

**DETERMINANTS OF THE UPTAKE OF PNEUMOCOCCAL CONJUGATE
VACCINE (PCV-10) IN MAKINDU DISTRICT, KENYA**

BY

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DECLARATION

I declare that this thesis is my original work and to the best of my knowledge has not been submitted before in any other university or learning institution for academic award.

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SUPERVISOR'S APPROVAL

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DEDICATION

I dedicate this thesis to my husband Collins, children Isaac and Sam for their dedication, support and encouragement, to my beloved mother Monicah Mutisya for her constant concern and prayers during the entire study period.

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ACRONYMS AND ABBREVIATIONS

AMREF	Africa Medical Research Foundation
BCG	Bacille Calmette-Guerin
CMR	Child Mortality Rate
DHIO	District Health Information Officer
DHMT	District Health Management Team
DMOH	District Medical Health Officer
DPHN	District Public Health Nurse
DTP	Diphtheria-Tetanus-Pertusis
EPI	Expanded Program for Immunization
GAPP	Global action plan for the prevention and control of pneumonia
GAVI	Global Alliance for Vaccines and Immunization
GIVS	Global Immunization Vision and Strategy
HCWs	Health Care Workers
IMR	Infant Mortality Rate
IPD	Invasive Pneumococcal Diseases
IPV	Inactivated Polio Vaccine
KDHS	Kenya Demographic Health Survey
KEPI	Kenya Expanded Program for Immunization
MDG	Millennium Development Goals
MNCH	Maternal Newborn Child Health
MOPHS	Ministry of Public Health and Sanitation
MVCV	Measles Virus-containing Vaccine
OPV	Oral Polio Vaccine
PD	Pneumococcal Disease
PCV	Pneumococcal Conjugate Vaccine
RED	Reaching Every District approach
SPSS	Statistical Package for Social Scientists
UNICEF	United Nations Children's Fund
WHO	World Health Organization

ABSTRACT

Over 1.8 million children under five years of age die from pneumococcal disease (PD) every year worldwide, most of them living in developing countries. In Kenya, pneumococcal infections are the leading cause of hospital admissions among children under five years. In 2008, pneumonia was the second leading cause of death among children under five years, with over 30,000 childhood deaths, accounting for 16% of child mortality in Kenya. Immunization is the cornerstone of health care policy and a key component in infectious disease prevention. Kenya rolled out the Pneumococcal Conjugate Vaccine (PCV-10) vaccine in January 2011, in all government hospitals with an aim of covering over 70% invasive pneumococcal diseases (IPD) by the end of 2011. The vaccine uptake at Makindu district has been sub-optimal and the reasons not yet determined, hence the need for this study. The objective of this study was therefore, to establish the caregivers and healthcare workers level of knowledge, attitude and practices and healthcare system influence on the uptake of the PCV-10. In a cross-sectional study, caregivers of children aged 3-12 months ($n=374$), health workers ($n=32$) and the healthcare system organization were investigated. The caregivers and healthcare workers were interviewed using structured interview schedules, questionnaires and observational checklist were used to collect additional information on healthcare system functioning. Data was entered, coded and analyzed using Microsoft excel and SPSS. Differences in proportions between groups were compared using the Chi square and Fishers' exact tests. Of the 374 children, 292 (78.1%) had received the PCV-10 vaccination. Multivariate logistic regression analysis showed that marital status of the caregiver ($P=0.022$), health facility delivery ($P<0.0001$), and knowledge of Kenya Expanded Program for Immunization (KEPI) immunization schedule ($P=0.048$), PCV-10 vaccine ($P<0.0001$), and hospital treatment for pneumococcal sick children ($P=0.036$) were associated with increased uptake of PCV-10 vaccination. However, low uptake of PCV-10 vaccination was associated with caregiver work related reasons ($P<0.0001$), and health facility challenges such as lack of vaccines ($P=0.012$), and inconvenient vaccination schedules ($P=0.002$). Healthcare workers level of qualification ($P<0.0001$) and attendance of KEPI refresher courses ($P=0.041$) significantly influenced the uptake of PCV-10 vaccination. The findings demonstrate healthcare systems shortfalls contributing to low vaccine uptake. This study recommends that health promotional interventions that target imparting of PCV-10 and KEPI knowledge to caregivers and healthcare staff, and enhancing healthcare system functioning may improve uptake of PCV-10 immunization.

CHAPTER ONE: INTRODUCTION

1.1 Background information

Immunization is the cornerstone of healthcare policy and the most effective tool for the control and prevention of life-threatening infectious diseases. It is estimated that immunization averts 2 to 3 million deaths each year (UNICEF, 2006). In addition, childhood vaccination reduces mortality by 99% against most infectious diseases including smallpox, polio, diphtheria, and measles (McCullers, 2007) as well as incalculable economic savings (Hausdorff, 2008).

Vaccination against childhood communicable diseases through the Expanded Program on Immunization (EPI) is one of the most cost-effective public health interventions available, with proven strategies that make it accessible to even the most hard-to-reach and vulnerable populations (UNICEF, 2006). According to WHO (2007), the widespread use of vaccines has greatly improved global public health, preventing millions of childhood hospitalizations and deaths each year, and also averts adult deaths through the prevention of hepatitis B (Hep B) virus-related chronic liver disease, liver cancer, and Human Papilloma virus-related cervical cancer.

Although some infections can be treated with antibiotics, many others, in particular the viruses are not sensitive to the remedies, and if uncontrolled can cause high morbidity and mortality (Levine, 2006). According to WHO (2007), the development of bacterial resistance to some of the most efficient antibiotics underlines the need for prevention through interventions such as immunization.

In 1974, as part of its drive towards “*Health for All*”, WHO initiated EPI to improve and expand the scope of the already existing immunization services globally (WHO, 2002). Initially, the program covered six diseases namely: BCG vaccination against tuberculosis, three doses of pentavalent vaccine covering diphtheria, tetanus, pertusis, *Haemophilus Influenzae* (Hib) and hepatitis B, oral polio vaccine (OPV) and measles vaccine for measles. These vaccinations are normally given during the first year of life.

In line with WHO-EPI, KEPI was launched in 1980 under the Ministry of Health, with the main objective of reducing morbidity and mortality rates by providing immunization against the targeted diseases to all children in Kenya (WHO, 2002). It recommends that children receive polio vaccine at birth and a 3 series of the vaccine at 6, 10 and 14 weeks, 3 series pentavalent vaccine at 6, 10, and 14 weeks, 1 dose BCG at birth, and 1 dose of measles vaccine at 9 months. To reduce morbidity and mortality related to Neonatal Tetanus, at least two doses of tetanus toxoid (TT) vaccine are recommended during pregnancy (Mutua *et al.*, 2011).

The introduction of pneumococcal conjugate vaccine (PCV-10) by WHO is an important step in the move towards the control of vaccine preventable diseases among children (Scott *et al.*, 2010). This vaccine protects against a group of Pneumococcal diseases (PD) caused by *Streptococcus pneumoniae* (pneumococcus), a gram-positive anaerobic bacteria. Such diseases include pneumonia, acute respiratory infections, meningitis, acute sinusitis, otitis media, bacteraemia, sepsis and endocarditis (Black *et al.*, 2008).

With support from Global Alliance for Vaccines and Immunization (GAVI), Kenya introduced the PCV-10 vaccine to its routine immunization schedule in January 2011, with an aim of covering over 70 per cent invasive pneumococcal diseases (IPD) by the end of 2011 (Scott *et al.*, 2010). Vaccine coverage surveys in Kilifi district, Kenya before and after the introduction of pentavalent vaccine showed that 88-100% of children in this area were immunized with three doses of pentavalent, and that many received their vaccines late mirroring findings from demographic health surveys (DHS) conducted in several developing countries (Ndiritu *et al.*, 2006). For diseases with high incidence in the first months of life such as *Streptococcus pneumoniae* infections, delays in immunization may diminish the impact of vaccine even if coverage at age 12 months is high (WHO/UNICEF, 2009).

Currently, children in Kenya receive a three series PCV-10 vaccination at the age 6, 10, and 14 weeks, at the right thigh (Ndiritu *et al.* 2006). The pentavalent vaccine injection on the left thigh and OPV-orally are co-administered with the PCV-10. The pneumococcal vaccines are also available in private hospitals which charge high prices, locking out many children from accessing the vaccine.

1.2 Problem statement

Pneumonia prevention and intervention targets have not been achieved in the 15 most affected countries, including Kenya, where three-quarters of deaths in children under 5 years occur from the disease each year (Black *et al.*, 2010). In addition, the development and spread of antibiotic resistance by *Streptococcus pneumoniae* to commonly used

antibiotic treatments has worsened the situation (Snidack *et al.*, 2005). Each year, more than 10 million children in low- and middle-income countries die before they reach their fifth birthdays (WHO, 2009). Most die because they do not access effective interventions that would combat common and preventable childhood illnesses (Levine, 2006).

Pneumonia is the number one vaccine preventable cause of death among under fives globally (Abdullahi, 2005). According to WHO/UNICEF (2009), pneumonia kills 1.8 million children under 5 years annually, most of them living in developing countries. It also estimates that pneumonia accounts for nearly 1 out of every 5 deaths in children under 5 years, and for each child who dies from pneumonia in an industrialized country, more than 2000 children die from pneumonia in a developing country. Around the world, pneumococcal disease is still killing more than 5500 children every day (UNICEF, 2010).

Pneumococcal disease cause severe financial difficulties and emotional burden for families and communities and contributes to the “Cycle of Poverty”. Further, few caregivers can recognize pneumonia symptoms – consequently less than 1/3 of children suffering from pneumonia receive antibiotics – which are available for less than a dollar – for treatment.

In the developing countries, children under the age of two are most at risk. Childhood pneumonia is a major public health issue for Kenya. In 2008, pneumonia was the second leading cause of death among under fives, claiming over 30,000 children’s lives, equivalent to 16 % of child mortality in Kenya (Black *et al.* 2010). Pneumococcal disease is the cause of the highest number of admissions in Kenyan hospitals and is the number

one cause of paediatric admissions and death (Scott *et al.*, 2010). Therefore, in order to reduce this unacceptably high paediatric morbidity and mortality more effective interventions such as vaccination are urgently required.

However, introduction of the PCV-10 vaccine came with its challenges like the re-training and updating of the healthcare workers on the new vaccine before its introduction. The update training on PCV-10 vaccine at Makindu district was rushed with too much information given in a short time, being more of a briefing rather than a training session, contrary to WHO's standards for training of the health workers.

Community sensitization was done by public health officers via schools, chief's barazas and public gatherings through-out the Makindu district. Moreover, most of the Makindu district rural health facilities do not have electricity, or any back-up system required to manage the vaccines. This also contributes to the need for this study, to assess whether healthcare system influences the uptake of the vaccine in this district. However, since introduction the PCV-10 vaccine uptake has been low with coverage of 50% in Makindu district as reflected by the district health records database.

1.3 Justification

GAVI is funding the PCV-10 vaccination process between 2011 and 2014 to the Kenyan government (Ndiritu *et al.*, 2006). This study aims to help the Ministry of Public Health and Sanitation maximize this support by detecting factors affecting the introduction phase and promptly facilitate appropriate intervention.

According to WHO (2002), the health workers are already familiar with the routine administration of the other KEPI vaccines as extensive trainings and continual updates have been ongoing (Ayaya, 2007). However, introduction of the new PCV-10 vaccine came with its own challenges. The first challenge was the re-training and updating of the health workers on the new vaccine before its introduction. This study therefore aimed at assessing how the above mentioned challenges have been met, for the purposes of taking the necessary action to meet the set standards.

Further, the reasons for the low uptake of the PCV-10 vaccine in Makindu district have not yet been determined. Since caregivers' of the involved children play a central role if improved uptake of the newly introduced vaccine is to be realized, therefore, the need to assess whether knowledge, attitude and practices among the caregivers, the health workers, and the healthcare system functioning affect its uptake.

The findings of this study will help the policy makers review and formulate guidelines aimed at improving the level of knowledge, attitude and practice of caregivers. This will in turn improve uptake of the PCV-10 vaccine, thus reducing morbidity, mortality and disability caused by the targeted immunizable diseases. Health workers' improved performance will also benefit the whole community.

Consequently, improved knowledge and practices of caregivers and healthcare workers will reduce the high recorded infant mortality rates (IMR) and child mortality rates

(CMR) related to pneumococcal diseases in Kenya, thus contribute to achievement of the MDG 4 for child survival.

1.4 Research Questions

- i. How does the level of knowledge, attitude and practice among caregivers influence the uptake of PCV-10 vaccine at Makindu district, Kenya?
- ii. How does the level of knowledge and attitude among health workers determine the uptake of PCV-10 vaccine at Makindu district, Kenya?
- iii. How does the healthcare system influence PCV-10 vaccine uptake at Makindu district, Kenya?

1.5 Objectives

1.5.1 Broad objective

To establish the determinants of pneumococcal conjugate vaccine (PCV-10) uptake at Makindu district, Kenya.

1.5.2 Specific objectives

- i. To assess the level of knowledge, attitude and practice on PCV-10 vaccine among caregivers at Makindu district, Kenya.
- ii. To establish the level of knowledge and attitude among health workers on PCV-10 vaccine at Makindu district, Kenya.
- iii. To determine how the healthcare system influences PCV-10 vaccine uptake and delivery at Makindu district, Kenya.

1.6 Significance and anticipated output

The results of the study will be shared with the various stakeholders and used to redesign approaches to immunization schedules in the country. Further, good practices identified on the PCV-10 immunization in Makindu district can be duplicated in other parts of the country to improve PCV-10 vaccination uptake and coverage.

Findings of the assessment of knowledge, attitude and practices on PCV-10 vaccine uptake among caregivers will be used in reshaping approaches to childhood immunization enhancing coverage and consequently decreasing IMR and CMR, thus contributing to the achievement of Millennium Development Goal (MDG) 4 for child survival.

1.7 Conceptual framework

A conceptual framework is a schematic diagram which shows how the independent and dependent variables interact and explains how these would influence the outcome of the study. In this study, the dependent variable is ‘children vaccination with PCV-10 vaccine’ The independent variables include; i) caregivers’ socio-demographic characteristics, knowledge of the PCV-10 vaccine, their attitude towards the vaccine, and practices. ii) Health workers socio-demographic characteristics, training, knowledge and skills on PCV-10, attitude and advocacy. iii) Healthcare system’s availability of PCV-10 vaccines, storage, staffing, immunization schedules, immunization outreach clinics, and other KEPI vaccines.

Confounding variables are those in between the dependent and independent variables, that affect the study outcome. In this study, confounding variables include; the caregivers' age, gender and education level.

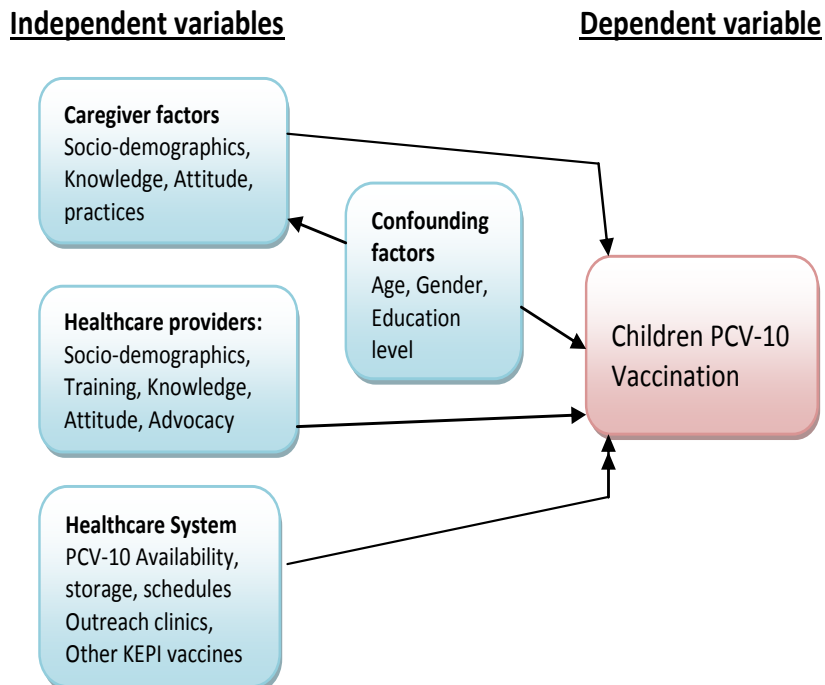


Figure 1.1: Conceptual framework

1.8 Limitation

Financial constraints were the major study limitations, whereby the researcher had to solicit funds from a sponsor.

1.9 Study assumptions

The study assumption was that, there were several community barriers that led to low PCV-10 vaccine uptake in the rural communities.

1.10 Operational definition of terms

For the purpose of this study, the following terms will be defined as follows:

Caregivers are defined as mothers or guardians of children 1yr. and below who have been eligible to receive the PCV-10 vaccine. Children 1 year and below are targeted because currently all are being immunized with PCV-10 vaccine countrywide.

Healthcare system is defined as the health facilities functioning or services related to immunization including staffing, vaccination schedules, health education to caregivers, availability and storage of vaccines, equipments, and outreach clinics to the community.

Healthcare workers: This includes doctors, nurses, clinical officers and public health officers who are involved in Child health and the immunization program in the study area.

Knowledge is defined as having information on PCV-10 vaccine. The information includes; what is pneumococcal vaccine, the diseases preventable by the PCV-10 vaccine, how and when vaccine is given to children and the benefits.

Pneumococcal conjugate vaccine (PCV-10): is a vaccine used to protect infants and young children against disease caused by the bacterium *Streptococcus pneumoniae* (pneumococcus). It is a *deca*valent vaccine, meaning that it contains ten serotypes of pneumococcus (1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, and 23F) which are conjugated to a carrier protein.

Pneumococcal disease (PD): These are infections that are caused by the *Streptococcus pneumoniae* (pneumococcus) bacteria. They include serious diseases, such as pneumonia, meningitis and febrile bacteraemia. Otitis media, sinusitis and bronchitis are more common but less serious manifestations of infection. Others infections include osteomyelitis, septic arthritis, endocarditis, peritonitis, pericarditis, cellulitis, and brain abscess.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

According to WHO (2005), one of the greatest challenges facing immunization programs is ensuring continued funding for vaccination of children in some of the poorest and most remote places on earth. Introducing new vaccines in low-income countries presents additional funding challenges. In 2000, Global Alliance for Vaccines and Immunization (GAVI), a global health partnership representing private and public stakeholders, was established to improve vaccination services in poor countries and to improve coverage with new and underutilized vaccines (WHO/UNICEF, 2005).

Since 2000, \$2.2 billion has been disbursed to approximately 70 countries to support vaccination services, injection safety, new vaccine introduction, and the strengthening of health service systems. Nonetheless, if the GIVS goal for global coverage is to be met, strategies known to be effective must be prioritized and implemented in all countries.

In 2002, WHO, UNICEF, and other partners developed the Reaching Every District (RED) approach to remove common obstacles to vaccination and build district-level capacity (WHO, 2004). Components of the RED approach include effective planning and management of resources, outreach to underserved communities, providing supportive supervision and training, linking health services with communities, and promoting the use of district level data for decision making (Vandelaer *et al.*, 2007).

In 2009, more children than ever benefited from vaccination worldwide. However, the global increase in vaccination coverage can obscure regional and local deficits in access to health services resulting from weak health systems, poor planning and resource

management, limited outreach, inadequate supervision, and ineffective use of data (WHO, 2004). A recent review of published literature found out that immunization program weakness was the leading reasons that children did not complete the DTP 3-vaccination series (KEMRI/CDC, 2008).

Immunization coverage in Kenya has increased markedly, though resource constraints, poor planning and ineffective use of data have been implicated to contribute to regional and local deficits in access to health services (KDHS, 2009). The proportion of children aged 12-23 months reported to have received all recommended vaccination is 77.4%, and it varied from 48.3% in North Eastern province to 85.8% in Central province (KDHS, 2009). Full immunization coverage in rural hard-to-reach parts of the country as well as urban slums has been very low compared to urban areas. This geographical inequality in coverage reflects the variation in the influence of determinants of vaccination across the different provinces (Mutua, 2011).

2.2 Pneumococcal Disease

2.2.1 *Streptococcus pneumoniae*

Streptococcus pneumoniae (pneumococcus) was discovered in 1881. It is a gram-positive coccus about 0.5-1.25 micrometers in diameter. Pneumococcus often appears in pairs that have a lancet-shaped appearance because the outer end of each bacterium in the pair is slightly pointed. Most Pneumococci are encapsulated (cell walls covered with complex polysaccharides). It is the encapsulated strains that cause disease in humans. Pneumococci are facultative anaerobic organisms. *Streptococcus pneumoniae* is part of the normal upper respiratory tract flora, but, as with many natural flora, it can become

pathogenic under the right conditions such as suppression of host immunity (Knuf *et al.* 2009).

To date, *Streptococcus pneumoniae* bacteria has approximately 40 serogroups and 93 serotypes (strains) that have been identified. Not all serotypes are implicated in pneumococcal disease. In fact only a minority of serotypes (24 serotypes) cause most cases of human disease (KEMRI/CDC, 2008). These serotypes differ in virulence, extent of drug resistance and prevalence across different regions in the world and within countries. PCV-10 acts on ten serotypes, with serotypes 1, 6B, 14, 5, 23F and 19A commonly occurring in most regions in Kenya (Scott *et al.*, 2010).

2.2.2 Diseases caused by *S. pneumoniae*

Streptococcus pneumoniae is a significant human pathogenic bacterium, as it is a frequent cause of serious diseases, such as pneumonia, meningitis and febrile bacteraemia. Otitis media, sinusitis and bronchitis are more common but less serious manifestations of infection (Sartori *et al.* 2010). Other infections include sepsis, osteomyelitis, septic arthritis, endocarditis, peritonitis, pericarditis, cellulitis, and brain abscess (Knuf *et al.*, 2009). Pneumococcal disease is more common in the very young (<2 yrs) and the very old (>65 yrs) (Dagan, 2000).

Although PCV-10 does not provide 100% protection against vaccine serotypes or protect against non-vaccine serotypes (Jackson *et al.*, 2003), several clinical studies demonstrated that PCV-10 is ~80-85% effective in preventing invasive disease caused by the pneumococcus bacteria (Knuf, 2010). In Kenya, previous trials showed that PCV-10 will be 80% effective in preventing pneumococcal infections (Scott *et al.*, 2010). PCV-10

protects infants and young children by stimulating long-lived antibody production through induction of immunologic memory against all vaccine serotypes after primary vaccination (Lee, 2003).

The frequency of pneumococcal serotypes and serogroups can vary over time and geographically which could influence the effectiveness of the vaccine in any given country. However, common serotypes are consistently identified worldwide with 13 (i.e., 19A, 6A, 3, 4, 6B, 9V, 14, 18C, 19F, 23F, 1,5, and 7F) most common serotypes causing at least 90% of invasive pneumococcal disease in children (KEMRI/CDC, 2008).

2.2.3 Pneumococcal disease impact in Kenya

Childhood pneumococcal infections are the leading cause of death among under fives, claiming over 30,000 children's lives, equivalent to 16% of child mortality in Kenya (Black et al. 2010). Young children, particularly infants, are the most vulnerable to the bacterium with those suffering from malnutrition, low birth weight, living with HIV/AIDS and not exclusively breastfed until six months of age at greatest risk (UNICEF, 2009).

Acute respiratory infections (ARIs) are a leading cause of childhood morbidity and mortality, causing 25-30% of all deaths in children in developing countries (WHO/UNICEF, 2009). Among patients with ARIs, pneumococcal disease is the most important cause of mortality and hospitalization; hence pneumococcal disease is a significant global public health problem in most countries in the world (Abdullahi, 2005).

Recent studies on the progress in prevention and control of pneumonia in the top 15 countries, that account for nearly three-quarters of all child pneumonia deaths worldwide indicate Kenya's coverage level on all target interventions at 48%, which is primarily through early detection and treatment with antibiotics (Sniadack *et al.*, 1995). This figure is expected to substantially increase with the national roll-out of the pneumococcal vaccine (IVAC, 2010).

2.2.4 Treatment of Pneumococcal infections

According to Dawn *et al.* (2010), penicillin is the first antibiotic of choice for treating pneumococcal infections, but many strains of pneumococcal bacteria resist common antibiotics. Three common antibiotics used to treat *Streptococcus pneumoniae* infections are ciprofloxacin, levofloxacin and ofloxacin. Ciprofloxacin, marketed as Cipro®, Cipro® XR, or Proquin® XR, is used for *S. pneumoniae* and other bacterial infections. Levofloxacin, marketed as Levaquin®, is used to treat chronic bronchitis caused by pneumonia. Ofloxacin, marketed as Floxin®, is also used for *S. pneumoniae*.

The continuing emergence of penicillin resistant and multi-drug resistant pneumococcal strains is an increasing threat posing serious therapeutic challenges. Emerging antibiotic resistant strains world-wide include 6B, 9V, 14, 19F, 19A, and 23F, with 19A becoming notorious for multi-drug (antibiotic) resistance internationally (KEMRI/CDC, 2008). In Kenya, the emerging antibiotic resistant strains are:-1, 3, 5, 6A, and 19A (KEMRI/CDC, 2008).

2.3 Pneumococcal conjugate vaccine

2.3.1 Pneumococcal conjugate vaccine (PCV)

Pneumococcal conjugate vaccine (PCV) is used to protect infants and young children against disease caused by the bacterium *Streptococcus pneumoniae* (Pneumococcus). There are currently three PCV vaccines available on the global market: Prevnar (called Prevenar in some countries), Synflorix (PCV-10) and Prevnar 13 (AAP, 2000).

Prevnar (PCV-7) is a *heptavalent* vaccine, meaning that it contains the cell membrane sugars of seven serotypes (4, 6B, 9V, 14, 18C, 19F, 23F) of pneumococcus, conjugated with diphtheria proteins. It is manufactured by Wyeth (Wyeth, 2006). In the United States, vaccination with Prevnar is recommended for all children younger than 2 years, and for unvaccinated children between 24 and 59 months old who are at high risk for pneumococcal infections (AAP, 2000).

Prevnar 13 (PCV-13) is produced by Pfizer. It is a *triskaivalent* vaccine, meaning that it contains thirteen serotypes of pneumococcus (4, 6B, 9V, 14, 18C, 19F, 23F, 1, 5, 7F, 3, 6A, 19A) which are conjugated to a carrier protein. Prevnar 13 was approved by the U.S. Food and Drug Administration for immediate release to the public on February 24, 2010. It is to be given on the same schedule as was Prevnar (FDA, 2010). PCV13 was officially launched in Kenya by Pfizer on 29th November 2011, and it is now available in private healthcare sector.

Synflorix (PCV-10) is produced by GlaxoSmithKline. It is a *decaivalent* vaccine, meaning that it contains ten serotypes of pneumococcus (4, 6B, 9V, 14, 18C, 19F, 23F, 1, 5 and 7F) which are conjugated to a carrier protein. Synflorix received a positive opinion

from the European Medicines Agency for use in the European Union in January 2009 and GSK received European Commission authorization to market Synflorix in March 2009 (Wysocki *et al.*, 2008).

PCV-10 contains antigen from ten pneumococcal serotypes: the seven that are contained in Prevnar, plus serotypes 1, 5, and 7F. Eight of the ten serotypes are linked to a protein carrier derived from non-typeable *Haemophilus influenzae* strains. The vaccine is an improved version of the previous PCV-7 (meaning it has the ability to prevent the attack of seven strains of pneumonia causing bacteria). It was rolled out in the year 2000 in the USA (Scott *et al.* 2010).

According to Dr. Scott (2010), PCV-10 acts on ten of the serotypes, seven of which are active in Kenya. PCV-10 does not provide 100 per cent protection against vaccine serotypes, against pneumonia caused by microbes other than *Pneumococcus* bacteria, nor does it protect against non-vaccine serotypes. *Streptococcus pneumoniae* bacteria have about 93 serotypes (strains) with the prevalence varying from region to region and country to country (Scott *et al.*, 2009). For instance, in Kenya the PCV-10 vaccine can protect against the predominant serotypes 1, 6B, 5, 19F, 23F and 14, but not others like 3, 6A, and 19A, that also occur in most parts of the region (Abdullahi., 2010).

The PCV-10, launched in line with Millennium Development Goal number four — reducing child mortality by two-thirds by 2015, was introduced in the US in 2000. Kenya became the third African country after South Africa and Gambia to introduce the vaccine in her immunization schedule in January 2011 (Scott *et al.*, 2010).

2.3.2 Impact of PCV-10 vaccination

Different impacts of the PCV vaccination programme have been observed in different countries. In the USA, a dramatic reduction in the invasive pneumococcal disease rates in both vaccinated and non-vaccinated population was observed shortly after the introduction of PCV-7 into their routine. Herd protection exceeded the effects of direct protection by the PCV-7 (Wyeth, 2006). On the other hand, in some European countries (France, Netherlands, Spain, UK), no reduction in IPD incidence among non-vaccinated adults was observed 2-3 years after the introduction of PCV7 in universal infant immunization (Wysocki *et al.*, 2008). In these countries, the reduction in vaccine-serotypes IPD rates was partially offset by the increase in non-vaccine serotypes IPD.

The differences in the results of the vaccination programme may be explained at least in part, by country-specific differences in PD rates, circulating serotypes causing disease, the adopted vaccine schedule (three or four doses, with or without catch-up vaccination of older children) and vaccine coverage (Sartori, 2010).

In Kenya, the circulating serotypes may be slightly different from those causing disease in other countries and the actual rates of PD are still difficult to obtain, and especially for the less severe diseases treated at the outpatient healthcare facilities (KEMRI/CDC, 2008). PCV-10 not previously used in routine immunization programme has been introduced, with cost-effectiveness studies having been part of decision process for the inclusion of new vaccines into the national immunization programme. However, an

active nationwide surveillance on PD is necessary in order to evaluate the impact and long-term benefits of the PCV-10 immunization programme.

The PCV-10 is given in all government vaccination centers to children aged 6, 10, and 14 weeks as part of the routine immunization schedule, with catch-up vaccination for under-1 children in the first year of the programme. The 13-valent pneumococcal conjugate vaccine (PCV-13) was recently introduced in the country but only in the private healthcare system, with low population coverage.

Pneumococcal disease mainly affects young children and the aged, perhaps due to poor immunity, but adults also carry the bacteria in the nose. Previous studies have shown that vaccinating children with PCV-10 protects adults through induction of "herd immunity" (Iannelli, 2008). Vaccinating a few individuals in the population protects most of the people in the population. This is because the bacterium lives in the nose, and it is transmitted through coughing, picking the nose and touching others. Therefore, if you vaccinate children, they will not transmit to the parents. Clinical trials revealed that the vaccine was also effective in children with HIV (Scott *et al.*, 2010).

2.3.3 Administration of PCV-10 vaccine

The 10-valent pneumococcal conjugate vaccine is administered in three doses at age 6, 10, and 14 weeks, with catch-up vaccination for under-1 children in the first year of the programme. PCV-10 is co-administered with routine childhood vaccines (pentavalent and OPV) (Knuf, 2010). PCV-10 injection is administered at the right thigh while the pentavalent injection is administered at the left thigh. This approach avoids additional visits, reduces

administration costs and enhances compliance and vaccination coverage (Clark *et al.*, 2009).

2.3.4 Side effects and contra-indications of Pneumococcal vaccine

Any medicine, including a vaccine, could possibly cause a serious problem, such as severe allergic reaction. However, the risk of any vaccine causing serious harm, or death, is extremely small. Pneumococcal vaccine uncommonly causes side effects, however, in clinical studies the most frequently reported adverse events included soreness and/or redness at the injection site, fever, irritability, drowsiness, restless sleep, decreased appetite, vomiting, rash, and diarrhoea (Wysocki *et al.*, 2008).

Risks are associated with all vaccines, including PCV-10. Hypersensitivity to any vaccine component, including diphtheria toxoid, is a contraindication to its use. Pneumococcal vaccine is not indicated for use in adults. The decision to administer PCV-10 should be based on its efficacy in preventing invasive pneumococcal disease (Sartori *et al.*, 2010).

2.4 Knowledge and Practices on pneumococcal vaccine

2.4.1 Knowledge, attitude and practices of caregivers on immunization

A global study involving over 5,000 parents revealed that 55% of them have either very little awareness of pneumococcal disease or none at all. As soon as they were provided with additional information about pneumococcal disease, 97% of all the parents surveyed said that if an effective and safe vaccine was available they would like their child to be vaccinated (WHO/UNICEF, 2009).

2.4.2 Knowledge and attitude of health workers on immunization

According to WHO (2002), the success of introduction of a new vaccine into the National immunization program depends on the knowledge about the vaccine and practices by the health workers and the community involved in the immunization. The incorporation and implementation of a new vaccine into national program is not recommended in the absence of specific trainings of health workers and community sensitization (WHO, 2002). Health care providers who care for children should have a thorough grasp of these potential complications and be prepared to educate parents appropriately so that barriers to adherence can be minimized (Tenreiro, 2005).

In Kenya, WHO (2005) reported that the initial KEPI training programme for pentavalent vaccine for the provincial and district key personnel was done without a standardized training tool. WHO found out that not all nurses giving immunization at health facilities in Kenya were trained, and there were no adequate reference materials available at any facility on pentavalent vaccine (WHO, 2005).

2.4.3 Effects of healthcare systems on uptake of vaccination

Although the benefits of vaccines are overwhelmingly positive from economic and medical science perspectives, complex issues – such as safety, adherence, and scheduling hinder the implementation of immunization programmes. In order to reach Millennium Development Goal (MDG) four for child survival, Global action plan for the prevention and control of pneumonia (GAPP) recommends a 90% coverage rate of pneumonia

immunization. Many of the countries that do not meet pneumonia prevention targets are expected to introduce new pneumonia vaccines, expand community-based case management and strengthen health systems (IVAC, 2010). Assuring that these plans are implemented will require funding and continued public attention to pneumonia, which will help contribute to a substantial decline in childhood pneumonia deaths (IVAC, 2010).

Pneumococcal disease is a major public health problem all over the world, and the leading cause of morbidity, hospital admissions and mortality among children under 5 years at Makindu district, yet the immunization coverage of children under 1 year with PCV-10 is 50% (DHRIS, 2011). *“This is contrary to the expectations based on the disease burden in this district”* according to the DMOH Makindu district.

CHAPTER THREE: MATERIALS AND METHODS

3.1 Research design

This was a descriptive cross-sectional survey as it allowed description of study variables at a given time without necessarily manipulating them. Quantitative and qualitative approaches through structured interview schedules, questionnaires and observational checklist were used to collect data on knowledge, attitude and practices regarding PCV-10 vaccine among caregivers, healthcare workers and healthcare system influence in Makindu district.

3.2 Study variables

The dependent variable in this study is children vaccination with PCV-10. The independent variables included; i) Caregivers: socio-demographic characteristics, knowledge, attitude and practices. ii) Healthcare workers: Socio-demographic characteristics, training, knowledge, health education/ advocacy and attitude. iii) Healthcare system: availability of electricity, staffing, and PCV-10 vaccines supplies, storage, outreach clinics, immunization schedules and other KEPI vaccines. The confounding variables comprised age and gender of caregivers, age and gender of children.

3.3 The Study area

3.3.1 Description of the study area

Makindu District was carved from Kibwezi District in 2008 and is one of the districts that form Makueni County, Eastern Kenya. The district borders Kajiado District to the West, Kibwezi District to the South, Kathonzwani District to the East and Nzau District to the

North. The District covers an area of 880.2 Km². The District comprises of one division, four locations, fifteen sub locations and seventy five villages (KNBS,2008).

3.3.2 Demographic characteristics

Makindu district is sparsely populated with population densities of 75 people per km². The total population estimate in 2009 was 101,657 people of which 5,000 were children aged below 1 year (KDHS, 2010). The district is mainly occupied by the Akamba community which forms approximately 94% of the total population. 6% comprises other communities mainly at the major towns of the district; Makindu and other small towns along Mombasa road (KNBS,2008).

The district is prone to frequent droughts and the only economic activity being done by the local people is livestock and poultry rearing and small scale irrigation along the permanent streams such as Kiboko, Kibwezi and the Athi river. The district is served by the Nairobi -Mombasa highway as well as Wote-Makindu road which provides a good means of transport. The district has an airstrip located at Makindu. The high levels of poverty is currently at 64.3% which is more severe amongst the women and children, a factor attributed to inequality and limited access to and ownership of assets, income generating opportunities, essential economic services and decision making (KNBS,2008).

3.3.3 Topography and climate

Makindu district lies in an arid and semi-arid zone at an altitude ranging from 300m in the lowlands of Mtito-Andei to 1100m on Chyulu Hills. The district experiences two rainy seasons, the long rains occurring in March to April while the short rains fall in November to December. The short rains are the more reliable in the district. The district receives on average between 351.9 mm-687.4 mm of rainfall per year. The high temperatures experienced in the low-lying areas cause high evaporation (KNBS, 2008).

3.3.4 Health facilities

Makindu district at the time of this study, had one district hospital, seven dispensaries and one private health facility, all of which carried out immunization services. Its child health indices are very poor, with under 5 mortality rate of 98/1000, and immunization default rates reported higher than the overall country's recorded rates (KDHS, 2010). According to a baseline survey conducted by AMREF (2010), the major health problems affecting children under five years in Makindu include; malnutrition, low immunization coverage, early cessation of breastfeeding and lack of exclusive breastfeeding.

3.4 Target population

The primary target population was children age one year and below, within the study area. Makindu district has an estimated population of 5,000 children below 1 year, who form about 4% of the total population of the district.

3.5 Study population

The study population was caregivers of children 3-12 months who were eligible for PCV-10 immunization at Makindu district, and health workers involved in immunization at rural health facilities. The **inclusion criteria** was, caregivers above 18 years old with children age one year and below, and health workers in rural health facilities involved in immunization, who were willing to participate and had been sampled to take part in the study. **Exclusion criteria** included all caregivers and health workers who did not meet the inclusion criteria, as well as those not consenting to participate in the study.

3.6 Sampling Techniques and Sample size

Makindu division was purposively sampled for the study. Multi-stage cluster sampling was used whereby the various administrative clusters were utilized as clusters, including; locations, sub-locations, villages and households. Two sub-locations from each of the four locations were randomly selected, giving a total of eight. Three villages from each of the selected sub-location were randomly selected giving a total of 24 villages. All households with children below 1year in the sampled villages were randomly selected, with the help of the respective village elders and community health workers (CHWs).

A total of 374 households from list were randomly sampled. The mother or main caregiver who fits the inclusion criteria in the sampled household was identified and selected to participate in the study during the study visit. Healthcare workers who met the inclusion criteria were randomly selected from all the health facilities in Makindu district, with a total of 25 healthcare workers filling the study questionnaires. The research

assistants filled in the observational checklist with the healthcare system data, at the time they visited the health facilities.

The formula by Fisher *et al* (1998) was used to determine the sample size. $n = Z^2 pqD/d^2$, where **n** is the required minimum sample size, **Z** is the normal standard deviation set at 1.96 which corresponds to 95% confidence interval, **p** is the expected population proportion of children not immunized (0.5) and **q** is 1-p (children immunized). The vaccine was rolled out in January 2011 and by June, 50% of the children had been immunized. Therefore, p=0.5 was used in sample size calculation. **D** is the design effect and **d** represents degree of accuracy set at 0.05 (n=384).

Since the total population of children 1 year and below in Makindu district is estimated to be 5,000 thus being less than 10,000, the correction formula below was used. Therefore, $nf = n/(1+n/N)$, where **nf** is the desired sample size, **n** is the estimated sample when the estimated total population (N) is greater or equal to 10,000. **N** is the estimated total population less than 10,000. Therefore, $384/(1+384/5000), = 384/1.0768=356.6$. A five percent (17) of the sample size was added to cater for non-response and other irregularities. This gave a sample size of 374.

Similarly, the formula by Fisher *et al*. was applied to calculate the sample size for health workers. Health workers involved in child health and immunization services at Makindu are 33 in total. Therefore, $nf = n/(1+n/N)$ substituted as $384/(1+384/33) =30.38$. An additional 5% (2) of the sample was added to cater for the irregularities (n=32). 17 of

which were selected from all the rural dispensaries because 80% of immunization in the district takes place here. The other 15 health workers were to be randomly sampled from the district hospital and private clinics.

3.7 Research Instruments

Structured interview schedules, questionnaires and observational checklists were formulated by the researchers and guidelines for constructing them were used. Pre-testing and corrections were done before the actual study. Then the standardized tools were used to collect quantitative data from caregivers, healthcare workers and qualitative data from health facilities using the observation checklists.

3.8 Pre-testing study tools

Pre-testing of the study tools was carried out at the neighbouring Kibwezi district whereby caregivers from a village were identified and 37 interview schedules pre-tested. 4 questionnaires and observational checklists were also pre-tested, 3 at various dispensaries and 1 at the Kibwezi sub-district hospital. This was important in operationalizing the study tools and the conceptual framework. Corrections and amendments on the interview schedules and questionnaires were then made before the actual study began. Collected data was entered, coded and analyzed using SPSS.

Kibwezi district is neighbouring and has similar conditions as the study area, Makindu. Thus it was appropriate for the pilot study. Reliability was ensured through use of well-designed interview schedules and questionnaires; selection, training and supervision of research assistants; and daily checking and correction of completed questionnaires.

3.9 Data collection Techniques

Data collection was carried out through administering structured interview schedules to caregivers, questionnaires to healthcare workers knowledge and attitude, and completing of observation checklist by the researcher on healthcare system functioning.

3.10 Data Quality Control

Data validity and reliability was achieved through pre-testing of the data collection instruments before the actual study in a population very similar to the one used in the actual study, training and close supervision of the research assistants by the principal investigator and data cleaning.

3.11 Logistical and Ethical Considerations

Scientific and ethical approval and authorization of the study was sort from Kenyatta University, Ministry of Higher Education, Science and Technology (MoHEST), and AMREF. Six research assistants were recruited and trained to assist in data collection. A vehicle was used to move the study team around while carrying out the study. Study guides were also utilized to locate the health facilities and households in the respective villages. Informed consent was sought from study participants after a clear explanation of the study and its purpose.

Data collected and reported was in a form that does not allow identification of individual participants. Study numbers and not personal identification were used in this study and these codes were not linked to the personal identification or names. A computer and internet facility were used for data entry, coding and analysis. The study findings will be communicated later through the DMOH to the stakeholders and the community.

3.12 Data management and analysis

Data was entered, coded and cleaned in the excel software (Microsoft office 2010, Texas, USA). Statistical analysis of the data was performed using SPSS version 17 (SPSS Inc. Chicago, USA). Differences in proportions between groups were compared using the Chi-square tests or the Fisher's exact tests where appropriate. Non-parametric test of medians using Mann-Whitney test on non-normalized data were used for comparisons of age between groups.

Caregiver's and health care workers' attitude on the uptake of PCV-10 vaccine was assessed using six statements each, on a 5-point Likert scale: +5 (strongly agree) to +1 (strongly disagree) for positive statements, and +5 (strongly disagree) to +1 (strongly agree) for negative statements. Additional statistical comparisons using the Fisher's exact test was done.

Further, a multivariate logistic regression model was constructed controlling for child and caregiver gender and age. $P < 0.05$ was considered statistically significant. Confidence interval (CIs) were set at the 95% confidence level, and all statistical tests were performed as two-sided. The results of the analyses were summarized using tables. Data collected from the health facilities was presented in proportions and percentages.

CHAPTER FOUR: RESULTS

4.1 The influence of caregivers on the uptake of pneumococcal vaccine

4.1.1 Demographic characteristics of the caregivers and children

The demographic characteristics of the caregivers and children are summarized in Table 4.1 and 4.2, respectively. A total of 374 matched child and caregiver pairs were enrolled into the study. Of the 374 children, 292 (78.1%) had received PCV-10 vaccination (vaccinated group), and 82 (21.9%) had not been vaccinated (unvaccinated group). Caregiver gender distribution differed significantly between the groups with the unvaccinated group having more males than the vaccinated group (8.5% *versus* 1.4%; $P=0.003$).

However, age of the caregivers was similar between the groups with median and IQR of 25.0 (21.0-32.0) and 26.0 (23.0-30.0) ($P=0.488$) for the unvaccinated and vaccinated groups respectively. Although gender of the children was not significantly different ($P=0.081$), the unvaccinated group had more female (59.8%) than male (40.2%) children. The children in the unvaccinated group were also significantly younger than those in the vaccinated group ($P=0.011$).

Religious affiliations of the caregivers did not differ significantly between the groups ($\chi^2=0.402$; $df=2$; $P=0.818$), whereas marital status of the caregivers was different, with the unvaccinated group having 1.85 times more individuals in “single” (single, divorced or widowed) families than the vaccinated group ($P=0.007$). The levels of education of the caregivers were not significantly different between the groups with a majority of the

caregivers in the vaccinated (74.5%) and unvaccinated (81.7%) groups having none or primary level of education ($P=0.240$).

Table 4.1: Demographic characteristics of caregivers

Characteristic	Unvaccinated (n=82)	Vaccinated (n=292)	χ^2 and df	P-value
Gender of caregiver				
Female	75 (91.5)	288 (98.6)	-	0.003^a
Male	7 (8.5)	4 (1.4)		
Age of caregivers (yrs.), median (Q1-Q3)	25.0 (21.0-32.0)	26.0 (23.0-30.0)	-	0.488
Religion				
Christian	77 (93.9)	279 (95.6)	$\chi^2=0.402$, df=2	0.818 ^c
Islam	4 (4.9)	10 (3.4)		
Others	1 (1.2)	3 (1.0)		
Marital status				
Married	57 (69.5)	243 (83.5)	-	0.007^a
Single, divorced or widowed	25 (30.5)	48 (16.5)		
Caregiver's education				
Secondary and tertiary	15 (18.3)	74 (25.3)	-	0.240 ^a
Primary and below	67 (81.7)	218 (74.7)		
Distance to nearest health facility (km)				
1-5	35 (42.7)	137 (46.9)	-	0.532 ^a
>5	47 (57.3)	155 (53.1)		
Transport mode to nearest facility				
Walking	47 (57.3)	183 (62.7)	$\chi^2=1.059$, df=2	0.589 ^c
Bicycle	14 (17.1)	49 (16.8)		
Motorbike/matatu	21 (25.6)	60 (20.5)		
Caregiver's number of children				
1	18 (22.0)	59 (20.2)	$\chi^2=0.627$, df=2	0.731 ^c
2-3	30 (36.6)	121 (41.4)		
4 or more	34 (41.4)	112 (38.4)		

Data are presented as number of subjects and proportions, n (%) unless otherwise indicated. Q1-Q3, 25-75th percentiles, respectively. Statistical analyses were performed by the ^aFisher's exact, ^bMann-Whitney and ^cChi-square tests. χ^2 , Pearson's chi-square value; df, degrees of freedom. Values in bold are significant P-values.

Table 4.2: Demographic characteristics of the children

Characteristic	Unvaccinated (n=82)	Vaccinated (n=292)	χ^2 and df	P-value
Gender of children				
Female	49 (59.8)	142 (48.6)	-	0.081 ^a
Male	33 (40.2)	150 (51.4)		
Age of children (mos.), median (Q1-Q3)	4.0 (4.0-8.0)	6.0 (4.0-9.0)	-	0.011^b
Place of child delivery				
Health facility delivery	4 (4.9)	218 (74.7)	-	<0.0001^a
Home delivery	78 (95.1)	74 (25.3)		
Place of child immunization				
At the district hospital	46 (56.1)	185 (63.4)	-	0.249 ^a
At a dispensary	36 (43.9)	107 (36.6)		
Birth order of the child				
1 st	19 (23.2)	60 (20.5)	$\chi^2=0.803$, df=2	0.669 ^c
2-3 rd	29 (35.4)	119 (40.8)		
4 or higher	34 (41.4)	113 (38.7)		

Data are presented as number of subjects and proportions, n (%) unless otherwise indicated. Q1-Q3, 25-75th percentiles, respectively. Statistical analyses were performed by the ^aFisher's exact, ^bMann-Whitney and ^cChi-square tests. χ^2 , Pearson's chi-square value; df, degrees of freedom. Values in bold are significant P-values.

Likewise, the distance to the nearest health facility was not significantly different between the groups ($P=0.532$) and walking was non-significantly the most common mode of transport to the health facilities in both the vaccinated (62.7%) and unvaccinated (57.3%) groups ($P=0.589$).

The place of child delivery differed significantly between the groups ($P<0.0001$) with most children delivered at hospital in the vaccinated group (74.7%) and those delivered at home in the unvaccinated group (95.1%). However, the place of immunization

($P=0.249$), birth order of the child ($\chi^2=0.803$; $df=2$; $P=0.669$) and caregiver's number of children ($\chi^2=0.627$; $df=2$; $P=0.731$) were not significantly different between the groups.

4.1.2 Influence of caregivers knowledge on the uptake of PCV-10 immunization

In order to determine the influence of caregiver's knowledge of childhood immunization on the uptake of PCV-10 vaccine, their knowledge on the types of childhood vaccines and immunization schedule were assessed (Table 4.3 and 4.4). The level of knowledge on common childhood vaccines differed between the vaccinated and unvaccinated groups, except for BCG (58.5% *versus* 50.7%; $P=0.214$).

However, the vaccinated group had more knowledgeable individuals on childhood vaccines than the unvaccinated group: polio (57.2% *versus* 36.6%; $P=0.001$), pentavalent (42.1% *versus* 18.3%; $P<0.0001$) and measles (60.3% *versus* 32.9%; $P<0.0001$).

4.3: Caregivers knowledge on childhood vaccines

Characteristic	Unvaccinated (n=82)	Vaccinated (n=292)	<i>P</i> -value
BCG			
Yes	48 (58.5)	148 (50.7)	0.214
No	34 (41.5)	144 (49.3)	
Polio			
Yes	30 (36.6)	167 (57.2)	0.001
No	52 (63.4)	125 (42.8)	
Pentavalent			
Yes	15 (18.3)	123 (42.1)	<0.0001
No	67 (81.7)	169 (57.9)	
Measles			
Yes	27 (32.9)	176 (60.3)	<0.0001
No	55 (67.1)	116 (39.7)	
Knowledge on KEPI childhood immunization schedule			
Yes	58 (70.7)	244 (83.6)	0.011
No	24 (29.3)	48 (16.4)	

Data are presented as number of subjects and proportions, n (%) unless otherwise indicated. Statistical analyses were performed by the ^aFisher's exact. Values in bold are significant *P*-values.

Table 4.4: Caregivers knowledge levels on PCV-10 vaccination

Characteristic	Unvaccinated (n=82)	Vaccinated (n=292)	<i>P</i> -value
Knowledge of PCV-10 vaccine			
Yes	64 (78.0)	285 (97.6)	<0.0001
No	18 (22.0)	7 (2.4)	
Knowledge of diseases preventable by PCV-10			
Yes	49 (59.8)	259 (88.7)	<0.0001
No	33 (40.2)	33 (11.3)	
Knowledge on availability of effective vaccines for pneumococcal infections			
Yes	42 (51.2)	225 (77.0)	<0.0001
No	40 (48.8)	67 (23.3)	
Knowledge of PCV-10 doses			
3 doses	30 (36.6)	255 (87.3)	<0.0001
Others/None	52 (63.4)	37 (12.7)	
Knowledge on PCV-10 contraindications			
Yes	26 (31.7)	181 (62.0)	<0.0001
No	56 (68.3)	111 (38.0)	

Table 4.4 above, data are presented as number of subjects and proportions, n (%) unless otherwise indicated. Statistical analyses were performed by the Fisher's exact test. Values in bold are significant *P*-values.

Consistent with the trend on childhood vaccines knowledge, the proportion of caregivers knowledgeable on PCV-10 was significantly higher in the vaccinated (97.6%) group relative to the unvaccinated (78.0%) group ($P < 0.0001$). The knowledge of the caregivers on childhood immunization schedule was also significantly ($P = 0.011$) different between the groups with about a third (29.3%) of the respondents in the unvaccinated group lacking appropriate knowledge on childhood immunization schedules compared to the vaccinated group (16.4%).

Similarly, the proportion of caregivers knowledgeable to at least one disease (i.e., pneumonia, otitis media and pneumococcal meningitis, bacteraemia, sinusitis, bronchitis) preventable by PCV-10 (88.7% *versus* 59.8%; $P < 0.0001$), availability of vaccines for pneumococcal infections (77.0% *versus* 51.2%; $P < 0.0001$), number of required PCV-10 doses (87.3% *versus* 36.6%; $P < 0.0001$) and PCV-10 contra-indications (62.0% *versus* 31.7%; $P < 0.0001$) was also significantly higher in the vaccinated group relative to the unvaccinated group, respectively.

4.1.3 Influence of caregivers attitude on the uptake of PCV-10 vaccine

The influence of the caregiver's attitude on the uptake of PCV-10 vaccine was assessed using six statements on a 5-point Likert scale: +5 (strongly agree) to +1 (strongly disagree) for positive statements, and +5 (strongly disagree) to +1 (strongly agree) for negative statements. Thus, the total possible scores ranged from 1 to 30. The caregiver's attitude was defined using the Likert scores as follows: ≤ 10 (negative attitude); 11-20 (undecided), and 21-30 (positive attitude).

The Likert scores ranged from 12-27 in the vaccinated group and 16-26 in the unvaccinated group. The proportion of individuals with a positive attitude towards PCV-10 vaccination was higher in the vaccinated group (92.1%) compared to the unvaccinated group (85.4%), although additional statistical comparisons using the Fisher's exact test showed no statistical significant ($P = 0.084$) (Table 4.5).

Table 4.5: Attitude levels of the caregiver's towards PCV-10 immunization

Attitude, n (%)	Unvaccinated (n=82)	Vaccinated (n=292)	P-value
Negative attitude	-	-	0.084
Undecided	12 (14.6)	23 (7.9)	
Positive attitude	70 (85.4)	269 (92.1)	

Data presented are number of subjects (n) and proportions (%) of individuals with negative (≤ 10), undecided (11-20) and positive (21-30) attitude scores. The proportions of negative, undecided and positive attitude scores were compared between the vaccinated and unvaccinated groups using the Fisher's exact test.

4.1.4 Influence of caregivers practices on the uptake of PCV-10 vaccine

Although all children in the vaccinated group had an immunization card, 6.1% of the unvaccinated children had no immunization card ($P < 0.0001$). Most of the caregivers in the vaccinated (97.3%) and unvaccinated (91.5%) groups responded to their children's pneumonia infection by visiting the hospital but 8.5% and 2.7% of the caregivers in these groups, respectively did not visit the hospital for consultation (i.e., treated their children at home) ($P = 0.027$).

However, most of the caregivers in the vaccinated (86.6%) and unvaccinated (62.2%) groups had no reasons preventing them visiting health facilities for their children's immunization ($P < 0.0001$). Although the caregivers in the vaccinated (35.3%) and unvaccinated (45.1%) groups cited lack of vaccines as a common health facility challenge influencing taking children to the hospital for immunization, majority (55.1% and 34.1%) of the caregivers in both groups, respectively had no reason for not taking children to the hospital for immunization ($P = 0.001$) (Table 4.6).

Table 4.6: Caregivers practices on immunization and PCV-10 vaccine

Characteristic	Unvaccinated (n=82)	Vaccinated (n=292)	χ^2 and df	P-value
Immunization card availability				
Yes	77 (93.9)	292 (100.0)	-	<0.0001
No	5 (6.1)	0 (0.0)		
Response to pneumonia infection				
Hospital consultation	75 (91.5)	284 (97.3)	-	0.027
No hospital consultation	7 (8.5)	8 (2.7)		
Reasons preventing visiting health facility for immunization				
Work commitments	19 (23.2)	14 (4.8)	$\chi^2=31.602,$ df=3	<0.0001
Sickness of child	3 (3.7)	6 (2.1)		
Long distance to health facility	9 (11.0)	19 (6.5)		
None	51 (62.2)	253 (86.6)		
Health facility challenges influencing immunization of children				
Attitude of health staff	3 (3.7)	10 (3.4)	$\chi^2=16.155,$ df=3	0.001
Lack of vaccines	37 (45.1)	103 (35.3)		
Inconvenient schedules	14 (17.1)	18 (6.2)		
None	28 (34.1)	161 (55.1)		

Data are presented as number of subjects and proportions, n (%) unless otherwise indicated. Statistical analyses were performed by the ^aFisher's exact and ^bChi-square tests. χ^2 , Pearson's chi-square value; df, degrees of freedom. Values in bold are significant *P*-values.

4.1.5 Caregiver factors predictive of the uptake of PCV-10 vaccination

Multivariate logistic regression analysis controlling for child and caregiver gender and age showed that married caregiver ($\beta=0.700$; OR, 2.014; 95% CI, 1.104-3.672; $p=0.022$), health facility delivery ($\beta=4.189$; OR, 65.945; 95% CI, 22.748-191.172; $p<0.0001$), knowledge of KEPI immunization schedule ($\beta=0.605$; OR, 1.831; 95% CI, 1.005-3.336; $p=0.048$), knowledge on PCV-10 ($\beta=2.431$; OR, 11.367; 95% CI, 4.394-29.408; $p<0.0001$), knowledge of pneumococcal diseases preventable by PCV-10 ($\beta=1.529$; OR,

4.615; 95% CI, 2.546-8.364; $p < 0.0001$) and hospital consultation for pneumococcal sick child ($\beta = 1.200$; OR, 3.320, 95% CI, 1.080-10.204; $p = 0.036$) were associated with increased uptake of PCV-10 vaccination (Table 4.7).

However, low uptake of PCV-10 vaccination was associated with work related reasons ($\beta = -1.728$; OR, 0.178; 95% CI, 0.080-0.393; $p < 0.0001$), lack of vaccines at hospital ($\beta = -0.717$; OR, 0.48; 95% CI, 0.279-0.855; $p = 0.012$), and inconvenient vaccination schedule and long waiting time at hospital ($\beta = -1.384$; OR, 0.251; 95% CI, 0.106-0.594; $p = 0.002$).

Table 4.7: Caregiver factors predictive of uptake of PCV-10 vaccination

Factor	β	Wald test	OR (95% CI)	<i>P</i>
Marital status				
Married	0.700	5.210	2.014 (1.104-3.672)	0.022
Single, divorced and widow	-	-	1	
Place of child delivery				
Health facility delivery	4.189	59.498	65.945 (22.748-191.172)	<0.0001
Home delivery	-	-	1	
Knowledge on KEPI childhood immunization schedule				
Yes	0.605	3.907	1.831 (1.005-3.336)	0.048
No	-	-	1	
Knowledge on PCV-10 vaccine				
Yes	2.431	25.119	11.367 (4.394-29.408)	<0.0001
No	-	-	1	
Knowledge on diseases preventable by PCV-10				
Yes	1.529	25.407	4.615 (2.546-8.364)	<0.0001
No	-	-	1	
Response to pneumonia infection				
Hospital consultation	1.200	4.389	3.320 (1.080-10.204)	0.036
No hospital consultation	-	-	1	
Reasons preventing caregiver from taking child for immunization				
Work related reasons	-1.728	18.232	0.178 (0.080-0.393)	<0.0001
Other reasons, e.g. child sick	-	-	1	
Health facility challenges hindering caregiver from taking child for immunization				
Lack of vaccines	-0.717	6.286	0.488 (0.279-0.855)	0.012
Inconvenient schedule	-1.384	9.871	0.251 (0.106-0.594)	0.002
None	-	-	1	

Data are shown as odds ratios (OR), with 95% confidence intervals (CI), for variables that were significantly associated with uptake of PCV-10 vaccination ($P < 0.05$) in the univariate analyses. 1 = reference variable. Only significant variables ($P < 0.05$) are shown in the table. β = set of coefficients estimated for the model controlling for age and gender of the caregivers and children.

4.2 The influence of healthcare workers on the uptake of pneumococcal vaccine

4.2.1 Demographic characteristics of the healthcare workers

A total of 25 health care workers comprising clinical officers (n=2), nurses (n=18) and public health officers (n=5) were enrolled into the study. The demographic characteristics of the health care workers stratified by qualification (1. diploma (n=13), and 2. certificate (n=12) holders) are presented in Table 4.8. Age ($P=0.643$) and gender ($P=0.428$) distribution of the health care workers were similar between the groups.

A majority of the certificate (61.5%) and diploma (83.3%) holders were nurses (KEN and KRCHN), respectively ($P<0.0001$). Duration in service after qualification was not significantly different between the groups with most of the diploma (61.5%) and certificate (33.3%) groups having been in service for <10 years ($P=0.411$), while most health workers in the diploma (84.6%) and certificate (66.7%) groups had been working at current stations for <5 years ($P=0.378$).

Previous KEPI training was not significantly different between the groups ($P=0.433$) with diploma (30.8%) and certificate (41.7%) holders having received training over 10 years ago. Attendance of KEPI refresher training differed significantly between the groups ($P=0.041$) with most certificate (83.3%) having undertaken refresher courses compared to diploma (61.5%) holders. However, attendance of PCV-10 vaccine training ($P=0.695$), duration of PCV-10 training ($P=0.695$), and reasons against attending training ($P=0.428$) were not significantly different between the groups (Table 4.8).

4.8: Demographic characteristics of healthcare workers

Characteristic	Diploma (n=13)	Certificate (n=12)	χ^2 and df	P-value
Age (yrs.), median (Q1-Q3)	35.0 (31.5-39.5)	36.0 (33.3-48.0)	-	0.643
Gender				
Male	7 (53.8)	4 (33.3)	-	0.428
Female	6 (46.2)	8 (66.7)		
Designation				
Nurses	8 (83.3)	10 (61.5)	$\chi^2=19.277$, df=2	<0.0001
PHO/CO	5 (16.7)	2 (38.5)		
Duration in service after qualification (yrs.)				
≤ 10	3 (23.1)	5 (41.7)	-	0.411
> 10	10 (76.9)	7 (58.3)		
Duration of service at current station (yrs.)				
≤ 5	11 (84.6)	8 (66.7)	-	0.378
> 5	2 (15.4)	4 (33.3)		
Previous KEPI training (yrs.)				
≤ 10	0 (0.0)	1 (8.3)	$\chi^2=1.674$, df=2	0.433
> 10	4 (30.8)	5 (41.7)		
No training	9 (69.2)	6 (50.0)		
Attendance of KEPI refresher training				
Yes	5 (38.5)	10 (83.3)	-	0.041
No	8 (61.5)	2 (16.7)		
Attended training on PCV-10 vaccine				
Yes	8 (61.5)	6 (50.0)	-	0.695
No	5 (38.5)	6 (50.0)		
Duration of PCV-10 training (days)				
1	8 (61.5)	6 (50.0)	-	0.695
None	5 (38.5)	6 (50.0)		
Reasons for not attending PCV-10 training				
Not selected or personal reasons	4 (30.8)	6 (50.0)	-	0.428
None	9 (69.2)	6 (50.0)		

Data are presented as number of subjects and proportions, n (%) unless otherwise indicated. PHO, public health officer; CO, clinical officer. KEPI, Kenya expanded programme of immunization. Statistical analyses were performed by the ^aFisher's exact and ^bChi-square tests. χ^2 , Pearson's chi-square value; df, degrees of freedom. Values in bold are significant P-values.

4.2.2 Healthcare workers' knowledge on PCV-10 vaccine

In order to establish the healthcare workers knowledge on PCV-10 vaccine, their knowledge on various aspects of the vaccine was assessed (Table 4.9). The knowledge of healthcare worker on pneumococcal infections was significantly ($P=0.001$) different between the groups with 92.3% of the diploma holders having appropriate knowledge compared to the certificate group (25%).

However, the high proportions of healthcare workers knowledgeable about individuals at risk of pneumococcal infections (76.9% *versus* 83.3%; $P=0.999$), determining vaccine potency (76.9% *versus* 91.7%; $P=0.593$), management of PCV-10 contra-indications (84.6% *versus* 100%; $P=0.480$) and age of PCV-10 vaccination in children (53.8% *versus* 66.7%; $P=0.688$) were not significantly different between the groups.

Similarly, knowledge of healthcare workers on the potency of PCV-10 in inducing life-long immunity (53.8% *versus* 41.7%; $P=0.695$) was not significantly different between diploma and certificate holders. Notably, all the healthcare workers were knowledgeable on the various types of infections preventable by PCV-10 vaccine and the number of doses of PCV-10 vaccine required per child for complete immunization.

The healthcare workers cited periodic lack of vaccines (84.6% *versus* 83.3%; $P=0.999$) as the major immunization challenge related to PCV-10, and distance to health facility (84.6% *versus* 91.7%; $P=0.999$) as the major challenge perceived to prevent caregivers from taking children for vaccination.

4.9: Healthcare worker's knowledge on PCV-10 vaccine

Characteristic	Diploma (n=13)	Certificate (n=12)	P-value
Knowledge of pneumococcal infection			
Yes	12 (92.3)	3 (25.0)	0.001
No	1 (7.7)	9 (75.0)	
Knowledge of individuals at risk of pneumococcal infections			
Yes	10 (76.9)	10 (83.3)	0.999
No	3 (23.1)	2 (16.7)	
Knowledge on types of infections preventable by PCV-10 vaccine			
Yes	13 (100.0)	12 (100.0)	-
No	0 (0.0)	0 (0.0)	
Knowledge on determining vaccine potency			
Yes	10 (76.9)	11 (91.7)	0.593
No	3 (23.1)	1 (8.3)	
Knowledge on PCV-10 vaccine conferring life-long immunity			
Yes	7 (53.8)	5 (41.7)	0.695
No	6 (46.2)	7 (58.4)	
Knowledge of age of PCV-10 vaccination in children			
Yes	7 (53.8)	8 (66.7)	0.688
No	6 (46.2)	4 (33.3)	
Knowledge of required doses of PCV-10 for child immunization			
Yes	13 (100.0)	12 (100.0)	-
No	0 (0.0)	0 (0.0)	
Knowledge of management of PCV-10 contra-indication			
Re-assure mother and refer	11 (84.6)	12 (0.0)	0.480
Others	2 (13.3)	0 (0.0)	
Immunization challenges related to PCV-10			
Periodic lack of vaccines	11 (84.6)	10 (83.3)	0.999
Lack of supportive educational materials	2 (15.3)	2 (16.7)	
Challenges preventing caregivers from taking children for PCV-10 vaccination			
Distance to the health facility	11 (84.6)	11 (91.7)	0.999
Others	2 (15.3)	1 (8.3)	

Data are presented as number of subjects and proportions, n (%) unless otherwise indicated. Statistical analyses were performed by the ^aFisher's exact and ^bChi-square tests. χ^2 , Pearson's chi-square value; df, degrees of freedom. Values in bold are significant *P*-values.

4.2.3 Attitude levels of healthcare workers on PCV-10 vaccination

The healthcare workers attitude towards PCV-10 vaccine was assessed using six statements on a 5-point Likert scale: +5 (strongly agree) to +1 (strongly disagree) for positive statements, and +1 (strongly agree) to +5 (strongly disagree) for negative statements. The individual Likert scores range was 1-30 with the diploma group having scores of 22-29 and certificate group 19-29.

All health workers in the diploma groups and majority (75.0%) of the certificate holders had a positive attitude towards PCV-10 vaccination. Additional statistical comparisons using the Fisher's exact test showed no statistical significance ($P=0.096$; Table 4.10).

Table 4.10: Health care workers attitude towards PCV-10 vaccination

Attitude, n (%)	Diploma (n=13)	Certificate (n=12)	<i>P</i> -value
Negative attitude	-	-	0.096
Undecided	0 (0.0)	3 (25.0)	
Positive attitude	13 (100.0)	9 (75.0)	

Data presented are number of subjects (n) and proportions (%) of individuals with of negative (≤ 10), undecided (11-20) and positive (21-30) attitude scores. The proportions of negative, undecided and positive attitude scores were compared between the vaccinated and unvaccinated groups using the Fisher's exact test.

4.3 Influence of health care system on the uptake of pneumococcal vaccine

In order to determine the influence of the health care system on PCV-10 delivery and uptake, the rural health facilities were categorized into two groups based on the type of

health facility: 1) district hospital and 2) dispensaries (n=7) and components of the health care system (i.e., equipment, supplies, storage, staffing, schedules, etc.) analysed. A majority of the rural health facilities (87.5%) were dispensaries with only one health facility being a district hospital. On staffing of the health facilities, 25% had one health staff, 50% two staff, and 12.5% had three staff, compared to the district hospital which had 12 health staff (at the MCH department).

While all the health facilities (dispensaries) had a refrigerator, a cold box and a vaccine carrier, 85% of the refrigerators were in good working condition. The district hospital had three functional refrigerators. The type of energy/power to maintain cold chain at the health facilities: 37.5% of the facilities use electricity, 50% use gas cylinders with 12.5% using solar panel/batteries. However, 37.5% of the dispensaries did not have a consistent energy supply whereas the hospital had consistent energy supply. All the facilities offered PCV-10 vaccine at the time of this study. On the availability of PCV10 vaccine since its introduction, 75% health facilities had PCV10 vaccine not available sometimes including the hospital while 25% facilities had the vaccine consistently available.

The proportion of health facilities with up-to-date inventory for vaccines was 85% while 15% did not have. The hospital had up-to-date vaccine/immunization records. Notably, 71.4% of health facilities conducted mobile outreach clinics. The frequency of the outreach clinics was once a month in all the health facilities. Moreover, 75% health facilities indicated that they encountered PCV-10 defaulters with no proper follow-up.

CHAPTER FIVE: DISCUSSION

5.1 Introduction

Pneumococcal diseases are a major public health problem all over the world, with high morbidity and mortality, especially in under-5 children (Abdullahi, 2005), and is responsible for more deaths annually than any other vaccine-preventable bacterial disease (WHO/UNICEF, 2009). Childhood pneumonia in Kenya caused an equivalent of 16% of child mortality in 2008 (Black *et al.*, 2010).

Since the licensure of the 7-valent pneumococcal conjugate vaccine (PCV7) in 2000, many high-income countries have included it in their immunization programmes. However, only a few low- and lower-middle-income countries had introduced pneumococcal vaccine into routine immunization in their childhood immunization programmes (Sartori *et al.*, 2010). Kenya introduced the PCV-10 vaccine in-to its routine immunization schedule in January 2011, becoming the third African country after South Africa and Gambia to introduce the vaccine in her immunization schedule (Scott *et al.*, 2010).

In 1974, as part of its drive towards “*Health for All*”, WHO initiated EPI to improve and expand the scope of the already existing immunization services globally (WHO, 2002). In line with WHO-EPI, Kenya launched KEPI in 1980 with the main objective of reducing morbidity and mortality rates by providing immunization against the targeted diseases to all children in Kenya (WHO, 2002). In order to reach Millennium Development Goal

four of child survival targets, GAPP recommends a 90 per cent coverage rate of pneumonia immunization.

However, pneumonia prevention and intervention targets have not been achieved (Black *et al.*, 2010) and a number of factors have been shown to hinder immunization uptake. The effectiveness of immunization programmes in resource-poor settings has been shown to be influenced by factors such as the coverage of the health network, the existence and quality of outreach services, the liaison of communities with health services, and several other factors that are related to the vaccine in use (Cutt *et al.*, 1989). The relative effect of each one of the above factors may significantly vary according to geographical areas (Carr *et al.*, 2000).

This study describes the determinants of pneumococcal vaccine uptake for children aged 3-12 months in Makindu district, Kenya. The study shows low PCV-10 coverage (78.1%) compared to WHO recommendations for vaccine coverage at 90%. In Makindu district, we found that 21.9% of the children 3-12 months of age were still in need of PCV-10 vaccination. Significant determinants of PCV-10 uptake in this community included marital status, place of child delivery, knowledge on KEPI schedule, knowledge on PCV-10, knowledge on diseases preventable by PCV-10, taking a sick child to hospital for treatment and work related reasons hindering caregiver from taking child for immunization. These results clearly indicate important areas for intervention to improve immunization uptake among the rural hard-to-reach parts in Kenya.

5.2 Caregivers' knowledge, attitude and practices on PCV-10

The Chi-square test, Fisher's exact test and Mann-Whitney test were used for descriptive analyses as appropriate. Caregivers' gender was significantly associated with PCV-10 vaccine uptake, with 98.6% of the vaccinated children belonging to female caregivers. More males caregivers had unvaccinated children compared to their female counterparts. This is probably explained by the fact that mothers have been shown to be better caregivers compared to fathers (Carr *et al.*, 2000). Whereas child gender had no significant impact on PCV-10 uptake in this study, there were slightly more unvaccinated females children (59.8%) than males-child (40.2%). Similarly, in some communities with cultural discrimination against female children, boys have a greater chance to be vaccinated (Nkonki, 2011).

Whereas caregivers' age was not significantly associated with the uptake of PCV-10 vaccine in this study, in other settings maternal age was found to influence vaccine uptake; specifically, children of younger mothers (<24 years) being less compliant (Falagas, 2008), while children with older mothers were more likely to be vaccinated (Ndumbe *et al.*, 2006). The low education level of mothers has been previously associated with low vaccine uptake (Zimmerman *et al.*, 2005). In this study, caregivers' education level had no influence on the child's vaccination status, probably because very few mothers had more than primary school education.

The results revealed that, while majority of the caregivers were Christians (96.0%), religious affiliations were not significantly associated with PCV-10 vaccine uptake.

Although the study findings indicated that majority (57.3%) of the caregivers traveled for over five kilometers to access health facility by walking (62.7%), the distance and mode of transport to the nearest health facilities were not significantly associated with vaccine uptake. Similar studies have identified accessibility as a function of distance and means of transport to have a strong negative influence on immunization uptake (Jani *et al.*, 2008).

This study results revealed that caregivers' knowledge on other childhood vaccines; pentavalent, measles and polio (except BCG) was found to be significant, which is positively related to increased PCV-10 vaccine uptake in the study area. The proportion of individuals with a positive attitude towards PCV-10 vaccination was higher in the vaccinated group (92.1%) compared to the unvaccinated group (85.4%). The high scores on the attitude indicated that caregivers' positive attitude contributed to increased uptake of pneumococcal vaccination in Makindu district. This is also explained by the caregivers understanding of the benefits of immunization and willingness to walk long distances to benefit from health care. A related study (Falagas, 2008) showed that parents' level of knowledge regarding vaccine preventable diseases, along with their beliefs and attitudes towards immunization determined the process of their decision making and health seeking behaviour.

In a multivariate logistic regression model, the results revealed factors predictive of uptake of PCV-10 vaccination in this community. Marital status of caregiver was found to be associated with increased uptake of PCV-10 vaccine, with married caregivers

having 2.0 times higher odds of child vaccination. While majority of the vaccinated children belonged to married caregivers, unmarried (single, divorced or widowed) caregiver had more unvaccinated (30.5%) than the vaccinated (16%) children. This shows that children belonging to single caregivers are more vulnerable to non-vaccination compared to children belonging to married caregivers. However, study findings on childhood vaccination by Mutua *et al.* (2011) showed that marital status was not significantly associated with full vaccination among the informal urban settlements in Nairobi.

The results further revealed that health facility child delivery significantly increased PCV-10 uptake. However, the high proportion of home deliveries (40.6%) observed in this study represents a significant public health concern, especially considering the limited role of traditional birth attendants in the community. Moreover, 95.1% of the unvaccinated children had been delivered at home. This finding is similar to studies (Owino, 2007), in Nairobi's slums which showed that children born at a health facility had 1.3 times higher chance of full vaccination. Hence, the increase in the proportion of deliveries within health facilities will lead to improved vaccine uptake and a better coverage of the KEPI, as it has been previously indicated (Jani *et al.*, 2008).

Caregiver's knowledge on KEPI childhood immunization schedule had 1.8 times higher odds of PCV-10 vaccination, while their knowledge on diseases preventable by the pneumococcal vaccine had 4.6 times higher odds of PCV-10 uptake. Hospital consultation in response to pneumonia infection in children, was also associated with

increased uptake of PCV-10 vaccination. This could probably be explained partly by the caregiver's attitude, that managing pneumococcal infections in children is expensive and tricky, thus they preferred taking them to hospital for treatment.

On the other hand, the odds for work related reasons among caregivers as one of the reasons preventing them from taking children for immunization, were 82% lower than those of other reasons e.g. child sick. This is probably because due to the low socio-economic status, the caregivers have other more pressing challenges that need to be prioritized (Mutua *et al.*, 2011). Thus, exploiting visits for curative care would be a cost-effective way of fully immunizing a child and increasing the KEPI coverage (Jani *et al.*, 2008).

Similarly, lack of vaccines and inconvenient immunization schedules at the health facilities were predictive of low uptake of PCV-10 vaccine in Makindu district. A friendly organization of the health facility and a good co-ordination between fixed and outreach activities could help to reduce the inconvenience and the time spent obtaining vaccination services. Further, a regular supply of vaccines and ensuring uninterrupted energy source would greatly improve vaccine utilization in Makindu district.

5.3 Healthcare workers knowledge and attitude towards PCV-10

Health workers were found to be the major source of information relating to the immunization program in this community. This emphasized their position as healthcare role models in the rural community. This study also revealed that attendance of KEPI

refresher training was significantly higher (83.3%) among certificate healthcare workers than the diploma healthcare workers (38.5%). This is probably due to the assumption that lower cadre healthcare workers need to attend refresher courses as they are considered having less training.

Irrespective of the cadre, all healthcare workers need refresher training in order to be up-to-date with the current knowledge and practices on health care. Knowledge also calls for review of curricula for the various training institutions so as to have standardized information on immunization. Improved knowledge among the HCWs will therefore translate to increased vaccine uptake in this region.

Though HCWs knowledge on management of PCV-10 vaccine contraindication showed no significant association in this study, the issue of side-effects and invalid contraindications of vaccinations continues to affect vaccine uptake. Other studies reviewed also documented that not only caregivers but also healthcare providers were reluctant to vaccinate children with a minor illness, such as mild fever or diarrhoea (Falagas, 2008). Generally the healthcare workers (100% *versus* 75%) had a positive attitude towards pneumococcal vaccination which is associated with increased uptake of the vaccine in this community.

5.4 Healthcare system influence on PCV-10 uptake

Unavailability of vaccines may not only prevent the currently scheduled vaccination, but lead to pessimism and non-adherence in the future, as caregivers assume that there

probably will not be any vaccines on subsequent visits (Schwarz *et al.*, 2009). Hence, vaccine shortages have to be avoided and the government may need to ensure regular supply of PCV-10 vaccine. Low staffing evident at the rural dispensaries is probably related to the long waiting time revealed to influence low vaccine uptake.

The reported inconsistent power source results into vaccines being transported back to the district hospital for safe storage, thus resulting to unavailability of vaccines at these health facilities at the time. Health facility hours for immunization and schedules should be adjusted and the problem of fragmentation of primary services addressed so that accessibility and availability of vaccination can be ensured.

CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS

6.1 CONCLUSIONS

- The low uptake of pneumococcal vaccination among children below one year old in Makindu district was found to be likely because of caregivers work related reasons, periodic lack of vaccines at health facility, inconvenient vaccination schedule and long waiting time at hospital.
- Caregivers had moderate-to-good knowledge of immunization programme, with a positive attitude towards PCV-10 vaccination. However, they faced many barriers to complete their children's vaccination including being busy with other work in place of taking child for immunization and lack of vaccines at the health facilities, among others.
- There were high proportions of diploma healthcare workers with good knowledge of PCV-10 than the certificate cadre of healthcare workers. HCWs in the certificate cadre attended KEPI refresher trainings more than their diploma counterparts. However, generally the healthcare workers had a positive attitude towards immunization.
- There were inconsistent supplies of PCV-10 vaccine at all the health facilities in the district with a marked shortage in staffing. These demonstrated that the healthcare system functioning contributed to the low uptake of immunization in Makindu district. These findings provide important insights into the determinants of PCV-10 uptake and general vaccine coverage that persists despite overall improvement in the use of the pneumococcal vaccination.

6.2 RECOMMENDATIONS

- The Ministry of Public Health and Sanitation should strengthen communication and health education systems to improve awareness concerning newly introduced vaccine and health facility child delivery, among the rural population as this is associated with higher likelihood of child immunization. Special attention should be paid to mothers with home delivery as a BCG at birth is the gateway into the KEPI.
- The strengthening of communication, education and information skills of the healthcare workers is an important step for improving immunization service delivery. Ministry of Public Health and Sanitation through KEPI should ensure cascading trainings on newly introduced vaccines are conducted using updated and standardized training tools so as to maintain uniformity and quality of training in all healthcare workers.
- Ministry of Public Health and Sanitation through KEPI and other health partners in this region should develop an effective approach to ensure regular supply of PCV-10 vaccine as well as other vaccines.
- A good coordination between fixed and outreach activities, including a strong involvement of the CHWs, could help to decrease the caregivers' expense on transport and time spent to obtain vaccination services.

6.3 SUGGESTIONS FOR FURTHER RESEARCH

- To evaluate the effectiveness of PCV-10 in protection against pneumococcal disease causing *Streptococcal pneumoniae* serotypes prevalent in the country.
- There is need for a longitudinal study to evaluate the impact and long-term benefits of the PCV-10 vaccine in Kenya.

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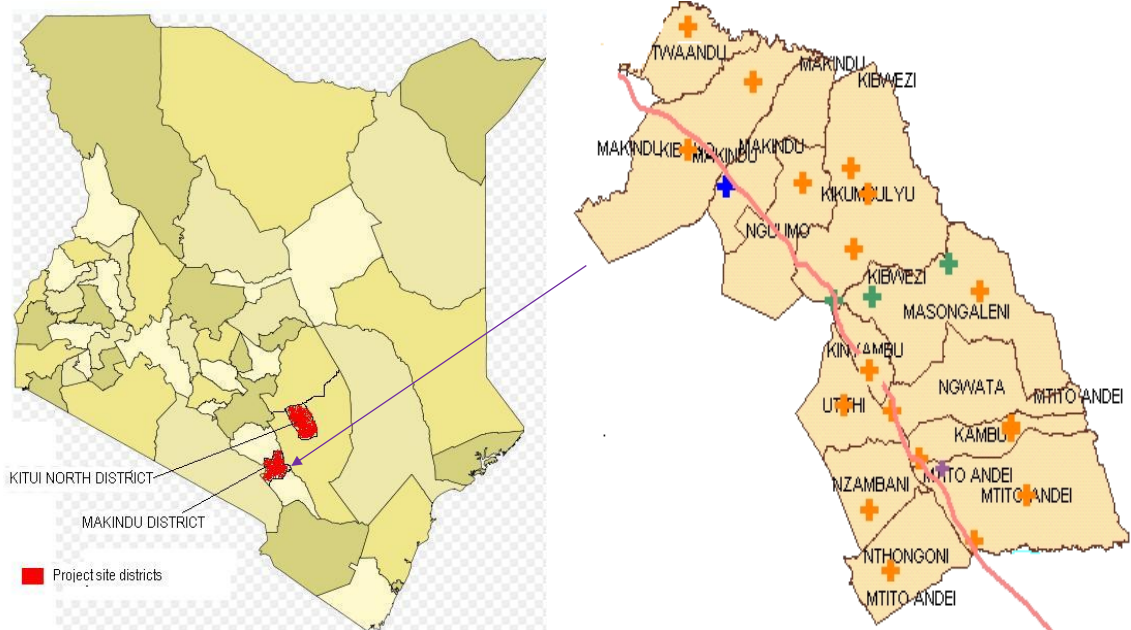
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APPENDICES

APPENDIX 1: Map of Kenya showing location of Makindu district (study area)



APPENDIX 2: Consent form

Study Title: *Determinants of pneumococcal conjugate vaccine (PCV-10) uptake at Makindu district, Kenya.*

Introduction

Hallo, my name is Felisters M. Mutisya, a postgraduate student at Kenyatta University working with AMREF. I wish to conduct a survey to assess the knowledge, attitude and practices on Pneumococcal Conjugate Vaccine among caregivers and healthcare workers. I wish to request for your participation and co-operation in answering the questions. The information you give will not be used against you in any way but will be used to improve immunization programmes in Kenya.

The aim and objectives of the study have been sufficiently explained to me. I have not been pressurized to participate in any way. I understand that participation in this study is completely voluntary and that I may withdraw from it at any time and without any adverse consequences. I am fully aware that the results of this study will be used for scientific purposes and may be published. I consent to participate in this study, provided my privacy and confidentiality is guaranteed.

Signature of informant:

Date:

Signature of Investigator :

Date:

APPENDIX 3: Interview Schedule for caregivers

Study Title: *Determinants of pneumococcal conjugate vaccine (PCV-10) uptake at*

Makindu district, Kenya.

Questionnaire number

Name of interviewer Date

Location Sub-location Village

Introduction

Hallo, my name is Felisters Mutisya, and I am interested in knowing more about knowledge, attitude and practices on the PCV 10 vaccine uptake among caregivers of children 1yr. and below. The information you will give is very important and therefore, I request for your cooperation and sincerity when responding to the questions. I assure you that the information received will be treated with utmost confidentiality.

Instructions: Please give all information required. Please tick as appropriate in the spaces provides and fill in the appropriate responses where necessary.

I. Respondents demographic data

1. Caregiver age in years.....

2. Gender Male [] Female []

3. Education level None [] Secondary []

 Primary [] Completed secondary []

 Completed primary [] Tertiary []

14. At what age is a child supposed to be fully immunized?

9 months 1 year

2 years 5 years

15. Have you ever had any training on pneumococcal vaccine? (if no, go to Qn.17).

Yes No

16. From where did you get the training on pneumococcal vaccine?

Chief's baraza Children from school

Health facility Social gatherings

17. Name the vaccines a child is supposed to be given

a. BCG c. Pentavalent e. Measles

b. Polio d. PCV-10 f. Other specify.....

18. Have you heard of the pneumococcal vaccine? Yes no

19. What diseases does the pneumococcal vaccine prevent?

a. Pneumonia

b. Otitis media

c. Acute Respiratory Infections

d. Don't know

e. Other specify

20. How many doses of PCV-10 should a child be given?

After receiving one dose of PCV-10

After receiving three doses of PCV-10

When the child is one year old

I don't know

I'll read for you some sentences, please give your response as True, false or otherwise.

21. There is no effective vaccine for pneumonia.

True [] False [] Don't know []

22. A child may develop slight fever or rash following immunization with PCV-10.

True [] False [] I don't know []

III. Respondents practices in relation to PCV-10 immunization

23. Has your child received the pneumococcal vaccine? (*confirm from immunization card*) (if 'yes' skip Qn 27, if 'no' skip Qn 24 &25).

Yes [] no [] Don't know []

24. At what age did your child receive the pneumococcal vaccine?

Before 4 months [] Before 1 year [] Don't know []

25. If vaccinated, how many doses?

One [] two [] three [] Don't know []

26. What would you do if your child suffers from pneumonia (cough, difficult breathing, fever)?

Treat the child at home []

Take the child to herbalist []

Take the child to hospital []

27. What reasons would probably prevent you from presenting your child for pneumococcal immunization?

- a) Busy with other work []
- b) Never heard of the of pneumococcal vaccine []
- c) Religion does not allow []
- d) Child was sick []
- e) Fear of side effects []
- f) Do not belief in immunization []
- g) Rumours about the vaccine []
- h) Long distance to the immunizing facility []
- i) No response []

28. What problems at the health facility would probably prevent your child from getting pneumococcal vaccine?

- a) Attitude of health workers []
- b) Lack of vaccines []
- c) Lack of staff []
- d) Days of immunization inconvenient []
- e) Not reminded by health staff when to return[]
- f) Long waiting time at the clinic []
- g) No response []

29. In your opinion, what do you think can be done to improve your ability to take your child for immunization?

- a).....
- b).....

IV. Respondents attitude towards PCV-10 immunization.

Here are a number of statements. Please state whether you agree with them, disagree with them or you don't know.

Attitude test- statements	Strongly agree	Agree	Undecided	Disagree	Strongly disagree
30. Children do not necessarily require PCV-10 vaccination.	(+1)	(+2)	(+3)	(+4)	(+5)
31. I do not trust vaccinations	(+1)	(+2)	(+3)	(+4)	(+5)
32. I am scared of vaccination because it may harm my child	(+1)	(+2)	(+3)	(+4)	(+5)
33. It is expensive to manage pneumococcal infections in children.	(+5)	(+4)	(+3)	(+2)	(+1)
34. I wish to learn more about pneumococcal vaccine and immunization	(+5)	(+4)	(+3)	(+2)	(+1)
35. The health workers attending to my child are friendly.	(+5)	(+4)	(+3)	(+2)	(+1)

END: Thank you very much for completing the questionnaire accurately and God bless you!

5. Does the health facility have the following equipment?

	Equipment	Yes	No	Remarks/condition
1.	Refrigerator			
2.	Cold boxes			
3.	Vaccine carriers			
4.	Ice packs			

6. Does the facility have power source which is available consistently when services are being offered? Yes[] no[]

c) Medicine and supplies logistics

7. Does the facility have 100% of offered vaccines available the day of the facility visit?

Yes[] no[]

8. Does the facility have an up-to-date inventory for vaccines and medicines?

Yes[] no[]

9. How has the availability of PCV-10 vaccine been since it was introduced?

Always[] sometimes[] rarely[] not at all[]

10. Does the facility have first-in first-out stock storage for vaccines to minimize drug expiration?

Yes[] no[]

11. Does the facility have all vaccines stored under conditions conducive to maintain

quality of items? Yes[] no[]

d) Management

12. Supervision by DHMT at this health facility? Yes [] No []
13. If yes, how often? Monthly [] 3 monthly [] 6 monthly [] not at all []
14. Does the facility have all staff having received continued education on PCV-10 vaccine?
 Yes [] no []
15. Does this facility offer preventive child and maternal services?
 Yes [] no []
16. What is the immunization administration schedule PCV-10 vaccine at this facility?
 daily [] weekly [] N/A []
 monthly [] twice wkly []
17. Are mobile immunization outreach clinics carried out? Yes [] No []
18. If yes, how often in a year? Monthly [] 3 monthly [] 6 monthly [] N/A []
19. How are vaccines transported during outreach clinics?
 Cold boxes [] vaccine carriers []
 ice packs [] other (specify).....
20. How do they handle used and remaining vaccines after an outreach exercise?
 Label and return to refrigerator for future use []
 Throw them after the exercise []
 Dispose used vaccines appropriately []
21. Any defaulters of pcv-10 vaccine encountered? Yes [] no []
22. Does the facility involve community members as routine participants in reviewing administrative issues in the facility? Yes [] no []

10. What was the duration of the training? 2 weeks[] 1 week []
 3 days [] 2 – 1 day []
 less than 1 day[] N/A []

11. If no, what were the reasons for having not received any training?

- I was not selected [] I was not interested []
 No funds [] Time was not available[]
 No need for training [] Others (specify)

N/A []

b) Knowledge on PCV-10 vaccination.

12. What is a pneumococcal infection?

A *Streptococcus pneumoniae* infection []

A *Haemophilus influenzae* infection []

Fungal infection []

I don't know []

13. Who are mostly at risk of pneumococcal infections?

Children below 2 years []

Children below 3-5 years []

The elderly >65 years []

Pregnant mothers []

I don't know []

14. Name some of the pneumococcal infections preventable by PCV-10.

Pneumonia [] Otitis media []

Meningitis [] Don't know []

RTIs []

15. How can you tell whether a PCV-10 vaccine vial is potent/ not expired?

Check the VVM []

Check expiry date []

Shake method []

16. Once immunized with PCV-10, a child cannot suffer from pneumococcal infections again.

True [] False []

17. At what age should a child receive PCV-10?

Anytime before he/she is 1 year old []

At 6, 10 and 14 weeks of age []

Anytime before 2 years old []

I do not know []

18. How many doses of PCV-10 vaccine should a child be given?

1 dose [] 3 doses []

2 doses [] I don't know []

19. What should be done to a child who severely reacts to a PCV-10 injection?

Re-assure the mother []

Report immediately to superiors []

Give the child the remaining doses as required []

Refer the child for further management []

I don't know []

20. In your opinion, what immunization challenges are related to the new PCV-10 vaccine at this health facility?

Periodic lack of vaccines []

Interrupted power to sustain cold chain []

Lack of supportive education tools []

Lack of motivation to staff []

21. In your opinion, what factors prevent mothers from bringing their children for PCV-

10 vaccine? Distance to the health facility []

Defaulting []

Fear of side effects []

Too many vaccines at one []

Education level of caregiver []

c) Attitude towards PCV-10 vaccination.

Attitude test- statements	Strongly agree	Agree	Undecided	Disagree	Strongly disagree
22. Caregivers do not necessarily require health education on PCV-10 vaccine.	(+1)	(+2)	(+3)	(+4)	(+5)
23. Mothers who bring dirty children for immunization should be sent back to clean them.	(+1)	(+2)	(+3)	(+4)	(+5)
24. Mothers who come to the clinic late should be attended to last.	(+1)	(+2)	(+3)	(+4)	(+5)
25. Children do not necessarily require the PCV-10 vaccine.	(+1)	(+2)	(+3)	(+4)	(+5)
26. Immunization services at the health facility are easy to offer.	(+5)	(+4)	(+3)	(+2)	(+1)
27. I wish to learn more about the pneumococcal vaccine.	(+5)	(+4)	(+3)	(+2)	(+1)

28. Any additional information (observed)

.....

APPENDIX 6: Research authorization letter

REPUBLIC OF KENYA

**NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY**

Telegrams: "SCIENCETECH", Nairobi
 Telephone: 254-020-241349, 2213102
 254-020-310571, 2213123
 Fax: 254-020-2213215, 318245, 318249
 When replying please quote

P.O. Box 30623-00100
 NAIROBI-KENYA
 Website: www.ncst.go.ke

Our Ref: **NCST/RRI/12/1/MED-011/181/4**

Date:
30th November, 2011

Felisters Mbithe Mutisya
 Kenyatta University
 P. O. Box 43844
 NAIROBI

RE: RESEARCH AUTHORIZATION

Following your application for authority to carry out research on "*Determinants of the uptake of pneumococcal conjugate vaccine (PVC-10) in Makindu District, Kenya*" I am pleased to inform you that you have been authorized to undertake research **Makindu District** for a period ending **30th June, 2012**.

You are advised to report to **the District Commissioner & the District Education Officer, Makindu District** before embarking on the research project.

On completion of the research, you are expected to submit **one hard copy and one soft copy** of the research report/thesis to our office.


P. N. NYAKUNDI
FOR: SECRETARY/CEO

Copy to:

The District Commissioner
 Makindu District

The District Education Officer
 Makindu District