association \((P<0.0001)\) between perception and previous training in AEFI surveillance. Since training is important in nurturing good perception, the ultimate outcome will be larger proportion of nurses who are knowledgeable with positive perception towards AEFI surveillance. Since having a degree in nursing education increased the likelihood of having good perception towards AEFI surveillance, there is need to encourage more nurses with diploma and certificate nursing education to advance their studies. However, this finding differs from studies in United Emirates where no difference on perception was observed between nurses with degree and diploma nursing education (Lisha et al., 2012). Although the type of AEFI training had no influence on one’s AEFI perception, having a previous AEFI training increased one’s likelihood of having good perception towards AEFI surveillance. This indicates the need to train more nurses so that they can have a good perception towards AEFI surveillance. On the contrary, no association was established between perception and other socio-demographic variables under study. There was no association between age and perception towards AEFI. In a study done in United Emirates, association between age and perception was noted yet similar perception levels were observed across the different ages of the nurses (Lisha et al., 2012).

5.4 The Practice of respondents on AEFI surveillance

The overall proportion of respondents with good practice towards AEFI surveillance was very low. However, a higher proportion (44.5%) of respondents in this study had ever seen an
AEFI reporting and investigation form compared to studies in Nigeria where only twenty six percent of the nurses had ever seen the reporting form (Fadare et al., 2011). On the contrary, a much higher proportion of respondents in the United States had ever seen an AEFI reporting and investigation form (McNeil et al., 2013). This variation could be explained in part by the national sensitization that had occurred in the US a year prior to the study. An AEFI reporting and investigation form is a basic tool in carrying out surveillance of AEFI and should always be readily available and accessible to all nurses working in outpatient departments. This huge difference between Africa and the US just emphasizes how Kenya and Africa as a whole still lags behind in AEFI surveillance. Fewer nurses (2.3%) in this study had ever diagnosed a patient with suspected AEFI. This is consistent with findings in the United States where almost a similar proportion of nurses had ever diagnosed a patient with suspected AEFI (Meranus et al., 2012).

Post-immunization anaphylactic reactions, though uncommon, are likely to occur during administration of most vaccines. However, a very small proportion of the respondents (14.2%) in this study had an anaphylactic pack in their immunization rooms. This indicates how nurses in this study are unprepared to handle anaphylactic reactions in case they arise. Lack of accessibility to AEFI reference guideline materials was cited by ninety five percent of respondents in a study in the United States (Meranus et al., 2012). In this study, only a small proportion of respondents (38.7%) had AEFI guidelines at their work stations. Despite the availability of reporting and investigation forms to some respondents in this study, only a very small proportion of nurses had ever reported an AEFI. For instance, whereas 32.1% of the respondents had experienced reportable AEFI, only 2.3% of them had reported such events.
This is consistent with findings of previous studies indicating low reporting rates among nurses in the United Emirates (Lisha et al., 2012) and United States (Meranus et al., 2012). The proportion of the respondents (2.3%) who had ever participated in AEFI investigation was quite low despite the WHO (2013) recommendation that health care providers who detect an AEFI ought to report and commence investigations immediately. Compared to the study in United States, where at least twenty percent of the respondents had ever reported an AEFI to Vaccine adverse Events Reporting System (VEARS), most respondents in this study did not know reportable post-immunization adverse events (McNeil et al., 2013). For instance, two point three percent of the respondents had ever reported AEFI despite experiencing such reportable events. On the contrary, AEFI reporting rates amongst nurses were much higher in studies conducted in Australia (Parella et al., 2013) and in the United States America (Hutchinson et al., 2007). This difference in reporting rates could be explained in part by the fact that all nurses interviewed were familiar with both paper and telephone reporting procedures in the two countries (Parella et al., 2013; Hutchinson et al., 2007). The findings of this study on recognition of reportable AEFI were similar to those in Australia (Parella et al., 2013) where there was conflicting views as to which events ought to be reported. A similar study on vaccine adverse events by Meranus et al., (2012) cited unclear definitions of reportable AEFI as a barrier to reporting suspected AEFI. The Australian qualitative study had, however, used six nurses as key informants and this could compromise the generalisability of this study finding.

The qualification of the respondents influenced their practice levels on AEFI surveillance. Nurses with degree nursing education displayed good practices towards AEFI surveillance
compared to nurses with diploma or certificate. As the years of experience increase, one tends to have good AEFI practice. Therefore, there is need to encourage mentorship by nurses with many years of experience. Despite the similar years of experience among nurses in this study and that of Parella et al., (2013), ten percent of respondents in the latter study had reported AEFI cases more than once. Nurses with previous training in AEFI were 6 times more likely to have good practices on AEFI surveillance. This confirms the finding of Dodoo et al., (2006) in Nigeria where such training yielded similar results.

5.5 Association between knowledge, perception and practices towards AEFI surveillance

This study generated association between knowledge, perception and practices towards AEFI surveillance. As the knowledge and perception of nurses on AEFI surveillance increases, their practice on AEFI surveillance increases. A similar trend was observed by Lisha et al., (2012) on reporting of adverse drug reactions. In addition, as the nurse’s perception score increases, their practice score on AEFI surveillance also increases. The low AEFI reporting rate in this study is not surprising since majority of them were not knowledgeable on which AEFI cases required reporting. This study therefore highlights the need to put in place strategies that will ensure nurses have good knowledge and good perception in order to enhance AEFI surveillance practices in Nairobi County.
6.1 Conclusions

1) Overall, majority of the respondents working at Nairobi County Health Centers had poor knowledge levels on AEFI surveillance. The lowest knowledge levels were in identifying causes of AEFI, how to report an AEFI, how to investigate and manage post-immunization anaphylaxis.

2) The overall perception level on AEFI surveillance amongst respondents working in Nairobi County Health Centers was poor. Some respondents believed they would feel guilty and feared personal consequences on reporting an AEFI. Whereas majority of the nurses acknowledged that it was their responsibility to carry out AEFI surveillance, some felt it was not their responsibility. However, majority of the respondents were ready to learn more about AEFI surveillance.

3) The practice of nurses working at City Council of Nairobi Health centers towards AEFI surveillance is poor. The lowest practice level scores were on respondents’ AEFI reporting, preparedness for possible post-vaccination reactions and participation in AEFI investigation. Majority of the respondents were not prepared to manage post-immunization anaphylactic reaction. A very small proportion of nurses had ever participated in AEFI investigation.

4) Knowledge, perception and practice of nurses working at City Council of Nairobi Health centers on AEFI surveillance is influenced positively by their educational qualification, years of experience, and having AEFI training.
6.2 Recommendations

1) Specific strategies for updating the knowledge of nurses working in Nairobi County Health Centers should be implemented by immunization managers at Nairobi County Health Centers and the Division of Vaccines and Immunization at the national Ministry of Health through incorporation of AEFI surveillance in continuing medical education programs.

2) Immunization managers at Nairobi County Health Centers and Division of Vaccines and Immunization at the national Ministry of Health should facilitate frequent immunization refresher trainings on vaccine safety among nurses.

3) Immunization managers at Nairobi County Health facilities and division of Vaccines and Immunization at the national Ministry of Health should enforce mentorship program where nurses working in Nairobi County Health Centers with many years of experience nurture young nurses on AEFI surveillance.

4) The Health Center In-charges or Matrons should encourage nurses working in Nairobi County Health Centers with certificate and diploma education to upgrade to nursing degree level.

6.3 Areas of further research

1. It will be important to conduct research into other factors that influence reporting of adverse events following immunization (such as method of reporting AEFI i.e. Paper versus online; proximity to reporting center, availability of transport, motivation and reward for reporting AEFI) to provide information necessary for planning and improving surveillance of AEFI in Kenya.
2. Future research that would inform strategies to improve AEFI surveillance should be carried out focusing on incorporating the perspectives of surveillance authorities such as Division of Vaccines and Immunization managers, District Public Health Nurse, WHO-Kenya, and District Medical Officer of Health

3. Since AEFI is an integral component of the immunization programs, it will be imperative to conduct similar studies across the country focusing at County levels to identify and develop County-specific guidelines on AEFI reporting and management systems.
REFERENCES


Division of Vaccines and Immunization, DVI (2013). Guideline on Adverse Events Following Immunization (AEFI) in Kenya


McNeil, M., Li, R., Pickering S., Real T., Smith P., Pemberton, M. (2013). Who is unlikely to report adverse events after vaccinations to the vaccine adverse event reporting system (VAERS)? Vaccine, 13(24), 2673-2679.


WHO (2013). Developing a national system for dealing with adverse events following immunization. 

WHO (2010): Surveillance of adverse events following immunization against yellow fever. 
Field guide for staff at the central, intermediate and peripheral level.

User manual for the revised WHO classification.


APPENDICES

Appendix I: Informed Consent

My name is Calistus Masika. I am a Masters student from Kenyatta University. I am conducting a study on “Nurses’ knowledge, perceptions and practices on surveillance of adverse events following childhood immunization in Nairobi County”. The information will be used by the Ministry of health to improve surveillance of adverse events in this health center as well as in other health facilities within Kenya.

Procedures to be followed
Participation in this study will require that you fill in the questions asked in the questionnaire. You will fill these questions on your own. You have the right to refuse participation in this study without any penalty. Please remember that participation in the study is voluntary. You may ask questions related to the study at any time. You may refuse to respond to any questions at any time. You may also stop being in the study at any time without any consequences now or in the future.

Discomforts and risks
Aside from time taken to fill this questionnaire (about 15 minutes), no other risks are foreseen. In case you are uncomfortable to answer some questions, you free to skip them. If this happens, you may refuse to answer these questions if you so choose.

Benefits and Reward
If you participate in this study you will help us to learn more about nurses’ knowledge, perception and practices towards monitoring of post-immunization adverse events. However, there are no monetary or financial benefits you derive from participating in this study.

Confidentiality
You are requested to fill this questionnaire in a private setting within the clinic if you so wish. Your name will not be recorded on the questionnaire. The questionnaires will be kept in a locked cabinet for safe keeping. Everything will be kept private.

Contact information
If you have any questions you may contact me on 0727642189. You can also contact my supervisors: Dr. Were on 0720326127 or Dr Harysone Atieli on 0721347437. You can also contact the Kenyatta University Ethical Review Committee Secretariat on chairman.kuerc@ku.ac.ke

Participant’s Statement
The above information regarding my participation in the study is clear to me. I have been given a chance to ask questions and my questions have been answered to my satisfaction. My participation in this study is entirely voluntary. I understand that my records will be kept private and that I can leave the study at any time. I understand that I will not be penalized or discriminated even if I declined to participate in this study.
Name of Participant…………………………………………………………
Signature or Thumbprint          Date

**Investigator’s statement**

I, the undersigned, have explained to the volunteer in a language s/he understands the procedures to be followed in the study and the risks and benefits involved.

Name of Investigator…………………………………………

_________________          ___________________

Investigator signature          Date
Appendix II: Questionnaire

Section 1: Demographic information

1. Age .................................................................................. (years)
2. Gender [ ] Male [ ] Female
3. Name of your facility ..............................................................
4. Duration of service at the facility in question 3 above ............... (Years)
5. Length of service as a nurse since qualification ......................... (Years)
6. Level of qualification
   [ ] Certificate [ ] Diploma [ ] Higher Diploma
   [ ] Degree [ ] Others {Specify} ............................................
7. Your employer
   [ ] City council of Nairobi [ ] GoK
   [ ] Others {Specify} ............................................................
8. Have you ever received any training on AEFI? .........................
9. If Yes in question 8 above, what type of training was it?
   a) On job training & Seminar/Workshop
   b) Seminar/Workshop
   c) On the job training
   d) College / University class & Seminar/Workshop
   e) College/University class

SECTION 2: Knowledge  {Please fill in appropriately}

1. What is an Adverse event Following immunization (AEFI)
2. What causes an AEFI?
3. What skin injection technique do you use when administering vaccines by IM injections?
4. Do you use Paracetamol and Ibuprufen used routinely in managing post-immunization fever?
5. What is the responsibility of District Health Management Team, DHMT on AEFI surveillance?
6. How is Adrenaline administered during post-immunization anaphylaxis?
7. How do position a baby during anaphylaxis following vaccination?
8. Who receives AEFI reports from health facilities?
9. What aspects of immunization programme does AEFI investigation examine?
10. When should AEFI Investigation be commenced?
11. Should all injection site absceses be reported?
12. Should all Injection site swelling and redness be reported?
13. When should treatment of coincidental illness falsely attributed to vaccine reaction be commenced?
14. What is the aim of immunization surveillance in respect to AEFI?
SECTION 3: Perception {Please fill in appropriately}

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<tr>
<th></th>
<th></th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Reporting an AEFI can lead to personal consequences</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Reporting an AEFI, such as injection abscess, will make me feel guilty about having caused harm and be responsible for the event.</td>
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</tr>
<tr>
<td>3</td>
<td>Nurses are reluctant to report an AEFI when they are not confident about the diagnosis</td>
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<td></td>
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<tr>
<td>4</td>
<td>Investigation of adverse events following immunization should be done by clinical officers or doctors and not nurses</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>5</td>
<td>Poor monitoring of AEFI can cause reduction of immunization coverage</td>
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<tr>
<td>6</td>
<td>The process of reporting an AEFI is long and tedious</td>
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<td></td>
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<tr>
<td>7</td>
<td>Reporting and investigating suspected AEFI is none of my business</td>
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<tr>
<td>8</td>
<td>Even if adverse events are reported to DVI/DPHN, no feedback is send back to the facility that reported the event</td>
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<tr>
<td>9</td>
<td>Enhancing surveillance of AEFI can help build public trust in our immunization programme</td>
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<tr>
<td>10</td>
<td>Nurses play a vital role in diagnosing, reporting, investigating and managing Adverse Events Following Immunization (AEFI)</td>
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<tr>
<td>11</td>
<td>I am ready to learn more about how to diagnose, report, investigate and manage Adverse Events Following Immunization (AEFI)</td>
<td></td>
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<tr>
<td>12</td>
<td>Every nurse working at a health facility should know about AEFI</td>
<td></td>
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<tr>
<td>13</td>
<td>I am always busy and there is no time to report AEFI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>I am not interested in investigating or reporting AEFI to DPHN/DVI</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION 4: Practice {Please fill in appropriately}

1. What information about the baby do you rule out prior to administering a vaccine?
2. Do you have an anaphylactic pack with adrenaline in the immunization room?
3. Prior to vaccine administration, what information about the vaccine and vaccination do you ensure that the caretaker is aware of?
4. Have you ever come across a child with injection site swelling, injection redness, abscesses, BCG lymphadenitis, convulsion, shock, AFP or fever>40°c?
5. If Yes in question 4 above, did you report it as an AEFI?
6. If Yes in question 4 above, did you participate in investigation of what caused that event?
7. What parameters about vaccine safety do you document during vaccination?
8. Have you ever seen an AEFI reporting and investigation form?
9. Do you have AEFI reference guidelines materials at your work station?
10. Do you have relevant AEFI specimen transportation containers at your work station?
Appendix III: Ethical Approval letter

KENYATTA UNIVERSITY
ETHICS REVIEW COMMITTEE
P. O. Box 43844 - 00100 Nairobi
Tel: 8710901/12
Fax: 8711242/8711575

Our Ref: KU/R/COMM/51/204

Date: August 13th, 2013

Calistus Masika Wanjala
School of Public Health
Kenyatta University
P.O. Box 43844-00100, Nairobi

Dear Mr. Calistus,

APPLICATION NUMBER PKU/130/1114 OF 2013 – ‘NURSES’ KNOWLEDGE, PERCEPTION AND PRACTICE TOWARDS SURVEILLANCE OF ADVERSE EVENTS FOLLOWING CHILDHOOD IMMUNIZATION IN NAIROBI COUNTY’ – VERSION 2.

1. IDENTIFICATION OF PROTOCOL

The application before the committee is with a research topic, ‘Nurses knowledge, perception and practice towards surveillance of adverse events following childhood immunization in Nairobi version 2 dated 10th August 2013 received on 12th August 2013.

2. APPLICANT

Calistus Masika Wanjala
School of Public Health
Kenyatta University
P.O. Box 43844-00100, Nairobi

3. SITE

Nairobi.

4. DECISION

The committee has considered the research protocol in accordance with the Kenyatta University Research Policy (section 7.2.1.3) and the Kenyatta University Ethics Review Committee Guidelines, and is of the view that against the following elements of review,

(i) Scientific design and conduct of study,
(ii) Recruitment of research participant,
(iii) Care and protection of research participants,
(iv) Protection of research participant’s confidentiality,
(v) Informed consent process,
(vi) Community considerations.

AND APPROVED that the research may proceed for a period of ONE year from August 13th, 2013.
5. **ADVICE/CONDITIONS**

i. Progress reports are submitted to the KU-ERC every six months and a full report is submitted at the end of the study.

ii. Serious and unexpected adverse events related to the conduct of the study are reported to this board immediately they occur.

iii. Notify the Kenyatta University Ethics Committee of any amendments to the protocol.

iv. Submit an electronic copy of the revised proposal to KU-ERC.

When replying, kindly quote the application number above.

If you accept the decision reached and advice and conditions given please sign in the space provided below and return to KU-ERC a copy of the letter.

![Signature]

PROF. NICHOLAS K. GIKONYO  
CHAIRMAN: KENYATTA UNIVERSITY ETHICS REVIEW COMMITTEE

I ........................................................................................................................................................................
accept the advice given and will fulfill the conditions therein.

Signature...........................................................................Dated this day............... of...................... 2013.

cc. Vice-Chancellor  
    Director: Institute for Research Science and Technology
Appendix IV: Research Permit

THIS IS TO CERTIFY THAT

Prof./Dr./Mr./Mrs./Miss/Institution
Calistus Masika Wanjala
of (Address) Kenyatta University
P.O Box 43844-00100, Nairobi

has been permitted to conduct research in

Location: Nairobi
District: Nairobi
County: Nairobi

on the topic: Nurses knowledge, perception and practice towards surveillance of adverse events following childhood immunization in Nairobi County,
for a period ending: 31st December, 2013.

Research Permit No.: NCST/RCD/12A/013/43
Date of issue: 27th August, 2013
Fee received: KSH. 1000

For: Secretary

National Commission for Science, Technology & Innovation

Signature

Applicant's

National Commission for Science, Technology & Innovation

Signature
Appendix V: Map of Nairobi County