

**FACTORS ASSOCIATED WITH INCOMPLETE VACCINATION
AMONG CHILDREN 12-23 MONTHS AT ALUPE SUB-COUNTY
HOSPITAL, BUSIA COUNTY, KENYA**

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**Factors associated with incomplete vaccination among
children 12-23 months at Alupe Sub-County Hospital, Busia
County, Kenya**

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**A thesis submitted in partial fulfillment for the degree of Master of
Science in Applied Epidemiology in the Jomo Kenyatta University of
Agriculture and Technology**

2019

DECLARATION

I declare that this thesis is my original work and has not been submitted in any other university for the award of a degree

Signature: Date:

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This thesis has been submitted for examination with our approval as university supervisors

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DEDICATION

I dedicate this work to my family for their steadfast support and to my many teachers for their patience and guidance over the years.

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TABLE OF CONTENTS

DECLARATION.....	ii
DEDICATION.....	iii
ACKNOWLEDGEMENT.....	iv
TABLE OF CONTENTS.....	v
LIST OF TABLES	viii
LIST OF FIGURES	ix
LIST OF APPENDICES	x
ABBREVIATIONS AND ACRONYMS.....	xi
DEFINITION OF TERMS.....	xiii
ABSTRACT.....	xiv
CHAPTER ONE	1
INTRODUCTION.....	1
1.1. Background Information.....	1
1.2. Problem Statement	3
1.3. Justification of the study	4
1.4. Objectives.....	5
1.4.1. General Objective	5
1.4.2. Specific Objective.....	5
CHAPTER TWO	7

LITERATURE REVIEW.....	7
2.1. Global progress of the expanded program on immunization	7
2.2. Challenges in immunization coverage	9
2.3. Contextual risk factors for under/non vaccination	10
2.4. Current strategies for improving immunization coverage in Africa	11
2.5. Conceptual framework	13
CHAPTER THREE	14
MATERIALS AND METHODS	14
3.1. Study Site	14
3.2. Study population.....	15
3.3. Study design	16
3.4. Sample size determination.....	16
3.5. Sampling plan.....	18
3.6. Case definition.....	20
3.7. Case selection	20
3.8. Control selection.....	20
3.9. Inclusion Criteria	20
3.10. Exclusion Criteria.....	21
3.11. Data management	21
3.11.1 Data collection	21
3.11.2 Data entry.....	21
3.11.3 Data analysis	21
3.11.4 Data dissemination.....	22

3.12. Variables.....	22
3.13. Ethical Considerations.....	23
CHAPTER FOUR.....	24
RESULTS	24
4.1. Retrospective records review	24
4.2. Case control study	25
4.2.1. Study participants	25
4.2.2 Univariate analysis.....	25
4.2.3. Bivariate Analysis.....	31
4.2.4 Multivariate Analysis.....	37
CHAPTER FIVE.....	39
DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS	39
5.1. Discussions.....	39
5.2. Conclusions	42
5.3. Recommendations	42
REFERENCES.....	43
APPENDICES	50

LIST OF TABLES

Table 3.1: Results of sampling process	18
Table 4.2: Univariate analysis of parental characteristics (Mothers N-182, Fathers N-180)	27
Table 4.3. Univariate analysis of health facility access.....	28
Table 4.4. Univariate analysis of health system utilization.....	28
Table 4.5: Univariate analysis of sources of immunization information, education and communication	30
Table 4.6: Univariate analysis of reasons for non-vaccination	30
Table 4.7: Bivariate analysis for socio-demographic characteristics for completion of vaccination	31
Table 4.8: Bivariate analysis of fathers' characteristics.....	33
Table 4.9: Bivariate analysis of mothers' characteristics.....	34
Table 4.10: Bivariate analysis of health facility access	35
Table 4.11: Bivariate analysis of health system utilization.....	36
Table 4.12: Analysis of immunization information sources	37
Table 4.13 Best fit model after multivariate analysis.....	38

LIST OF FIGURES

Figure 2.1: DPT coverage in Kenya, WHO AFRO region and the world, 1980-2017 (WHO, 2018)	8
Figure 2.2: Conceptual framework.....	13
Figure 3.1: Map of Kenya showing location of Alupe Subcounty Hospital	15
Figure 3.2: Sampling plan for the case control study.....	19
Figure 4.1: Comparison of vaccine uptake in DHIS and Health Facility Register	24

LIST OF APPENDICES

Appendix I: Consent Form for Mother or Care-Giver of Study Child.....	50
Appendix II: Immunization Completion Rate Questionnaire	52
Appendix III: KNH/UON-ERC Letter of approval.....	59
Appendix IV: Research proposal approval.....	60
Appendix V: Publication	61

ABBREVIATIONS AND ACRONYMS

ANC	Ante-Natal Clinic
BCG	Bacille-Calmette-Guerrin
CHW	Community Health Worker
DCAH	Division of Child and Adolescent Health
DHIS	District Health Information System
DVI	Division of Vaccines and Immunization
DTP/DPT	Diphtheria, Pertussis, Tetanus
DVI	Division of Vaccine and Immunization
EPI	Expanded Program on Immunization
FIC	Fully Immunized Child
GAVI	Global Alliance
GIVS	Global Immunization Vision and Strategy
HCW	Health Care Worker
KDHS	Kenya Demographic Health Survey
KEMRI	Kenya Medical and Research Institute
KEPI	Kenya Expanded Programme on Immunization

KHBIS	Kenya Household Budget Indicator Survey
MCH	Maternal and Child Health
MDGs	Millennium Development Goals
MICS	Multiple Indicator Cluster Survey
MOH	Ministry of Health
OPV	Oral polio vaccine
REC	Reach Every Child
RED	Reach Every District
SCH	Sub-County Hospital
SDH	Sub District Hospital
UNICEF	United Nations Children Fund
VPDs	Vaccine Preventable Diseases
WHO	World Health Organization

DEFINITION OF TERMS

- BCG coverage:** percentage of births who received one dose of Bacillus Calmette Guerin vaccine.
- Polio 0 coverage:** percentage of surviving infants who received the birth dose of polio containing vaccine.
- Polio 3 coverage:** percentage of surviving infants who received the 3 doses of polio containing vaccine.
- DTP1 coverage:** percentage of surviving infants who received the 1st / 3rd dose, respectively, of diphtheria and tetanus toxoid with pertussis containing vaccine.
- DTP3 coverage:** percentage of surviving infants who received the 1st / 3rd dose, respectively, of diphtheria and tetanus toxoid with pertussis containing vaccine.
- IPV 1 coverage:** percentage of surviving infants who received at least one dose of inactivated polio vaccine.
- IPV 2 coverage:** percentage of surviving infants who received at least two doses of inactivated polio vaccine.

ABSTRACT

Immunization is a proven and cost effective intervention for the reduction of vaccine preventable diseases. Significant progress was made to increase global immunization coverage between 1980 and 1990 however since then global DPT 3 has stagnated at about 85%. The number of deaths caused by traditional vaccine-preventable diseases (diphtheria, measles, neonatal tetanus, pertussis and poliomyelitis) has fallen from an estimated 0.9 million in 2000 to 0.4 million in 2010. Despite this progress, many regional, national and sub-national coverage discrepancies persist and overall about 20 % of children remain inadequately immunized. This study sought to determine factors associated with incomplete vaccination among children 12-23 months who had received at least one childhood vaccine at Alupe Sub-District Hospital. The study site was chosen due to its low immunization coverage in a county with generally high immunization coverage rates. Facility and National Health Information System immunization coverage data were compared. A case control study was then conducted to determine significant contextual risk factors for the incomplete vaccination among children 12-23 months. Data was collected through an interviewer administered structured questionnaire. Data was analyzed by Epi Info 3.5.4. Ethical clearance was obtained from the Kenyatta National Hospital Ethics and Scientific Review Board. Independent risk factors for incomplete vaccination were age of the child [aOR 4.2(1.8-9.6)], age of the mother [aOR 2.5(1.1-5.0)], timely receipt of BCG [aOR 3.2(1.4-7.3)] and receipt of at least 2 doses of tetanus toxoid by the mother during the antenatal period [aOR 2.5(1.2-5.4)]. Strategies to improve completion rates should target younger mothers during the antenatal period to increase contact with the health system so as to encourage hospital delivery and subsequently early initiation of the immunization schedule.

CHAPTER ONE

INTRODUCTION

1.1. Background Information

Reduction of child morbidity and mortality is one of the key planks of global development (Sustainable Development Goal 3)(United Nations, 2019).Key interventions in reduction of child morbidity and mortality are improved water, sanitation and hygiene, immunization, improved nutrition and judicious use of antibiotics. Immunization is a proven and cost effective intervention for reduction of child mortality(The Partnership for Maternal, Newborn and Child Health 2011; UNICEF 2016). The early success of the smallpox eradication program 1967-1977 inspired the global health community to introduce the Expanded Program on Immunization (EPI) in 1974(WHO, 2013a). The World Health Assembly meeting at Alma Ata (USSR) in 1978 further strengthened the global resolve to expand the reach of vaccines to more children(WHO & UNICEF, 1978). In Kenya, the Kenya Expanded Program on Immunization(KEPI) was launched in 1980(MOH, 2013; MoPHS, 2015). By 1990, 80% of the world's children were fully immunized. However, after the success of the 1980s, performance began to lag behind in the 1990s. Efforts to rectify this scenario were initiated with assistance from the Gates Foundation in 1999. The Foundation donated US \$ 750 million which led to the inception of the Global Alliance on Vaccines Initiative (GAVI) in 2000. Consequently, two strategies to increase immunization access have been adopted by WHO and global health partners. The global immunization vision and strategy (GIVS) 2002-2015 aimed at attaining the fourth millennium development goal (MDG4) to reduce under- five mortality rate by two thirds of 1990 levels while the Decade of Vaccines 2016-2020 which was endorsed in 2012 is meant to drive the objectives of the sustainable development goals(SDGs).

Since the inception of EPI, polio infections have dropped by 99% and eradication is now in sight, five million people have escaped paralysis, measles cases have dropped by 78% and neonatal tetanus has been eliminated in 20 out of 58 countries (WHO,2013).

The number of deaths caused by traditional vaccine-preventable diseases (diphtheria, measles, neonatal tetanus, pertussis and poliomyelitis) has fallen from an estimated 0.9 million in 2000 to 0.4 million in 2010. Global vaccination completion rate in 2015 was 86%. In Kenya completion rate was 71.1% in 2014(KDHS, 2014).

However, in spite of these advances, widespread inter-country and intra-country immunization disparities persist. In 2012, an estimated 6.6 million children died before their fifth birthday due to vaccine preventable diseases globally. In 2016, 19 million infants remain under-immunized. Almost 20% of children in GAVI supported countries were not fully immunized (WHO/UNICEF). In Kenya, almost 30% of children under - five years were not fully immunized while 4 in every 100 infants died before their first birthday (KDHS, 2014).

To address these concerns, the 194 Member States of the World Health Assembly in May 2012 endorsed the Global Vaccine Action Plan 2002-2015 with the goal of increasing immunization coverage at national level to $\geq 90\%$ and $\geq 80\%$ at district level through the RED (Reaching Every District) strategy by improving outreach services and supportive supervision, linking services to the community, monitoring and use of data for action and improved planning and management of resources. Subsequently, reaching every child in every community with all available immunizations was adopted as part of the Decade of vaccines declaration 2016-2020. The plan envisages that countries would attain universal immunization coverage with all available vaccines in all communities by the year 2020. This is in recognition of the fact that the full benefit from vaccination is derived from timely completion of all required vaccines by the index child and by a

majority of eligible children in a community. This will also help nations achieve the objectives of the health-related sustainable development goals.

To be able to reach all children in all communities, it is vital to identify communities with low immunization indicators and subsequently to identify the reasons why children are not completing their vaccinations so as to design effective and efficient interventions to remedy the underperformance. Discrepancies in national and facility data however present great challenges for program/ policy decision making. Periodic cross sectional surveys would help solve this dilemma but most including the Kenya Demographic Health Survey (KDHS) , Kenya Household Budget Indicator Survey (KHBIS) and the multiple indicator cluster survey (MICS) are often national or county level assessments which fail to pick out immunization performance at a more basic level such as health facility catchment or community/village level. The WHO recommends a cluster survey approach(WHO,2015). This is resource intensive and also requires a lot of technical know-how. The present study proposes a simpler cost-effective approach that can be used by facilities and local health authorities for operational research to improve their immunization performance especially where facility access is not a major impediment to immunization services as indicated by high rates of BCG/birth polio coverage rates.

1.2. Problem Statement

Immunization services have dramatically improved over the last 40 years however almost 20% still remain either unvaccinated or under-vaccinated. This has been attributed to failure to reach children disadvantaged by various reasons including physical distance, demographic, socioeconomic and health facility utilization. Artefactual underperformance due to under-reporting has however been noted to affect program decision making. To programmatically address these immunization challenges, it is critical to identify regions or facilities with reporting as well as immunization indicator underperformance. This can be done through periodic evaluation of indicator data in the routine Health Information System and comparison with national/sub-national surveys. Information generated from these evaluations however is population

based and does not identify individual risk factors for incomplete immunization. In order to identify these factors, the WHO recommends use of cluster sampling at community level. Lot quality assessments have also been utilized to identify individual risk factors. The present study proposes a facility based operational research approach for facilities where facility access is not a problem.

1.3. Justification of the study

From the Kenya Health Information System, Teso South Sub-county had low childhood vaccination completion rates compared to contiguous sub-counties in Busia County. The largest facility in the sub-county, Alupe SDH, had even lower immunization completion rates (43 % in 2012). The area borders Uganda where immunization services are generally performing sub-optimally. This places individuals and the community served at large at high risk of VPDs due to the accumulation of at-risk population and low community herd immunity. As a border district, poor immunization performance exposes it to trans-boundary disease outbreaks. This also puts the rest of the country as a whole at risk of vaccine preventable diseases.

Evaluating the modifiable risk factors associated with low immunization completion rates is vital in designing new programs or modifying current programs to ensure greater immunization coverage as a means to attaining millennium development goal 4 of reducing child mortality by two thirds of 1990 level by 2015. Increased vaccination completion rates will protect the individual child against vaccine preventable morbidity and mortality. It will also increase communal herd immunity and hence protect the local community from disease and reduce health related expenditure at all levels. The study will expound on the interplay of various determinants of full vaccination in this setting and also add to current knowledge on context specific risk factors for low vaccination completion rates in the country. While national immunization program (KEPI) gives general guidelines on implementation of immunization services, identification of specific contextual determinants of complete vaccination will help in contextualized re-planning

of immunization services in the study area. This will ensure efficiency and effectiveness of local immunization programs.

The present study adopted two methodological approaches. First, a retrospective data review was conducted to evaluate the accuracy of data reported at national level. Secondly, a case control study was conducted to determine statistically significant factors associated with incomplete immunization since study population and outcome data was readily available from the MCH immunization register. Similarly, due to resource and technical capacity constraints at facility and sub-national levels to conduct the recommended WHO cluster surveys and riding on the expanded reach of community health workers/volunteers, the present study represents a simple, statistically valid approach for facilities to improve their vaccination completion rates.

1.4. Objectives

1.4.1. General Objective

To determine factors associated with incomplete vaccination among Kenyan children 12-23 months who had received at least one basic childhood vaccine at Alupe Sub County Hospital, Busia County Kenya, between the period 1st September 2012 and 31st August 2013.

1.4.2. Specific Objective

The specific objectives for this study were:

1. To determine immunization completion rates at Alupe SCH and compare it with routine HMIS data.
2. To describe the socioeconomic and demographic characteristics of the study population.
3. To determine health service access factors associated with incomplete vaccination in the study area.

4. To determine factors related to health utilization that were associated with incomplete vaccination coverage at the Alupe Sub District Hospital, Busia County Kenya.
5. To establish the subjective parental/care givers reasons for incomplete vaccination

CHAPTER TWO

LITERATURE REVIEW

2.1. Global progress of the expanded program on immunization

Reduction of child mortality has been a key thrust of global health interventions over the years. One of the tested and widely accepted and effective ways of achieving this has been through immunization programs (Andre *et al.*, 2008). The expanded program on immunization was established in 1974 through World Health Assembly resolution 27.57 aiming to ride on the success of the smallpox eradication program between 1967-1977. The program targeted universal access to vaccines against 6 diseases namely tuberculosis, polio, diphtheria, whooping cough, tetanus and measles. Today many countries have added to their schedules vaccines against Haemophilus influenza Type B, hepatitis B, pneumococcal disease and rotavirus. Globally and across WHO regions and member states complete vaccination coverage, measured by DPT3 coverage, increased rapidly during the period 1980-1990. However, from 1991 to 1999 coverage stagnated and even dropped in some countries. This led to the launch of the Global Alliance for Vaccines Initiative (GAVI) that spurred a modest increase in coverage during the first decade of the century. Despite all these efforts almost 20% of the world's children have remained un- or under immunized from 2010 to date (**Figure 2.1**).

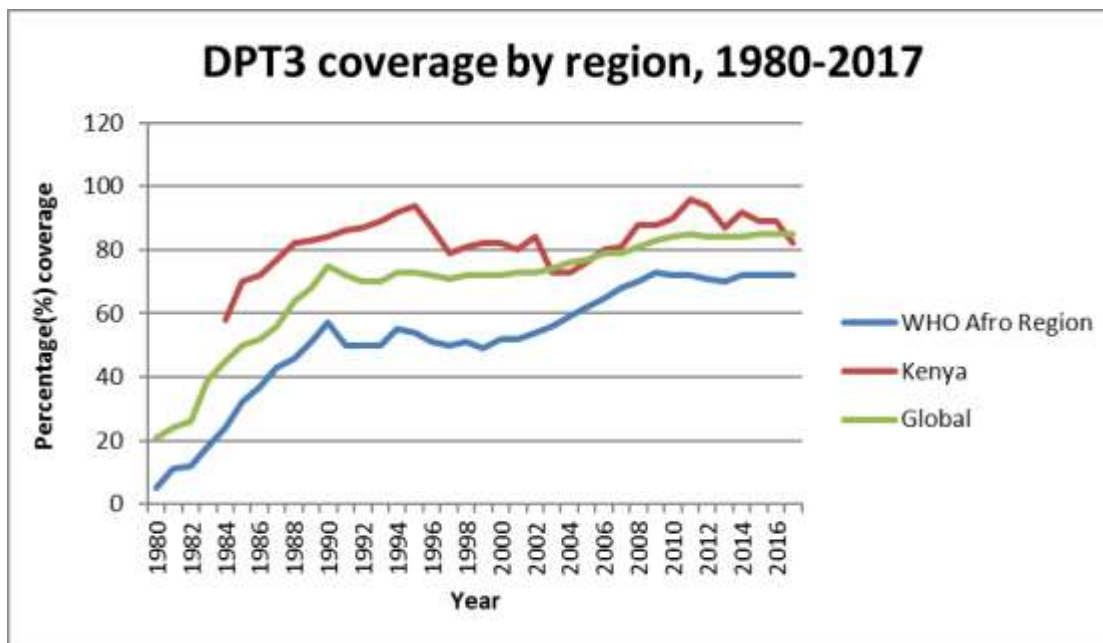


Figure 2.1: DPT coverage in Kenya, WHO AFRO region and the world, 1980-2017 (WHO, 2018)

Nonetheless polio infections have dropped by 99%, 5 million people have escaped paralysis due to polio, between 2000-2008 measles cases dropped by 78% and the disease is now targeted for elimination while maternal and neonatal tetanus has been eliminated in 20 out of 58 high risk countries and has saved many lives. The global immunization vision and strategy launched in 2006 targeted to increase access to high quality vaccines across all ages in the context of global interdependence(WHO, 2013b). By 2010, 85% of children globally had received DPT3. However, despite all these advances many areas of the world remain at high risk of vaccine preventable diseases especially in Africa and Asia(United Nations, 2013). In these areas of the world, though overall (<) 5 year mortality has declined, more deaths are occurring among neonates, the poor, unimmunized or partially immunized and among children with illiterate mothers.

The global health observatory estimates for 2008 show communicable diseases accounted for 71.1% of the disease burden in Africa and 71.8% in Kenya. Measles accounted for 1%, diarrhoea 21% and pneumonia 16%. According to the Kenya

Demographic and Health Survey conducted during 2008-09, measles coverage in Kenya was 85% while full vaccination coverage was 77%. A key focus of the global action plan against pneumonia and diarrhoea is the identification of groups at greater risk or missed by services and development of targeted approaches to reach them. Key to identification of these groups is the utilization of accurate and reliable health information system data to flag out facilities and regions with poor immunization indicators.

2.2. Challenges in immunization coverage

The reliability of immunization program data has unfortunately been a challenge in many GAVI supported countries which are mainly low income countries(Ozawa, et al., 2016). Discrepancies between national and facility immunization data have been attributed to weak monitoring systems which include the inconsistent use of monitoring charts; inadequate monitoring of vaccine stocks, injection supplies and adverse events; unsafe computer practices; and poor monitoring of completeness and timeliness of reporting(Ronveaux *et al.*, 2005). In a study in Tunisia, over-reporting or under-reporting of doses being administered in all health facilities was noted(Chahed, Bellali, Alaya, Mrabet, & Mahmoudi, 2013). Similar differences were found in Mozambique for all vaccine types at facility and district levels yet supervision focused on criticism and consistency checks but not data quality(Mavimbe, Braa, & Bjune, 2005). Other sources of data discrepancies are denominator and numerator challenges(Global Alliance for Vaccines and Immunisations, 2006; WHO, 2012). To identify high risk children, there is need to evaluate routine program data to isolate low performing regions. This implies that data quality should be good for program data to be reliable for decision and policy making. Once low performing regions are identified then risk factors for non/under immunization can be determined through appropriate operational research. Many studies have been done to elicit these risk factors however the relevance of each particular risk factor may vary by geographical, religious or socio-demographic context.

2.3. Contextual risk factors for under/non vaccination

A review of polio outbreaks between 1976 to 1995 clearly demonstrated the role of clusters of immunization refusals (Patriarca, Sutter, & Oostvogel, 1997). In Oman (1988), Namibia (1988), Jordan (1991-92), Bulgaria (1991), Taiwan (1982), Canada (1982), Netherlands (1982) and Kenya (2011), the outbreaks occurred in populations with otherwise high overall coverage rates with clusters of immunization refusals such as Gypsies and some religious sects. In India , gender and household inequalities were major determinants of vaccination completion.(Singh, 2012) In Pakistan, maternal literacy was a major factor associated with low completion rates(Owais, Hanif, & Siddiqui, 2011).In Gambia with a national vaccination coverage >90% , the main determinants of incomplete vaccination were residence in rural areas and originating from the Mandika ethnic group (Payne, Townsend, Momodou, & Yamundou, 2013).In rural Nigeria , the completeness of vaccination was significantly correlated with knowledge of mothers on immunization and vaccination at a private health facility.(Odusanya, Alufohai, & Meurice, 2008).In Ethiopia, factors associated with full vaccination were antenatal care follow-up , being born in a health facility , mother's knowledge about age at which vaccination begins and ends.(Belachew & Wakgari, 2012) Predictors of defaulting from full vaccination in Ethiopia were: Knowledge of the mothers about child immunization, monthly family income, postponing child vaccination and perceived health institution support.(Gedlu & Tesemma, 1997; Tadesse, Deribew, & Woldie, 2009)

Studies in Kenya in areas with similar characteristics as Teso South have identified several determinants of low immunization completion. In Kaptebwa location of Nakuru district which is a peri-urban low class and high poverty area , predictors of full vaccination included number of children within the family, place of birth of the child, advice on date of next visit for growth monitoring and opinion on the health immunization services offered(Maina, Karanja, & Kombich, 2013). In Kilifi which is predominantly rural and poor , distance from health facility , family size and rainy seasons were the main determinants(Ndiritu *et al.*, 2006). A study conducted in Mathare

slums of Nairobi , the immunization status was significantly influenced by the maternal age, ethnicity, presence of child welfare card at home , ignorance on need for immunizations and on return dates, fear of adverse events following immunization, negative attitude of health care providers and missed opportunities(Owino *et al.*, 2009).

In 2009, the World Health Organization commissioned two systematic reviews of both published and grey literature to determine factors associated with non-vaccination(Favin, Steinglass, Fields, Banerjee, & Sawhney, 2012; Rainey *et al.*, 2011). Risk factors identified were distance from the nearest health facility, poverty and mothers' education. Associated factors identified were bad experiences at health facility/outreach), competing priorities/too busy, missed opportunities to vaccinate, fears/rumors, lack of appreciation of basic benefit of vaccination and lack of understanding (e.g. of need for multiple doses, when and where to return).

This information is vital in designing and targeting interventions. However due to the differences in relative importance of these identified factors across countries and within countries, investigation of all unique clusters of low/no vaccination is necessary(Aharona & Nichols, 2012; Curtale, Perrelli, & Mantovani, 2010).

2.4. Current strategies for improving immunization coverage in Africa

Studies conducted in different countries across the continent have identified numerous strategies that have been associated with routine immunization (RI) service improvement. LaFond and colleagues assessed strategies that correlated with improved RI performance in Ethiopia, Cameroun and Ghana(LaFond *et al.*, 2015). They found four direct and two enabling drivers of improvement. Direct drivers were: the availability of paid cadre of community-centered health workers, stakeholder engagement in planning and execution of immunization services, raise awareness and define strategies to reach all children, data use for performance improvement and adapting services to community needs. Enablers of RI improvement were found to be: political and social commitment to routine immunization and national and local-level

support provided by development agencies through funding, technical advice, capacity building, and commodities and equipment.

Further work in Cameroun by Russo and colleagues, identified key strategies for RI improvement as strengthening of ANC services, improvement of parents' information and attitude towards immunization and targeting younger parents and families living far away from vaccination centers using appropriate communication strategies(Russo *et al.*, 2015a).

In urban slums, strategies for improvement of immunization include intersectoral collaboration, use of all opportunities to vaccinate eligible children and mothers, identification of high risk groups and providing focused services for them and enhanced disease surveillance and operational research for program performance at the sub-national level(Cutts, 1991).

2.5. Conceptual framework

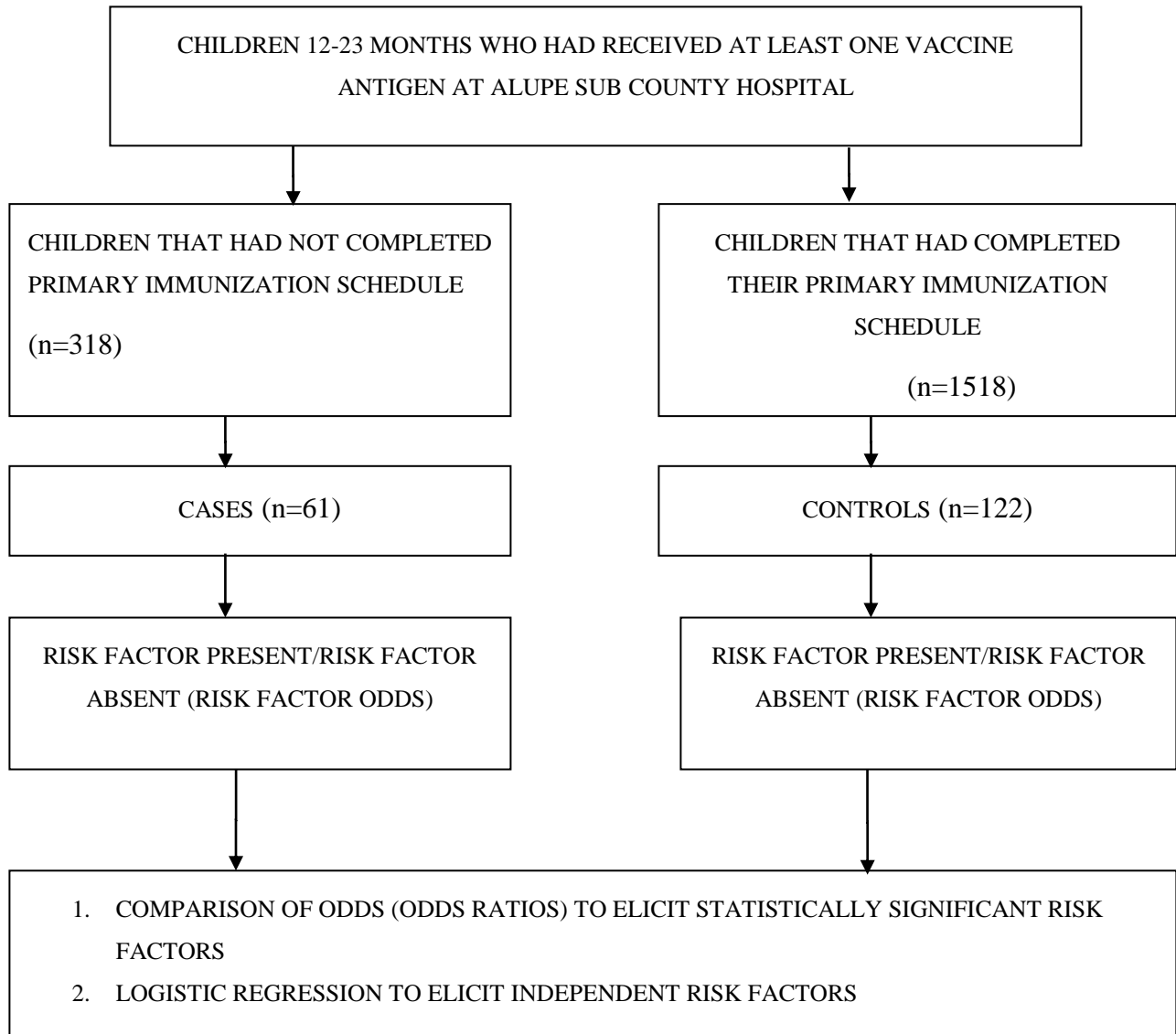


Figure 2.1: Conceptual framework

CHAPTER THREE

MATERIALS AND METHODS

3.1. Study Site

The study was conducted at Alupe Sub County hospital in Alupe division of Teso South Sub-county, Busia County. The division serves as the main catchment area of Alupe Sub-County Hospital within Kenya. However, the facility also serves the neighbouring Amukura division in Teso North sub county, Busia Sub County in Kenya and the neighbouring Busia district in Uganda. The hospital is a level 4 facility with a catchment population of 40,000. It offers both out-patient and in-patient services. It is currently linked to two community health units.

The population served is multi-ethnic though Teso is the predominant ethnic group. Most people are Christians. The majority of the population lives below the national poverty line of KShs 3000 per month. Teso South is a border district with a poverty rate above 60% compared to the national average of 45.9%. National poverty line for Kenya is \$ 1.25 per person per day at 2005 purchasing power parity. Literacy rate as per Kenya Integrated Household Budget Survey (2005/06) was 76% with males at 84.2% and females at 68.1%. The predominant religion is Christianity, though Islam is also present as are traditional African religions. The sex ratio is 98 males for 100 females. Children 0-14 years account for 47.5% of the population 45.9 % of the population lives more than 5 kilometers away from the nearest health facility. The average household size is 5.9 members. More than half (57%) of household heads are married in monogamous unions, 23% in polygamous unions, 15% are widowed and 0.3% has never married. Two thirds (66.5%) of households were male led and 33.5% female led. Latrine coverage is above 99% although more than 58.2% of households share latrines. More than 60 % of households have access to safe drinking water although about half have to walk more than 30 minutes to access it.(World Bank, 2013)

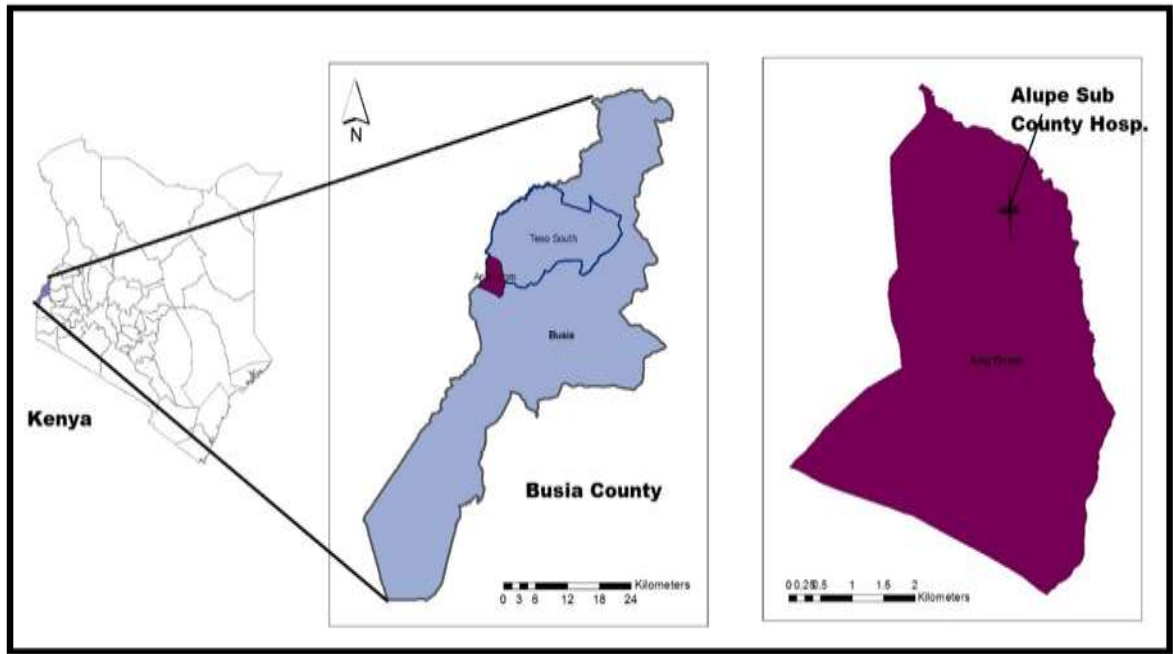


Figure 3.1. Map of Kenya showing location of Alupe Subcounty Hospital

The subcounty continues to expand its vaccine schedule in line with government policy especially with the recent introduction of Hepatitis, Haemophilus influenza, Pneumococcal and Rotavirus vaccines. The study however assessed the six basic antigens: BCG and birth polio (at birth-2 weeks), OPV1 and DPT1 (6 weeks), OPV2 and DPT2 (10 weeks), OPV3 and DPT3 (14 weeks) and measles (9 months). Children who received at least one infant vaccine at Alupe SCH during the period 1st September 2011 to 31st August 2012 were studied.

3.2. Study population

The study interviewed mothers of children aged 12-23 months who had received at least one dose of childhood vaccine at Alupe Sub County Hospital in Alupe Sub County of Busia County.

3.3. Study design

Three methodological approaches were employed. First, vaccination completion rates at the health facility were computed by abstracting immunization data for the study period from the immunization register into a Microsoft Excel sheet. All children aged 12-23 months who had completed their basic immunization schedule were counted and divided by the total number of children for the period and converted into percentage. The age group was chosen since it is the World Health Organization standard age group for assessment of immunization completion and timeliness in countries whose basic immunization schedule terminates with the first measles dose at 9 months (Burton, Monasch, & Lautenbach, n.d.). The result was compared with data from the District Health Information System (DHIS).

Secondly, a 1:2 unmatched case control study was conducted to determine statistically significant risk factors for incomplete vaccination. Two comparison groups, cases and controls, were selected on a predefined outcome case definition. Two controls were selected for each case to increase the power of the study. Different exposure variables were analyzed against outcome and measures of association were computed to determine significant determinants of full vaccination status in children 12-23 months resident in Kenya that had received at least one infant vaccine at Alupe SDH. Univariate, bivariate and multivariate analyses were done.

Finally, a semi-structured questionnaire was administered to mothers/caregivers of children who had not completed their basic immunizations to find out the reasons for non-completion.

3.4. Sample size determination

Sample size determination was conducted using Fleiss formula with continuity correction (Sullivan & Soe, 2007).

$$n' = \frac{\{z_{1-\alpha/2}\sqrt{(r+1)\bar{p}(1-\bar{p})} + z_{1-\beta}\sqrt{rp_1(1-p_1) + p_2(1-p_2)}\}^2}{r(p_1 - p_2)^2}$$

$$n_1 = \frac{n'}{4} \left\{ 1 + \sqrt{1 + \frac{2(r+1)}{n'r |p_1 - p_2|}} \right\}^2$$

$$n_2 = rn_1$$

Where:

p_0 = Exposure among controls=87% (0.87)

p_1 = Exposure among cases=67% (0.67)

\bar{p} = $(p_1+p_0)/2$ = (77%) 0.77

\bar{q} = $1 - \bar{p}$ =0.23

q_1 = $1-p_1$ = 0.33

q_0 = $1-p_0$ =0.13

Z_α = 95% Significance, two tailed = 1.96

Z_β = For 80% Power =0.84

r =number of controls per case=2

n' =number of cases needed before continuity correction

n =number of cases needed after continuity correction

$r \times n_1$ =number of controls needed after continuity correction

Sample size was estimated by Fleiss formula with continuity correction using OpenEpi software (“OpenEpi Menu,”2019). A prevalence of complete vaccination status among children 12-23 months whose mothers had completed primary education of 87% and

among those who had not completed primary education (Maina, Karanja, & Kombich, 2013; Ndiritu *et al.*, 2006)of 67% was applied (DHS, 2008-09). Maternal education was selected for sample size calculation since it is considered the single most significant determinant of child health and is commonly evaluated in routine national surveys. Other assumptions applied were power(β) of 80% , confidence level($1-\alpha$) of 95% , a ratio of cases to controls of 1:2 and least extreme odds ratio to be detected of 0.30. The sample size was increased by 10% to factor in non-response rate. Sixty one cases and 122 controls were recruited.

Table 3.1: Results of sampling process

	Calculated	Adjusted for non-response
Sample size-cases	55	61
Sample size-controls	110	122
Total sample size	165	183

3.5. Sampling plan

Sixty one cases inclusive of an allowance of 10% non-response rate were recruited. These were sampled from 318 children who had not completed their basic immunizations during the period 1st September 2011 to 31st August 2012. One hundred and twenty two controls inclusive of 10% allowance for non-response rate were recruited from 1518 fully vaccinated children in the MCH register for the period 1st September 2011 to 31st August 2012. Two controls were recruited for every case. All children 12 - 23 months resident in Kenya who received at least one basic vaccine at Alupe SDH between 1st September 2012 and 30th August 2013 and were documented in the MCH register at the health facility were listed then stratified into cases and controls

based on a predetermined case definition. Three hundred and eighteen (318) cases and 1518 controls were extracted from MCH register. A sample of 61 cases and 122 controls were enrolled by systematic random sampling. A random number between 1 and 10 was generated by balloting and formed the starting point for the systematic sampling. Every fifth case was enrolled till 61 cases were enrolled. The same procedure as for cases was used for controls. After balloting to generate the starting number every twelfth control was enrolled till 122 controls were attained.

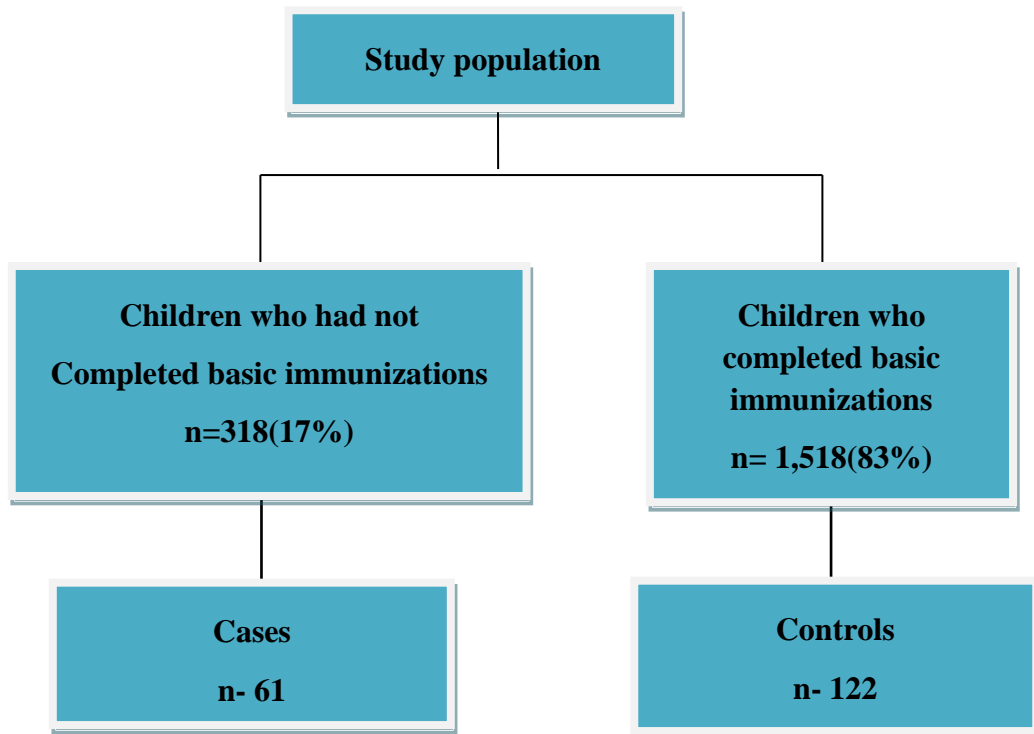


Figure 3.2. Sampling plan for the case control study

3.6. Case definition

A child aged 12 - 23 months resident in Teso South, Kenya who has received at least one infant vaccine Alupe SCH but had not completed all vaccinations up to first dose of measles.

3.7. Case selection

All children fitting case definition extracted from MCH register were traced to their households using household registers maintained by CHWs and assisted by the village elders/chiefs. Vaccination status was confirmed by card. Those not found [5(8.2%)] were systematically replaced until the anticipated sample size was reached. Those found but were fully vaccinated were excluded from the study.

3.8. Control selection

Controls were sampled from the MCH register and traced to their households. Controls were children aged 12-23 months who started their primary infant vaccination schedule at Alupe SDH and were now fully vaccinated. One hundred and twenty two controls were recruited and traced to their households. Vaccination status was confirmed by card.

A similar situation obtained relating to controls not found as for cases not found. Twelve (9.8%) of potential controls listed were not found and were systematically replaced.

3.9. Inclusion Criteria

Children, who received at least one infant vaccination at Alupe SCH, are aged 12 -23 months, were resident in Teso South, Kenya and parents or guardians consented to inclusion in the study.

3.10. Exclusion Criteria

Children who were resident in Uganda were excluded for administrative reasons. The study was not approved for trans-boundary investigation.

3.11. Data management

3.11.1 Data collection

After the interviews, data cleaning was done. Data collected by questionnaires was entered into an Epi Info 3.5.4 make-view screen installed on password protected computer with appropriate back up.

3.11.2 Data entry

Data was entered into an Epi Info 3.5.4 make-view screen installed on password protected computer with appropriate back up.

3.11.3 Data analysis

Data analysis was done using Epi info. 3.5.4 Software. Univariate analysis was done to establish the relative magnitudes of individual variables among cases and among controls. Percentages were calculated and compared. Two by two tables were generated with calculated odds ratios, their 95% confidence intervals and tests of significance (p-values) to identify factors associated with incomplete immunization status. Multivariate analysis by backwards stepwise method was done. Variables with a p-value (\leq) 0.1 from bivariate analysis were entered into a model and sequentially eliminating those with p-values ($>$) 0.05 starting with the one with the highest p-value till the best fit model was reached. This was done to identify factors that were independently associated with incomplete immunization.

3.11.4 Data dissemination

Findings of the study were disseminated through publication of a manuscript in the Pan African Medical Journal. Further, findings were also shared with my faculty, fellow residents, Alupe SCH and Teso South sub-county health teams.

3.12. Variables

A. Records review

The variables assessed were individual vaccine antigen uptake rates and overall immunization completion rate.

B. Case control study

Independent variables:

1. Socio-demographic factors
 - a) Residence by location
 - b) Residence by urban/rural
 - c) Age (Months)
 - d) Sex
 - e) Birth order
 - f) Children 0-5 years in household
 - g) Children 6-15 years in household
 - h) Access to radio
 - i) Access to television
 - j) Access to internet
2. Parental characteristics
 - a) Age
 - b) Income
 - c) Occupation
 - d) Has received information on immunization
 - e) Religion
 - f) Marital status
 - g) Highest education level attained
3. Health system access factors
 - a) Distance to health facility
 - b) Migration
 - c) Age appropriate OPV0
 - d) Age appropriate BCG
4. Health system utilization factors
 - a) Age appropriate OPV3
 - b) Age appropriate DPT3
 - d) Mother attended ANC
 - e) Place of delivery

- c) Age appropriate MCV 1
- f) Mother received 2 TT

5. Sources of immunization information

- a) CHW
- b) HCW
- c) Neighbor
- d) Friend
- e) Radio
- f) Television

Dependent variable:

Immunization completion status at 12-23 months of age was the dependent variable.

C. Reasons for incomplete immunization given by mothers or caregivers

- a) Vaccine absent
- b) Mother too busy
- c) Place/time of vaccination unknown
- d) Place too far
- e) Unaware of need for vaccination
- f) Child ill brought but not vaccinated
- g) Time inconvenient
- h) Others

3.13. Ethical Considerations

All data collected was stored in password-enabled computers and backups were done. The requisite consent was sought from the medical superintendent to conduct the study. Voluntary informed consent was sought from each child's mother or guardian interviewed. The consent was written, detailed and in simple language without medical jargon. It was in English with verbal translation into Kiswahili or other appropriate local language by a trained study interpreter where necessary. Ethical approval to conduct the study was obtained from the Kenyatta National Hospital Scientific and Ethical Review boards. No personal information was disclosed to third parties during conduct of the study. All study participants' parents or guardians were given health education on vaccine preventable diseases and immunization and those children found to be incompletely immunized were linked to the health facility for updating of their schedule.

CHAPTER FOUR

RESULTS

4.1. Retrospective records review

The facility enrolment for the study period was 1836 against a projected catchment population for 2013 of 1663 (MOH-Kenya, 2013). There were discrepancies between DHIS data and health facility data especially in respect of BCG, DPT1 and DPT3. Complete immunization rate was 47% by DHIS and 83% by health facility data. The highest uptake rate was noted for BCG (54% DHIS, 94% Facility) while the lowest was birth OPV (27% DHIS, 80% Facility).

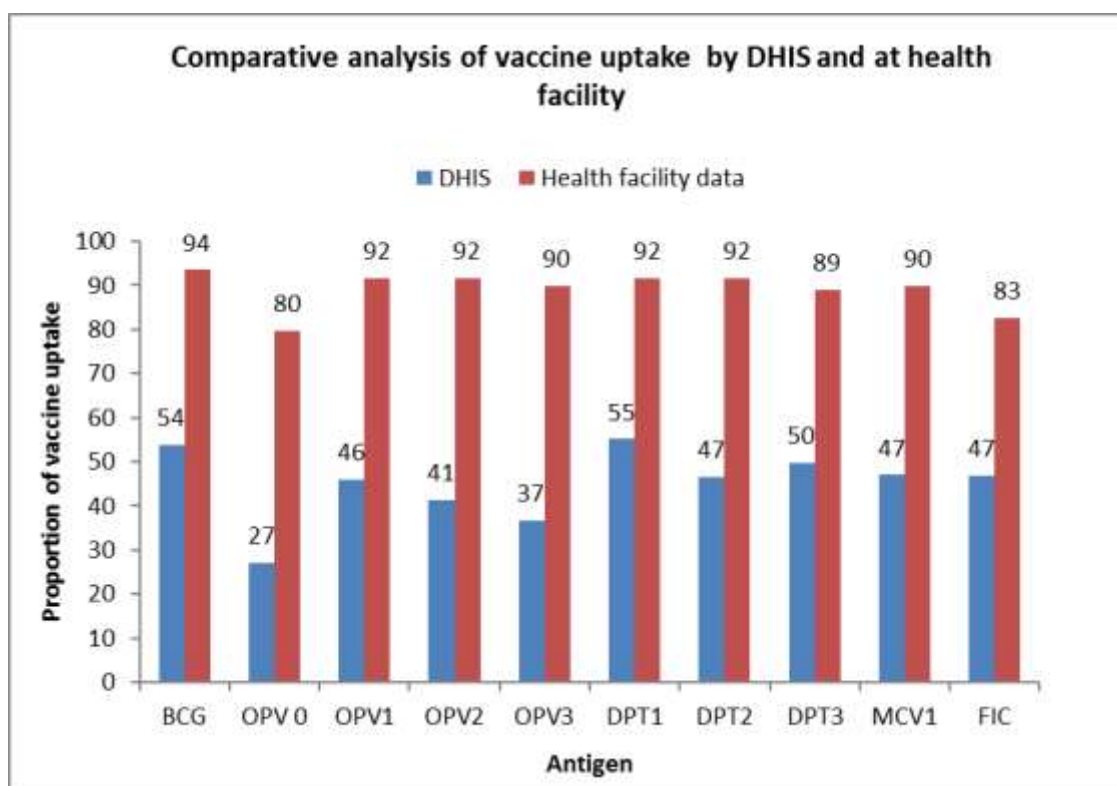


Figure 4.1: Comparison of vaccine uptake in DHIS and Health Facility Register

4.2. Case control study

4.2.1. Study participants

One hundred and eighty three (183) study participants aged 12-23 months who had received at least one childhood vaccine at Alupe Sub-District Hospital between 1st September 2011 and 31st August 2012 were enrolled. Of these 61 were cases and 122 were controls.

4.2.2. Univariate analysis

4.2.2.1. Univariate analysis of socio-demographic characteristics of participants

Males were slightly higher at 96 (52%) and more children 138 (75%) were aged between 18-23 months. A slightly higher number 101 (55%) resided in a rural setting with Angorom and Amagoro locations having a higher number of children at 82 (45%) and 75 (41%) respectively. Most households 168 (92) had 0-2 children under the age of five years. Radio was available in 157 (86%) of the households while Televisions were available in only 7 (4%) of the households and internet was accessible in 43 (23%) other households (Table 4.1).

Table 4.1: Univariate analysis of socio-demographic factors of participants (N-183)

Characteristics	n(%)
Residence by location	
Amagoro	75 (41)
Angorom	82 (45)
Ochude	15 (8)
Okame	11 (6)
Residence by urban/rural	
Rural	101 (55)
Urban	82 (45)
Age (Months)	
12-17	45 (25)
18-23	138 (75)
Sex	
Male	96 (52)
Female	87 (48)
Birth order	
1-2	89 (49)
≥3	94
Children 0-5 years in household	
0-2	168 (92)
3+	15 (8)
Children 6-15 years in household	
0-2	132 (72)
3+	51 (28)
Access to radio	
Yes	157 (86)
No	26 (14)
Access to television	
Yes	7 (14)
No	176
Access to internet	
Yes	43 (23)
No	140 (77)

4.2.2.2. Univariate analysis of parental characteristics

Most of the children's fathers 106 (58) were age above 30 years of age, while most of the mothers 98 (54%) were less than 26 years. Most were peasant agriculture, small business at 177 (98%) and 87 (48%) earned less than 3000 per month, while 149 (82%) of mothers were peasants and 138 (76%) earned less than 3000 per month. Majority of the fathers 115 (64) had attained complete primary school education, while only 91 (50%) of mothers had attained the same. Most, 173 (96%) of fathers and 178 (98%) of mothers belonged to the Christian faith and 148 (92%) fathers and 147 (81%) of mothers reported they were in monogamous marriages. Almost all the parents had received some information on immunization at 177 (98%) and 179 (98%) among the fathers and mothers respectively.

Table 4.2: Univariate analysis of parental characteristics (Mothers N-182, Fathers N-180)

Characteristics	Paternal n (%)	Maternal n (%)
Age		
<30/ <26	77 (43)	98 (54)
30+/ 26+	103 (57)	84 (46)
Income		
<3000	87 (48)	138 (76)
3000+	93(52)	44 (24)
Occupation		
None	3 (2)	33 (18)
Peasant agriculture, small business	177 (98)	149 (82)
Highest education level attained		
Not completed primary	65 (36)	91 (50)
Completed	115 (64)	91 (50)
Religion		
Christian	173 (96)	178 (98)
Other	7 (4)	4 (2)
Marital status		
Monogamous	148 (82)	147 (81)
Polygamous, other	32 (18)	35 (19)
Has received information on immunization		
Yes	177 (98)	179 (98)
No	3 (2)	3 (2)

4.2.2.3. Univariate analysis of health facility access factors

Only 35 (19%) respondents lived within 1 km of a health facility, 25 (14%) had migrated into or out of their catchment area while 21 (13 %) of sampled children had received OPV0 at the appropriate time, and only 63 (36%) had received BCG at the appropriate time

Table 4.3. Univariate analysis of health facility access

Characteristic	n (%)
Distance to health facility	
<1km	35 (19)
≥1km	148 (81)
Migration	
Yes	25 (14)
No	158 (86)
Age appropriate OPV 0	
Yes	21 (13)
No	140 (87)
Age appropriate BCG	
No	63 (36)
Yes	113 (64)

4.2.2.4. Univariate analysis of health system utilization

Majority of mothers 176 (97%) attended ANC clinic, while 89(62%) had received maternal tetanus, and only 90 (49%) deliveries were conducted at a health facility. Among the children, 150 (87%) had received MCV1 at the appropriate age, 121 (71%) had received DPT3 at the appropriate age and 130 (76%) had received OPV3 at the appropriate age.

Table 4.4. Univariate analysis of health system utilization

Characteristics	n (%)
Age appropriate OPV3	
No	42 (24)
Yes	130 (76)
Age appropriate DPT3	
No	50 (29)
Yes	121 (71)
Age appropriate MCV 1	
No	22 (13)
Yes	150 (87)
Mother ANC clinic	
No	6 (3)
Yes	176 (97)
Place of delivery	
Hospital facility	90 (49)
TBA	92 (51)
Mother received 2 TT	
No	54 (38)
Yes	89 (62)

4.2.2.5. Univariate analysis of sources of information, education and communication

Most common source of information on immunization was from HCWs at 174 (95%), CHWs at 159 (87%) and Radio at 115 (63%). Television was the least source of information at 8 (4%)

Table 4.5: Univariate analysis of sources of immunization information, education and communication

Source of IEC	n (%)
CHW	159 (87)
Yes	24 (13)
No	
HCW	
Yes	174 (95)
No	24 (5)
Neighbors	
Yes	43 (23)
No	140 (77)
Friend	
Yes	73 (40)
No	110 (60)
Radio	
Yes	115 (63)
No	68 (37)
Television	
Yes	8 (4)
No	175 (96)

4.2.2.6. Univariate analysis of reasons for non-vaccination

Mothers of one third (33%) of children that had not completed their vaccination schedule cited vaccine absence as the reason for non-completion

Table 4.6: Univariate analysis of reasons for non-vaccination

Reason for incomplete vaccination	Number of responses (N=61)	(%)
Vaccine absent	20	33
Mother too busy	5	8
Place/time of vaccination unknown	5	8
Place too far	4	7
Unaware of need for vaccination	4	7
Child ill brought but not vaccinated	3	5
Time inconvenient	2	3
Others	18	30

4.2.3. Bivariate Analysis

4.2.3.1. Bivariate analysis of socio-demographic factors

At Bivariate analysis, age of the child was the only statistically significant socio-demographic factor for completion of immunization.

Table 4.7: Bivariate analysis for socio-demographic characteristics for completion

of vaccination

Characteristics	Cases n (%)	Controls n(%)	OR, 95% CI	p-value
Residence	33 (57)	68 (56)		
Rural	28 (43)	54 (44)	1.0(0.6-1.4)	0.88
Urban				
Age (months)				
12-17	26 (43)	19 (16)		
18-23	35 (57)	103 (84)	4.0(2.0-8.2)	<0.01
Sex				
Male	35 (57)	61 (50)		
Female	26 (43)	61 (50)	1.3(0.7-2.5)	0.43
Birth order				
1-2	26 (43)	63 (52)		
≥3	35 (57)	59 (48)	0.7(0.4-1.3)	0.27
Children 0-5 years in household				
0-2	59 (97)	109 (90)		
3+	2 (3)	13 (10)	3.2(0.7-15)	0.12
Children 6-15 years in household				
0-2	43 (72)	89 (76)		
3+	18 (28)	33 (24)	0.8(0.4-1.6)	0.53
Access to radio				
Yes	51 (84)	106 (87)		
No	10 (16)	16 (13)	0.8(0.3-1.8)	0.65
Access to television				
Yes	3 (5)	4 (3)		
No	58 (95)	118 (97)	1.5(0.3-7.0)	0.69
Access to internet				
Yes	18 (30)	25 (20)		
No	43 (70)	97 (80)	1.6(0.8-3.3)	0.20

4.2.3.2. Bivariate analysis of parental characteristics

Children of younger fathers were two times more likely to have completed their childhood vaccination schedule. Age of father Age of mother was the only statistically significant maternal factor associated with incomplete vaccination. The odds of a child of a younger mother completing the basic immunization schedule were 2.5 times higher than those of older mothers OR 0.4 (95% C.I 0.2 -0.8). Other commonly reported parental factors were not statistically significant at bivariate analysis.

Table 4.8: Bivariate analysis of fathers' characteristics

Characteristics	Cases n (%)	Controls n(%)	OR, 95% CI	p-value
Age				
<30	19 (32)	58 (48)		
30+	41 (68)	63 (52)	0.5 (0.3-1.0)	0.04
Income				
<3000	33 (54)	54 (45)		
3000+	28 (46)	66 (55)	1.4 (0.8-2.7)	0.27
Occupation				
None	2 (3)	1 (1)		
Peasant agriculture, none	58 (96)	119 (99)	4.1 (0.4-46.6)	0.26
Highest education attained				
Not completed primary school	20 (33)	45 (38)		
Completed primary school	40 (67)	75 (62)	1.2 (0.6-2.3)	0.7
Religion				
Christian	59 (98)	114 (95)		
Other	1 (2)	6 (5)	3.1 (0.4-26.4)	0.43
Marital status				
Monogamous	45 (75)	103 (85)		
Polygamous, other	15 (25)	17 (15)	0.5 (0.2-1.1)	0.51

Table 4.9: Bivariate analysis of mothers' characteristics

Characteristics	Cases n (%)	Controls n (%)	OR, 95% C.I	p-value
Age				
≤ 25	24 (40)	74 (61)		
> 25	36 (60)	48 (39)	0.4(0.2-0.8)	0.01
Monthly income				
<Kshs 3000	47 (78)	91 (75)		
Kshs 3000+	13 (22)	31 (25)	1.2(0.6-2.6)	0.71
Occupation				
None	12 (20)	21 (17)		
Peasant agriculture, none	48 (80)	101 (84)	1.2(0.5-2.6)	0.68
Education				
Not completed primary school	28 (46)	63 (52)		
Completed primary school	32 (54)	59 (48)	0.8(0.4-1.5)	0.53
Religion				
Christian	59 (97)	120 (98)		
Other	1 (3)	2 (2)	0.5(0.1-3.6)	0.60
Marital status				
Monogamous	45 (75)	102 (84)		
Other	15 (25)	20 (16)	0.6(0.3-1.3)	0.23
Has received information on immunization				
Yes	59 (97)	120 (98)		
No	1 (3)	2 (2)	0.5(0.1-3.6)	0.60

4.2.3.3. Bivariate analysis of health facility access

Delay in receiving OPV0 and BCG were the only health facility access factors that were statistically associated with failure to complete the basic immunization schedule (OR 3.1 95% CI 1.2-7.9, OR 2.9 95% CI 1.5-5.6).

Table 4.10: Bivariate analysis of health facility access

Determinant	Cases n (%)	Controls n(%)	OR, 95% CI	p-value
Distance from health facility	8 (13)	27 (25)		
<1km	53 (87)	95 (75)	0.5(0.2-1.3)	0.17
≥1km				
Migration				
Yes	10 (16)	15 (12)		
No	51 (84)	107 (88)	1.4(0.6-2.7)	0.50
Age appropriate OPV 0				
No	10 (16)	11 (9)		
Yes	32 (84)	108 (91)	3.1(1.2-7.9)	0.02
Age appropriate BCG				
No	30 (53)	33 (28)		
Yes	27 (47)	86 (72)	2.9(1.5-5.6)	<0.01

4.2.3.4. Bivariate analysis of health System utilization

Not receiving OPV3 at the appropriate age and mothers who had not received at least 2 TT during the index pregnancy were health system utilization predictors for not completing the basic immunization schedule on bivariate analysis.

Table 4.11: Bivariate analysis of health system utilization

Characteristics	Cases n(%)	Controls n(%)	OR (95%) C.I	P value
Age appropriate OPV3				
No	21 (40)	21 (18)		
Yes	32 (60)	98 (82)	3.0(1.5-6.3)	0.002
Age appropriate DPT3				
No	18 (35)	32 (27)		
Yes	34 (65)	87 (73)	1.4(0.7-2.9)	0.20
Age appropriate MCV 1				
No	8 (15)	14 (12)		
Yes	45 (85)	105 (88)	1.3(0.5-3.4)	0.35
Mother ANC clinic				
No	1 (2)	5 (4)		
Yes	60 (98)	116 (96)	0.5(0.1-4.4)	0.5
Place of delivery				
Health Facility	30 (51)	60 (51)		
TBA	30 (49)	62 (49)	1.1(0.6-2.0)	0.5
Mother received 2 TT				
	30 (49)	24 (27)		
	25 (45)	64 (73)	3.2(1.6-6.5)	<0.01

4.2.3.5. Bivariate analysis of sources of information

There were no statistically significant risk factors for non-completion in respect of sources of information on immunization.

Table 4.12: Analysis of immunization information sources

Sources of immunization information	Cases n(%)	Controls n(%)	OR (95%) C.I	P value
CHW				
Yes	49 (80)	110 (90)		
No	12 (24)	12 (10)	0.4(0.2-1.1)	0.5
HCW				
Yes	57 (93)	117 (96)		
No	4 (7)	5 (4)	0.6(0.2-2.4)	0.35
Neighbor				
Yes	14 (23)	29 (24)		
No	47 (77)	93 (76)	1.0(0.5-2.0)	0.52
Friend				
Yes	19 (31)	54 (44)		
No	42 (69)	68 (56)	0.6(0.3-1.1)	0.06
Radio				
Yes	38 (62)	77 (63)		
No	23 (38)	45 (37)	1.0(0.5-1.8)	0.52
Television				
Yes	3 (5)	5 (4)		
No	58 (95)	117 (96)	1.2(0.3-5.2)	0.53

4.2.4 Multivariate Analysis

The statistically significant risk factors after multivariate analysis were the age of child, maternal age, timely receipt of BCG and receipt of at least 2 tetanus toxoid injections during the index pregnancy.

Table 4.13 Best fit model after multivariate analysis

Characteristic	Unadjusted OR (95% C.I.)	p-value	Adjusted OR, 95% C.I.	p-value
Age group of child (months)				
12-17	4.0(2.0-8.2)	<0.01	4.2(1.8-9.6)	<0.01
18-23				
Age group of mother				
15-25				
>25	0.4(0.2-0.8)	<0.01	2.5(1.1-5.0)	0.03
Age-appropriate BCG				
No				
Yes	2.9(1.5-5.6)	0.001	3.2(1.4-7.3)	0.005
Child protected against neonatal tetanus (Maternal TT \geq 2)				
No				
Yes	3.2(1.6-6.5)	<0.01	2.5(1.2-5.4)	<0.02

CHAPTER FIVE

DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS

5.1. Discussions

The wide discrepancies between DHIS and facility data could be due to problems with data abstraction as well as reporting. Such inaccuracies present a programmatic challenge when planning for commodities and supplies, human resources and other immunization improvement interventions. The projected catchment population for the hospital for 2013 based on the 2009 census was 1663 yet the number enrolled during the study period was 1836. Denominator under-estimation can lead to under estimation of resources such as vaccines and syringes which in turn will lead to stock-outs. Stock-outs have been shown to be significant determinant of immunization completion(Gibson *et al.*, 2015). The uptake of individual vaccines and overall completion by DHIS was much lower than the national target for districts (80%) for the period and even lower than the Healthy People 2020 target of 90%(WHO, 2015). The study population will wrongly therefore be deemed to be at high risk of vaccine preventable disease outbreaks and hence unnecessary interventions may be instituted yet uptake rates at facility level are actually above national targets. The discrepancy between BCG and OPV0 which are administered concurrently is likely to arise from documentation errors at the maternity or late presentation of children for initial vaccines leading to OPV0 being considered as OPV1.

The study population was almost equally distributed between rural and urban areas and most parents or caregivers earned less than KShs. 3000 monthly. So this was generally a catchment with poor socio-demographic indicators. However, these poor indicators did not appear to have a significant effect on immunization completion rates.

Independent determinants of immunization completion were the child's age, maternal age, prompt receipt of BCG and receipt of at least 2 doses of maternal tetanus toxoid. Key risk factors for incomplete immunization identified by the WHO SAGE globally were poverty, low maternal education and increased distance from health facility (WHO, 2016). Many studies in Africa and other low income countries have flagged these risk factors too (Chidiebere, Uchenna, & Kenechi, 2014; Jani, De Schacht, Jani, & Bjune, 2008; Lakew, Bekele, & Biadgilign, 2015; Legesse & Dechasa, 2015; Russo *et al.*, 2015b).

In Kenya, studies in Nakuru, Kilifi and Mathare also showed distance was a significant determinant of immunization completion. In the study area though 81% of participants lived more than one kilometer away from the health facility, immunization completion was not associated with physical distance. This could be attributed to the proliferation of motor cycle riders who have made transportation easier. The general terrain of the area which is generally flat may also have cancelled out the effect of physical distance on immunization service utilization. The findings highlight the need for context specific risk factor identification in order to improve immunization completion rates.

Maternal education has been found to be a major determinant of incomplete immunization (Calhoun *et al.*, 2014; Mutua, Kimani-Murage, & Ettarh, 2011; Onsomu, Abuya, Okech, Moore, & Collins-McNeil, 2015). Poverty also influences immunization completion by limiting access to health due to financial constraints (Kawakatsu, Tanaka, Ogawa, Ogendo, & Honda, 2015; Mutua *et al.*, 2011). However, at Alupe SCH this is not a prominent risk factor. Contextualized studies to identify location specific risk factors for incomplete immunization are vital.

Older children (≥ 18 months) were four times more likely to have completed their basic immunizations by 23 months of age in this study population. This possibly reflects more opportunities for immunization.

Children of younger (≤ 25 years) mothers were more than 2.5 times more likely not to have completed their primary immunization schedule at 23 months. This may be attributed to inexperience and hence limited contact with the health system (Mutua *et al.*, 2011; Negussie, Kassahun, Assegid, & Hagan, 2016; Russo *et al.*, 2015b).

Children who received BCG vaccine on time had a higher likelihood of completing their immunization schedule. Early receipt of BCG could be an indicator of not just more opportunities for immunization but also early contact with the health system particularly during the antenatal period leading to hospital delivery. In this study, 97% of all participant mothers attended antenatal clinic at least once during the index pregnancy while 49% of mothers delivered at a health facility. However, only 13% received age appropriate birth OPV and 36% received age appropriate BCG. Children whose immunization schedule is initiated on time were 3 times more likely to complete their schedule by their second birthday. This cascade from ANC to immunization represents key areas of intervention. Increased ANC visits encourage bonding between users and healthcare providers which build trust in the system and further lead to increased hospital deliveries and hence timely initiation of the immunization schedule (Odotola *et al.*, 2015; Rosenthal *et al.*, 2004).

Children of mothers who had received at least 2 tetanus toxoid shots were 2.5 times more likely to be fully immunized. This reinforces the association noted with early BCG initiation and points to the importance of health provider/user relationship in attracting mothers to utilize health services. Increased utilization of antenatal services coupled with good experience at the health facility encourages mothers to deliver in health facilities.

From subjective assessment, the most common reason for incomplete immunization was vaccine stock-outs which could arise from under estimation of vaccine requirements due to wrong planning population. Other reasons such as the mother being too busy, place/time of vaccination unknown and mothers being unaware of need for

immunization highlight the need for increased health education and advocacy to address mothers concerns and help design appropriate interventions. While use of CHWs for immunization advocacy was not an independent determinant of completion, it was associated with increased likelihood for completion at bivariate analysis. More research needs to be undertaken to evaluate the strategy as an immunization service improvement strategy.

5.2. Conclusions

1. There were wide data disparities between the DHIS and health facility data.
2. Most widely reported socio-demographic factors were not statistically significant predictors of complete immunization.
3. Independent factors associated with incomplete vaccination were child's age, timely receipt of BCG and birth OPV and receipt of at least 2 doses of tetanus toxoid by the mother.
4. The main subjective reason for incomplete immunization was vaccine stock-outs
5. Use of CHWs may be an important source of immunization advocacy.

5.3. Recommendations

1. Periodic data quality audits are essential for improvement of services.
2. To improve immunization completion rates younger mothers should be targeted during antenatal period to enable them to develop confidence in the health system.
3. Continuous operational research is necessary to identify context specific risk factors for poor immunization program performance.
4. More innovative modalities of advocacy should be explored including use of CHWs.
5. The methodology used in this study could be adopted and refined to guide operational research at sub-national levels.

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APPENDICES

Appendix 1: Consent Form for Mother or Care-Giver of Study Child

STUDY TO FIND OUT IF THERE ARE REASONS FOR THE LOW LEVELS OF IMMUNIZATION AT ALUPE SUB-DISTRICT HOSPITAL

INTRODUCTION:

I work with the Ministry of Health and I am currently pursuing further studies. As part of my training I have to undertake a thesis project. From the ministry records Teso South has low levels of immunization. I decided to find out why immunization levels here in Teso South are low so that the ministry can find better ways of improving the situation

WHY IS THIS STUDY BEING DONE?

When the number of children who have not been immunized in a place is big, diseases against which the vaccines are usually protective against are more likely to occur and in big numbers. Many people have reasons why their children are not immunized but the government may not know. When the results of this study are published the government can use them to improve immunization services.

WHAT IS REQUIRED TO PARTICIPATE?

We can only ask you questions with your permission for which you must sign this document to confirm that you gave us permission.

If you agree to participate, we shall ask you a few questions and also request to see your MCH booklet. The questions are simple and straightforward. The process will take roughly 15 to 30 minutes. If your baby is not immunized and you are willing to have it immunized, we shall direct you to the appropriate healthcare worker to assist you.

BENEFITS OF BEING IN THE STUDY:

You can ask us any question on health matters and if we can, we shall provide you with appropriate answers or any possible assistance.

RISKS:

There are minimal risks involved with this study. There is a very small chance of that the information you give us may be accessed by other people. However, we shall try our utmost to prevent this from happening.

PRIVACY:

We will keep the information about you private to the extent allowed by law. Only the study team, JKUAT, KEMRI and the ministry of health can see your information. All the information will be kept in locked computer files. Information will be in summarized in reports. No one will be able to identify you or your household. All personal

□

information that can identify you will be destroyed and will not be used in any publication.

VOLUNTARY:

You are free to choose whether or not to be in this study. You are also free to say no to any part of this study. Even if you say yes, you may change your mind at any time.

WHO TO CONTACT:

If you have questions or concerns about this study, you can call Emmanuel Okunga Wandera at 0729576963. If you have concerns regarding your personal rights in the study, you can call the Secretary of the Institutional Review Board in Nairobi at **(020)726300-9**

AGREEMENT:

The risks and benefits of this study have been explained to me. I have had a chance to ask questions. All my questions were answered. I can choose to be in this study. I can drop out of the study at any time. I will receive a copy of this form.

I agree to participate.

(If parent or guardian is illiterate, you will need thumbprint and signature of witness)

Name (print): _____

Signature: _____

Date (DD/MM/YY): ___ / ___ / ___

SIGNATURE OF WITNESS: (if parent or guardian of participant is illiterate)

I have heard the explanation of this study. The procedures, risks, and possible benefits were explained to me. I do not work with the principal investigator or with any other person who works under or with the investigator. I confirm that the participant has voluntarily consented to allow his or her household to participate in this study.

Witness Name (print)	Thumb Print of Person Being Witnessed
Witness Signature	

Appendix II: Immunization Completion Rate Questionnaire

Adapted from WHO EPI survey questionnaire and Poverty Score Card for Kenya: By Mark Schreiner, Microfinance Risk Management, L.L.C., 2441 Tracy Avenue, Kansas City, MO 64108, U.S..A, mark@microfinance.com

Tick or fill appropriate response

Date of interview _____

Name of interviewer: _____

Household ID: _____

1. Household number _____
2. Division _____
3. Location _____
4. Sub-location _____
5. Village _____
6. Distance from facility as reported by informant
_____kilometers
7. Do you own or have access to any of the following media?
 - a. Radio
 - b. Television
 - c. Internet
8. Have you migrated into or out of this area in the last 5 years?
 - a. Yes
 - b. No

Household head's details :(If mother skip to next section: Mother's details)

1. Father (Name) _____
2. Other (Name and Specify relationship)

3. Age of household head _____
4. Sex _____

5. Marital status
 - Married in monogamous union
 - Married in polygamous union
 - Widowed
 - Single
 - Cohabiting/co-we-stay
 - Other (Specify)_____
6. Occupation
 - a. Does not work
 - b. No male head/spouse
 - c. Agriculture, hunting, forestry, fishing, mining or quarrying
 - d. Any other (Specify)_____
7. Religion _____
 - Muslim
 - Catholic
 - Protestant (Specify sect) _____
 - Hindu
 - Other (Specify)_____
8. Highest level of education attained:
 - a. None
 - b. Primary but did not complete
 - c. Completed primary
 - d. Secondary but did not complete
 - e. Completed secondary
 - f. College
 - g. University
9. Self-reported Income per month?
 - a. Under 3000
 - b. 3000 – 6000
 - c. 6000 -12000
 - d. 12000-24000
 - e. 24000-48000
 - f. 48000-96000
 - g. Above 96000
10. Have you received any information/education on immunization?
 - a. Yes
 - b. No
11. If yes, from where?
 - a. Health worker

- b. Provincial administration
- c. CHW
- d. Neighbor
- e. Friend
- f. Radio
- g. Television
- h. Other (Specify)_____

Mother's details

1. Age of mother _____
2. Maternal marital status
 - Married in monogamous union
 - Married in polygamous union
 - If in polygamy, marital order? (1st, 2nd, etc.) _____
 - Widowed
 - Single
 - Cohabiting/co-we-stay
 - Other (Specify)_____

3. Occupation.

- a. Does not work
- b. No male head/spouse
- c. Agriculture, hunting, forestry, fishing, mining or quarrying
- d. Any other (Specify)_____

4. Religion

- a. Catholic
- b. Mainstream Protestant
- c. Evangelical Protestant
- d. Muslim
- e. Hindu
- f. Traditional African
- g. Other (Specify)_____

5. Education level:

- a. None
- b. Primary but did not complete
- c. Completed primary
- d. Secondary but did not complete
- e. Completed secondary
- f. College

- g. University
- 6. Self-reported Income per month?
 - a. Under 3000
 - b. 3000 – 6000
 - c. 6000 -12000
 - d. 12000-24000
 - e. 24000-48000
 - f. 48000-96000
 - g. Above 96000
- 7. Have you received any information/education on immunization?
 - c. Yes
 - d. No
- 8. If yes, from where?
 - i. Health worker
 - j. Provincial administration
 - k. CHW
 - l. Neighbor
 - m. Friend
 - n. Radio
 - o. Television
 - p. Other (Specify) _____

Child data

- 1. Name of child _____
- 2. Date of birth _____
- 3. Age in months _____
- 4. Birth order _____
- 5. Case status: Case _____ Control _____

6. Persons in household

Name	Age	Sex

- 7. Number of children: < 5 years _____ 5-15 years _____
- 8. Does child have immunization card? Yes _____ No _____
- 9. If yes, when was child vaccinated?

Vaccine	Where received	Date given	Age	Appropriate/Not
BCG				
OPV 0				
OPV 1				
OPV 2				
OPV 3				
DPT 1				
DPT 2				
DPT 3				
Measles				

- 10. Immunization status?
 - a. Partial _____
 - b. Fully _____

11. If partial, reasons for non-completion
 - a. Unaware of need for immunization
 - b. Unaware of need for return for next dose
 - c. Place and/or time of immunization unknown
 - d. Fear of side effects
 - e. Wrong ideas about contraindications e.g. sick child, HIV etc.
 - f. Postponed till another time
 - g. No faith in immunization
 - h. Rumors
 - i. Place of immunization too far
 - j. Time of immunization inconvenient e.g. rainy season, planting season
 - k. Vaccinator absent
 - l. Vaccine not available
 - m. Mother too busy
 - n. Family problem including illness of mother
 - o. Child ill – not brought
 - p. Child ill – brought but not vaccinated
 - q. Long waiting time
 - r. Other
-

Maternal history where applicable

1. Immunization card available?
 - a. Yes _____
 - b. No _____
2. Attended ANC?
 - a. Yes _____
 - b. No _____
3. Other visits to health facility during this pregnancy?
 - a. Yes _____
 - b. No _____
4. If yes, how many? _____

Vaccine	Where received?	Date given?
TT1		
TT2		

TT3		
TT4		
TT5		

5. Is child protected against neonatal tetanus?

- a. Yes _____
- b. No _____

6. Where did you deliver?

- a. Dispensary _____
- b. Health Centre _____
- c. Hospital _____
- d. TBA _____
- e. Private Clinic _____
- f. Private Hospital _____

NAME OF INTERVIEWER: _____ **DATE:** _____

Appendix III: KNH/UON-ERC Letter of approval

Appendix III: KNH/UON-ERC Letter of Approval



UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Tel: 254-20 2726000 Fax: 4-0355

KNH/UON-ERC
Email: knh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke



KENYATTA NATIONAL HOSPITAL
P O BOX 30723 Code 00202
Tel: 724380-9
Fax: 733772
Telegrams: MEDHOSP, Nairobi

Ref: KNH-ERC/A/066

Link: www.uonbi.ac.ke/activities/KNH/UoN

14th November 2013

Okunga Emmanuel Wandera
TM 312/0860/2012
INTROMID
JKLIAT

Dear Emmanuel

RESEARCH PROPOSAL: MODIFIABLE FACTORS ASSOCIATED WITH LOW FULL IMMUNIZATION COVERAGE AT ALUPE SUB-DISTRICT HOSPITAL, BUSIA COUNTY (P434/82013)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 14th November 2013 to 13th November 2014.

This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
- Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
- Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal).
- Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
- Submission of an **executive summary** report within 60 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website www.uonbi.ac.ke/activities/KNH/UoN.

Appendix IV: Research proposal approval

Appendix IV: Research Proposal Approval



JOMO KENYATTA UNIVERSITY
OF
AGRICULTURE AND TECHNOLOGY

DIRECTOR, BOARD OF POSTGRADUATE STUDIES

P.O. BOX 62000
NAIROBI - 00200
KENYA
Email: director@jkuat.ac.ke

TEL: 254-007-52711/52141-4
FAX: 254-007-52144/52520

REF: BPS/TM312-0860/2012

05th December, 2014

Mr. Okunga Emmanuel Wandera
C. /o COHES
JKUAT

Dear Mr. Wandera,

RE: APPROVAL OF RESEARCH PROPOSAL AND SUPERVISORS

Kindly note that your research proposal entitled: "Modifiable factors associated with low full immunization coverage at Alupe sub-district hospital, Busia county." has been approved. The following are your approved supervisors:-

1. Prof. Helen Kutima
2. Dr. Samuel Amwayi
3. Dr. Collins Tabu

Yours sincerely


PROF. MATHEW KINYANJUI
DIRECTOR, BOARD OF POSTGRADUATE STUDIES

Copy to: Principal COHES,

As

JKUAT is ISO 9001:2008 Certified
Setting Trends in Higher Education, Research and Innovation

Appendix V: Publication



Research

Determinants of childhood vaccination completion at a peri-urban hospital in Kenya, December 2013 -January 2014: a case control study

Okunga Wandera Emmanuel^{1,2}, Amwayi Anyangu Samuel¹, Kutima Lydia Helen¹

¹Field Epidemiology and Laboratory Training Program, Ministry of Health, Nairobi, Kenya, ²Jomo Kenyatta University of Agriculture and Technology, Nairobi, Kenya

*Corresponding author: Okunga Wandera Emmanuel, Field Epidemiology and Laboratory Training Program, Ministry of Health, Nairobi, Kenya

Key words: Vaccination, determinants, children, case control, Kenya

Received: 26/10/2014 - Accepted: 18/03/2015 - Published: 20/03/2015

Abstract

Introduction: vaccine preventable diseases account for about 17% of deaths among children below five years in Kenya. Immunization is one the most cost-effective ways of reducing child mortality and morbidity worldwide. In Kenya, national full vaccination coverage today stands at above 80%. However there continue to be pockets of low full vaccination coverage like the catchment area of Alupe Sub-District Hospital which pose a threat to the rest of the country. **Methods:** this was a case-control study at Alupe Sub-District Hospital, Western Kenya. Sixty one (61) cases and 122 controls were sampled from the facility maternal and child health register by systematic random sampling and traced to their households. Cases were defined as children 12-23 months resident in Kenya who received at least one infant vaccine at the facility but were not fully vaccinated at the time of the study, while controls were children 12-23 months who were fully vaccinated by the time of the study. Pretested structured questionnaires were used for data collection. Data entry and analysis was done using Epi-Info 3.5.4 statistical software. **Results:** independent determinants of infant vaccination completion were the child's age < 18 months (AOR 4.2(1.8-9.6), $p < 0.01$), maternal age < 25 years (AOR 2.5(1.1-5.0), $p = 0.03$), maternal tetanus toxoid vaccination status < 2 TT doses (AOR 2.5(1.3-5.4), $p < 0.02$) and late receipt of BCG (AOR 3.2(1.4-7.3), $p = 0.005$). **Conclusion:** strategies to increase full vaccination should target young mothers especially during antenatal period.

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Introduction

In Africa, the mortality rate in children less than 5 years is 119/1000 live births and in Kenya it is 74/1000 live births [1]. About 17% (1.5 million) of all these deaths under five years are estimated to arise from vaccine preventable diseases. Immunization is one of the most cost effective ways of reducing childhood mortality and morbidity globally. Immunization programs vary worldwide in the diseases they target and strategies applied. In Kenya, the Ministry of Health delivers free immunization through the Division of Vaccines and Immunization. The country targets to achieve at least 90 % national vaccination coverage with Pentavalent3, measles and fully immunized child. The country also targets at least 80 % immunization coverage with Pentavalent 3, measles and fully vaccinated child in all districts and 90% in all high-risk districts [2]. The country has made great strides in attaining these targets however wide regional and facility level disparities remain which pose a threat to the whole national program. In the former Western province of Kenya, vaccination coverage has been traditionally high with most districts performing at above 80% fully vaccinated child coverage. However, Teso South district performance is very low compared to its neighbouring districts. Fully vaccinated child coverage in 2012 was: Busia 106%, Samia 90%, Butula 86%, Bunyala 88%, Teso North 74% while Teso South was 61%. At Alupe Sub District Hospital which is the biggest facility in Teso South District of Busia County, Western Kenya all immunization indicators remain dismally low. Most children initiate their vaccinations at the facility but completion of the required vaccinations is very low compared to national and county rates. During 2012, the mean annual DPT 1 coverage was 64 %, DPT 2 was 53%, DPT 3 was 48%, fully vaccinated child coverage was 43%, measles was 39% and DPT 1/ measles dropout rate was 21% [3]. Clusters of low immunization completion rates have been identified as a major cause of vaccine preventable disease outbreaks in areas with otherwise high immunization coverage. This was seen during polio outbreaks in Oman (1988), Canada (1982), Netherlands (1982), Bulgaria (1991) and Taiwan (1982) [4]. In the United States where endemic measles transmission was eliminated in 2000, outbreaks have continued to occur due to unvaccinated groups [5]. Similarly in Europe where high measles coverage had been attained, concerns about vaccine safety led to under vaccination and subsequent outbreaks [6]. In Africa, measles outbreaks during 2009-2010 were reported to arise due to non-vaccination. Reasons for non-vaccination included vaccine unavailability, infrequent vaccine sessions, exclusion of children > 12 months and unwillingness to receive vaccination by some religious groups in Zimbabwe, Botswana, Malawi and South Africa [7]. Many factors have been associated with low immunization completion rates including immunization system factors, parental attitudes and knowledge, family characteristics and communication and information factors [8-11]. However, the interplay of these factors and their relative significance varies from place to place. This makes it essential for all unique clusters of low immunization to be investigated to identify cluster specific modifiable factors.

Methods

Study site

The study was conducted at Alupe Sub district hospital in Alupe division of Teso South sub-county, Busia County. The division serves as the main catchment area of Alupe Sub-District Hospital within Kenya. However, the facility also serves the neighbouring Amukura

division in Teso North sub county, Busia Sub County in Kenya and the neighbouring Busia district in Uganda. The hospital is a level 4 facility with a catchment population of 40,000. It offers both out-patient and in-patient services. It is currently linked to two community health units. The population served is multi-ethnic though Teso is the predominant ethnic group. Most people are Christians. The majority of the population lives below the national poverty line of KShs 3000 per month. Teso South is a border district with a poverty rate above 60% compared to the national average of 45.9%. National poverty line for Kenya is \$ 1.25 per person per day at 2005 purchasing power parity. Literacy rate as per Kenya Integrated Household Budget Survey (2005/06) was 76% with males at 84.2% and females at 68.1%. The predominant religion is Christianity, though Islam is also present as are traditional African religions. The sex ratio is 98 males for 100 females. Children 0-14 years account for 47.5% of the population. Orphan hood was estimated at 10.2% for either one or both parents. 45.9 % of the population lives more than 5 kilometers away from the nearest health facility. The average household size is 5.9 members. More than half (57%) of household heads are married in monogamous unions, 23% in polygamous unions, 15% are widowed and 0.3% has never married. Two thirds (66.5%) of households were male led and 33.5% female led. Latrine coverage is above 99% although more than 58.2% of households share latrines. More than 60 % of households have access to safe drinking water although about half have to walk more than 30 minutes to access it [12]. Busia County lies in western Kenya along the border with Uganda (Figure 1). It comprises 6 districts (sub-counties). The predominant ethnic communities are Luhya and Teso although there are also a sizeable proportion of other ethnicities including Luo, Kikuyu and Kamba. The main economic activities are subsistence agriculture, fishing and small scale commerce. Poverty is widespread in the county. The district as most of the country uses the six antigen vaccine schedule with the recent introduction of Hepatitis, Haemophilus influenza, Pneumococcal and Rotavirus vaccines. The study assessed the six antigens: BCG and birth polio (at birth-2 weeks), OPV1 and DPT1 (6 weeks), OPV2 and DPT2 (10 weeks), OPV3 and DPT3 (14 weeks) and measles (9 months).

Study population: children who received at least one infant vaccine at Alupe SDH during the period 1st September 2011 to 31st August 2012 were studied.

Study design: a 1:2 un-matched case-control study design was employed. Two comparison groups, cases and controls, were selected based on a predefined outcome case definition. Two controls were selected for each case to increase the power of the study. Different exposure variables were analyzed against outcome and measures of association were computed to determine significant determinants of full vaccination status in children 12-23 months resident in Kenya that had received at least one infant vaccine at Alupe SDH. The age range was chosen in line with WHO recommendations for immunization coverage surveys for countries where the final primary vaccination was measles at 9 months [13].

Sample size: sixty one cases inclusive of an allowance of 10% non-response rate were recruited. These were sampled from 318 defaulters fitting case definition during the period 1st September 2011 to 31st August 2012. One hundred and twenty two controls inclusive of 10% allowance for non-response rate were recruited from 1518 fully vaccinated children in the MCH register for the period 1st September 2011 to 31st August 2012. Two controls were recruited for every case. Sample size was estimated by Fleiss formula with continuity correction using OpenEpi software. A prevalence of FIC among mothers who had completed primary

education of 87% and among those who had not completed of 67% was applied [1]. Other assumptions were: 95% confidence level, power 80% and least extreme odds ratio to be detected 0.03. The sample was increased by 10% to accommodate for non-response. This brought cases to 61 and controls to 122.

Sampling frame: all children 12 - 23 months resident in Kenya who received at least one infant vaccine at Alupe SDH between 1st September 2012 and 30th August 2013 and were documented in the MCH register at the health facility were listed then stratified into cases and controls based on a predetermined case definition. Three hundred eighteen (318) cases and 1461 controls were extracted from the MCH register. A sample of 61 cases and 122 controls were enrolled by systematic random sampling. A random number between 1 and 318 was generated by OpenEpi software and assigned as the first case, and then every fifth case was enrolled till 61 cases were enrolled. The same procedure as for cases was used. A random number between 1 and 1518 was generated and every twelfth control was enrolled till 122 controls were enrolled.

Case definition: a child aged 12 - 23 months resident in Teso South, Kenya who has received at least one infant vaccine Alupe SDH but has not completed all vaccinations up to first dose of measles.

Case findings: all children fitting case definition extracted from MCH register were traced to their households using household registers maintained by community health workers (CHWs) and assisted by the village elders/chiefs. Vaccination status was confirmed by card for 59 children and by history and BCG scar for 2 children. Those not found were systematically replaced until we reached the anticipated sample size. Those found but were fully vaccinated were excluded from the study.

Control findings: controls were sampled from the MCH register and traced to their households. Controls were children aged 12-23 months who started their primary infant vaccination schedule at Alupe SDH and were now fully vaccinated. One hundred and twenty two controls were recruited and traced to their households. Vaccination status was confirmed by card for 119 children and by history and BCG scar for 3 children. We systematically replaced those not found until the anticipated sample size was attained.

Inclusion criteria: children, who received at least one infant vaccination at Alupe SDH, are aged 12 -23 months, were resident in Teso South, Kenya and parents or guardians consented to inclusion in study.

Exclusion criteria: children who were resident in Uganda were excluded.

Fieldwork and data collection: community entry was through the area chief, community health extension worker and CHWs acted as guides to homesteads of the study participants. They also introduced the researcher to the community members through informal meetings. Voluntary informed consent from mothers or care-givers of children using detailed informed consent forms in common English with verbal translation to Kiswahili and/or local languages where necessary was obtained. An interpreter, who was a CHW from the locality, accompanied the researcher to assist in case of language barriers. Data was collected through face to face interviews with mothers or guardians using structured interviewer administered standard WHO EPI survey questionnaires merged with a poverty index tool (Mark Schreiner, Microfinance Risk Management, L.L.C., 2441 Tracy Avenue, Kansas City, MO 64108, U.S.A., mark@microfinance.com) with minimal adjustments for local context. Mothers of children not fully vaccinated were given

appropriate health education and advised on completion of the vaccination schedule where appropriate. Mothers who were willing to have their children vaccinated were linked to the facility and followed up by CHWs.

Data management: a pilot study involving 10% of the main study sample size was conducted. Responses not anticipated in initial data collection tool were identified and final coding of the questionnaire was done. Practical field problems related to language barrier were noted and appropriate translators identified. The relatively high number of anticipated study participants resident in Uganda was unexpected. However, sampling was continued till target sample size was found in the main study. Data was entered into an Epi Info 3.5.4 make-view screen installed on a password protected computer with appropriate back up. All cover pages of questionnaires with personal identifiers were destroyed immediately after data entry and cleaning while the main questionnaires were retained by the researcher. Data analysis was done using the same software.

Variables:

Input variables: demographic indicators selected for the study and elicited through interviewer administered questionnaires were: child's age, gender and birth order, place of residence, paternal age and maternal age. Socioeconomic factors selected and elicited through interviewer administered questionnaires were parental income, education level and religion. Children were further grouped into two groups: 12-17 months and 18-23 months to represent the younger and older halves of the study children's age group. Mothers were grouped into two also: (\leq) 25 years since half of the study mothers were aged below 25 years. Healthcare access indicators chosen and elicited through interviewer administered questionnaires were: distance from health facility, migration in the preceding two years, antenatal clinic attendance (at least once during index pregnancy) confirmed by ANC card, receipt of age appropriate birth polio and receipt of age appropriate BCG. Health system factors selected and also elicited through interviewer administered questionnaires were facility utilization indicators: place of delivery, receipt of at least 2 doses of neonatal tetanus by mother confirmed by ANC card (143/183 study mothers/care-givers had ANC cards) and age appropriate receipt of late vaccinations (OPV 3, DPT 3 and measles). Reasons for non-vaccination given by mothers/care-givers as well as main sources of maternal information, education and communication on immunization services were elicited.

Output variable: full immunization status at 12-23 months of age was the output/dependent variable. This variable is the standard WHO measure of full infant vaccination.

Data analysis: frequency tables were drawn using Epi Info data analysis program. Percentages were calculated and compared. Two by two tables were generated with calculated odds ratios, their 95% confidence intervals and tests of significance (p-values) to measure association between known determinants of immunization and full immunization status. Multivariate analysis by backwards elimination method was done. Variables with a p-value (\leq) 0.1 from bivariate analysis were entered into a model and by sequentially eliminating those with p-values ($>$) 0.05, starting with the one with the highest p-value, the best fit model was reached. Dependent variables entered were: age-group of the child, age-group of the father, age-group of the mother, age-appropriate BCG, source of maternal IEC being a CHW, source of maternal IEC being a friend, age-appropriate OPV3 and receipt of (\geq) 2 doses of tetanus toxoid. This was done to identify interactions among factors identified from bivariate analysis.

Ethical considerations: the requisite consent was sought from the medical superintendent to conduct the study. Voluntary informed consent was sought from each child's mother or guardian interviewed. The consent was written, detailed and in simple language without medical jargon. It was in English and Kiswahili. Verbal translation into local language was done where necessary by a trained study interpreter. Ethical approval to conduct the study was obtained from the Kenyatta National Hospital Ethical and Research Board. No personal information was disclosed to third parties during conduct of the study. All study participants' parents or guardians were given health education on vaccine preventable diseases and immunization. Confidentiality of all participant information was ensured as per international guidelines on protection of human research participants.

Results

Study participants

One hundred and eighty three (183) study participants aged 12-23 months who had received at least one infant vaccination at Alupe Sub-District Hospital and were resident in Kenya were enrolled. Of these 61 were cases and 122 were controls. All study participants were from Alupe division. Majority of children were from two locations: Angorom 82(45%) and Amongura 75(41%).

Demographic factors

Cases were more likely to be younger than 18 months [OR 4.0(2.0-8.2), <math>p<0.01</math>], likely to have to have younger fathers [OR 0.5(0.3-1.0) $p=0.04$] and younger mothers [OR 0.4(0.2-0.8) $p=0.01$]. However they were similar with respect to card availability [OR 0.7(0.1-4.6)], sex [OR 1.3(0.7-2.5) $p=0.43$] and birth order [OR 0.7(0.4-1.3), $p=0.27$].

Household and socioeconomic characteristics

Cases were similar to controls in respect of all household and socioeconomic determinants of immunization reported in other studies (Table 1, Table 2, Table 3).

Factors related to access to immunization services

Delayed receipt of birth OPV and BCG were the only significant access factors associated with full immunization coverage (Table 4). Distance from health facility was not a significant determinant of full vaccination.

Health system factors

The statistically significant health system factors/indicators were delayed receipt of OPV3 (OR 3.0(1.5-6.3) $p=0.02$) and failure by the mother to receive (\Rightarrow) 2 doses of antenatal tetanus toxoid (OR 3.2(1.6-6.5) $<math>p<0.01</math> (Table 5). There were no statistically significant differences between cases and controls in respect of sources of maternal IEC from bivariate analysis. However, CHWs (OR 0.4(0.2-1.1), $p=0.05$) and friend (OR 0.6(0.2-1.1), $p=0.06$) were included in the multivariate analysis model. Cases and controls were similar in respect of getting their immunization IEC from radio ($p=0.52$), television (OR 1.2(0.3-5.2) $p=0.53$), healthcare workers (OR 0.6(0.2-2.4) $p=0.35$) and neighbours (OR 1.0(0.5-2.0) $p=0.52$). The main reasons for non-vaccination given by case-mothers/care-givers ($n=61$) were vaccine stock-outs (33%), mother too busy(8%),unaware of time of vaccination(8%),place of vaccination too far(7%),unaware of need for vaccination(7%), child$

ill brought but not vaccinated(5%), time of vaccination inconvenient(4%) and other not specified(18%).

Multivariate analysis of risk factors (Unconditional Logistic Regression)

Variables with $p<0.1$ from bivariate analysis included in the model were child age group, maternal age group, paternal marital status, timely birth OPV, timely BCG, timely OPV3, (\Rightarrow) 2 doses of maternal tetanus toxoid, receipt of immunization IEC from CHWs and receipt of immunization IEC from friends. Only four factors remained statistically significant after unconditional logistic regression as shown in (Table 6).

Discussion

Younger children were less likely to be fully immunized at 12 months probably reflecting fewer chances for immunization. This could also arise due to a recent period of poor immunization services such as healthcare workers strikes as occurred in Kenya in November-December 2013 [14, 15]. These findings are consistent with studies in most sub-Saharan countries [16]. Children of younger mothers were more likely to be incompletely immunized when confounding was controlled for. This is consistent with many studies conducted in similar settings. Paternal age was not a significant determinant of full immunization. In this study gender was not found to be associated with incomplete immunization as found in India [17-19]. Similarly birth order which has been found to be associated with incomplete immunization in Nigeria and India was not a statistically significant determinant of incomplete immunization. Place of residence (urban/rural) did not influence completion rates. Paternal and maternal income, education and religion were not significantly associated with full immunization status. Higher maternal education attainment has been associated with improved immunization completion rates in many similar settings. Physical access to immunization was not a barrier to immunization completion. Distance from health facilities and migration have been associated with low full immunization status [9, 20-23]. In this study area, most participants lived more than one kilometre away from health facilities but this did not affect completion rates. This could be attributed to better means of transportation particularly the presence of motorcycle riders. Few participants had migrated out of the area but even so this did not affect immunization completion rates. Non-physical barriers indicated by low coverage with age-appropriate birth vaccines (OPV and BCG) were noted to exist. Half of the study participants were delivered by TBAs. This could have contributed to the low coverage by age-appropriate vaccines. Non-availability of vaccines when children presented themselves for birth vaccines may also have contributed to low coverage with age-appropriate vaccines. This is both an access as well as health system determinant of full immunization.

Health system utilization was a significant determinant of full immunization as indicated by age-appropriate coverage with OPV 3, DPT 3 and measles. Owino and colleagues working in a slum area in Nairobi, Kenya found that health system utilization remained low in spite of excellent access to immunization services [20]. Delivery at a health facility and attending ANC at least once during the index pregnancy was not significantly associated with higher completion rates however attending ANC more than twice as indicated by receipt of at least 2 tetanus toxoid doses was significantly associated with full immunization. This suggests that the more contact with the health system during ANC period the more likely one is to complete infant vaccinations. This is consistent with

findings by Tadesse and Belachew in Ethiopia [8, 24], Hu et al in Chinese immigrants [23] and Rahman and Obaida-Nasrin in Bangladesh [22]. Neonatal tetanus protection is an indicator of good ANC attendance and general acceptance of antenatal services. This was also found in Mali [25]. Strategies to improve full immunization coverage should target increasing ANC attendance. The most common reason for children not being vaccinated was vaccine stock outs. Weaknesses in EPI services have long been recognized as deterrents to immunization completion [26, 27]. Evaluation of the source of information on immunization revealed that CHWs and friends may be an important way of reaching mothers as compared to the more traditional modes such as the provincial administration, healthcare workers and radio.

Study Limitations

Children resident in Uganda were not included in the study due to administrative reasons. This could have introduced information bias. Case findings efforts of the present study traced 38/61 (62%) from the original sample and the control finding efforts traced 85/122 (70%). Through key informant interviews with the community leaders, the missed children were noted to reside on the Ugandan side of the border. It was noted also that the parents of these children register them as Kenyan residents because the health facility charges non-Kenyan residents more to access charged services. This unexpectedly high number of non-residents may have biased our study. This is a special population that needs study.

Conclusion

The main determinants of full immunization were child's age (12-17 months), maternal age (≤ 25 years), timely receipt of birth OPV and receipt of at least 2 doses of neonatal tetanus toxoid by the mother. Physical distance, socioeconomic and household factors were not significant determinants of full vaccination as reported in many studies in similar settings. Strategies to increase full immunization should aim at increasing the frequency of ANC attendance to at least twice per pregnancy, ensuring comprehensive IEC to the whole community with special focus to younger mothers, early initiation of the vaccination schedule and improving health system performance. CHWs and peer education through friends may be an important addition to traditional modes of immunization IEC for mothers.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

OWE was involved in the conception, design, analysis, data interpretation and report writing. AAS and XLH were involved in the protocol design, study supervision and report writing. All authors read and approved the final manuscript.

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Tables and figure

Table 1: Household characteristics of study participants

Table 2: Paternal socioeconomic characteristics of study participants

Table 3: Maternal socioeconomic characteristics of study participants

Table 4: Health facility access factors

Table 5: Analysis of health system determinants

Table 6: Multivariate analysis of risk factors with $p < 0.1$ from bivariate analysis

Figure 1: Map of Busia County, Western Kenya showing the constituent sub-counties including Teso South sub-county

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Table 1: Household characteristics of study participants

Household characteristic	Cases(n)	%	Controls(n)	%	OR, 95% C.I.	p-value
Rural	33	57	68	56		
Urban	28	43	54	44	1.0(0.6-1.4)	0.88
Distance from water source						
0-30 minutes	59	97	120	98		
>30 minutes	2	3	2	2	0.5(0.1-3.6)	0.6
No. of habitable rooms in house						
One	41	67	85	70		
Two or more	20	33	37	30	0.9(0.5-1.7)	0.87
Floor type						
Wood, soil, other	53	87	107	88		
Cement or tiles	8	13	15	12	0.9(0.4-2.3)	0.87
Lighting fuel						
Firewood, Paraffin	58	95	118	97		
Electricity	3	5	4	3	0.7(0.1-3.0)	0.69
Ownership of mosquito nets						
None	4	7	7	6		
One or more	57	93	115	94	1.2(0.3-4.1)	1
Access to media						
Radio						
Yes	51	84	106	87		
No	10	16	16	13	0.8(0.3-1.8)	0.65
Television						
Yes	3	5	4	3		
No	58	95	118	97	1.5(0.3-7.0)	0.69
Internet						
Yes	18	30	25	20		
No	43	70	97	80	1.6(0.8-3.3)	0.2

Table 2: Paternal socioeconomic characteristics of study participants

Paternal characteristic	Cases(n)	%	Controls(n)	%	OR, 95 % C.I.	p-value
Income(Ksh)						
<3000	33	54	54	45		
3000+	28	46	66	55	1.4(0.8-2.7)	0.27
Occupation						
None	2	3	1	1		
Peasant agriculture, Small business, other	58	96	119	99	4.1(0.4-46.6)	0.26
Highest education level attained						
Has not completed primary school	20	33	45	38		
Completed at-least primary school	40	67	75	62	1.2(0.6-2.3)	0.7
Religion						
Christian	59	98	114	95		
Other	1	2	6	5	3.1(0.4-26.4)	0.43
Marital status						
Monogamous	45	75	103	85		
Polygamous, Other	15	25	17	15	0.5(0.2-1.1)	0.1
Has received information on immunization						
Yes	60	100	117	98		
No	0	0	3	2	3.1(0.2-62.4)	0.51

Maternal characteristic	Cases(n)	%	Controls(n)	%	OR, 95% C.I.	p-value
Income(Ksh)						
<3000	47	78	91	75		
3000+	13	22	31	25	1.2(0.6-2.6)	0.71
Occupation						
None	12	20	21	17		
Peasant agriculture, Small business, Other	48	80	101	84	1.2(0.5-2.6)	0.68
Highest education level attained						
Has not completed primary school	28	46	63	52		
Completed at-least primary school	33	54	59	48	0.8(0.4-1.5)	0.53
Religion						
Christian	59	98	119	97		
Other	1	2	3	3	1.5(0.2-14.6)	1
Marital status						
Monogamous	45	75	102	84		
Other	15	25	20	16	0.6(0.3-1.3)	0.23
Has received information on immunization						
Yes	59	97	120	98		
No	2	3	2	2	0.5(0.1-3.6)	0.6

Determinant	Cases	(%)	Controls	(%)	OR,95%CI	p-value
Migration in the last 5 years						
Yes	10	16	15	12		
No	51	84	107	88	1.4(0.6-2.7)	0.5
Distance from health facility						
<1km	8	13	27	25		
=>1km	53	87	95	75	0.5(0.2-1.3)	0.17
Age-appropriate birth OPV						
No	10	16	11	9		
Yes	32	84	108	91	3.1(1.2-7.9)	0.02
Age-appropriate BCG						
No	30	53	33	28		
Yes	27	47	86	72	2.9(1.5-5.6)	<0.01

Table 5: Analysis of health system determinants

Health system indicator	Cases (n)	%	Controls (n)	%	Odds Ratio, 95% Confidential Interval	p-value
Age-appropriate OPV3						
No	21	40	21	18		
Yes	32	60	98	82	3.0(1.5-6.3)	0.002
Age-appropriate DPT3						
No	18	35	32	27		
Yes	34	65	87	73	1.4(0.7-2.9)	0.2
Age-appropriate Measles						
No	8	15	14	12		
Yes	45	85	105	88	1.3(0.5-3.4)	0.35
Mother attended ANC clinic						
Yes	60	98	116	97	0.5(0.1-4.4)	0.5
Place of delivery						
Health facility	31	51	60	51		
Traditional birth attendant	30	49	62	49	1.1(0.6-2.0)	0.5
Mother has received (= >) 2 doses of tetanus toxoid						
No	30	49	24	27		
Yes	25	45	64	73	3.2(1.6-6.5)	<0.01

Table 6: Multivariate analysis of risk factors with p= <0.1 from bivariate analysis

Characteristic	Unadjusted OR, 95% Confidence limit	p-value	Adjusted OR, 95% Confidence Interval	p-value
Age group of child(months)				
<18				
18-23	4.0 (2.0-8.2)	<0.01	4.2 (1.8-9.6)	<0.01
Age group of mother				
15-25				
>25	0.4(0.2-0.8)	<0.01	2.5(1.1-5.0)	0.03
Age-appropriate BCG				
No	2.9(1.5-5.6)	0.001	3.2 (1.4-7.3)	0.005
Child protected against neonatal tetanus (Maternal TT =>2)				
No	3.2(1.6-6.5)	<0.01	2.5 (1.2-5.4)	<0.02

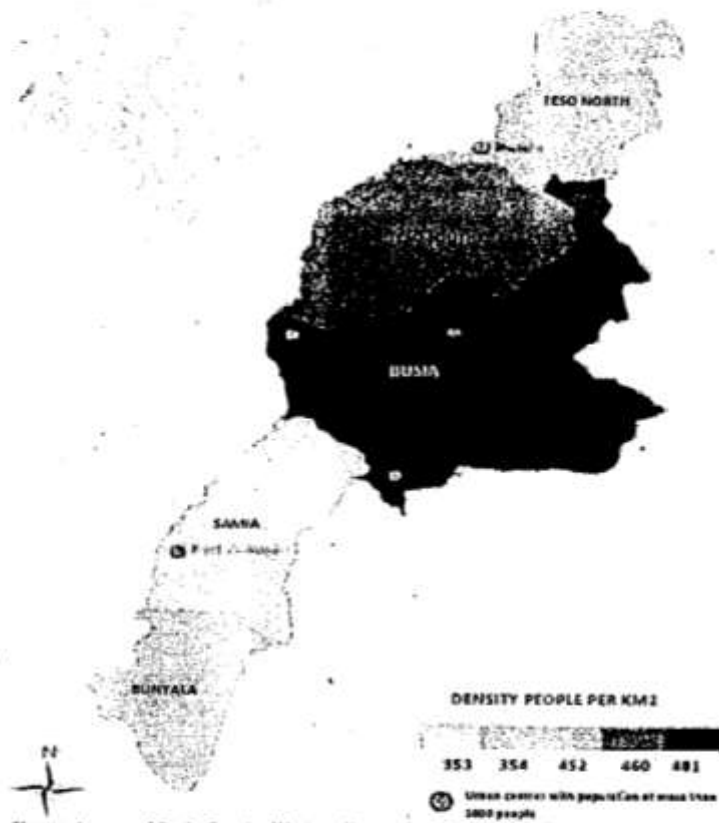


Figure 1: map of Busia County, Western Kenya showing the constituent sub-counties including Teso South sub-county
 Map source: Commission on Revenue Allocation-Kenya