DETERMINANTS OF ACCESS AND UTILIZATION TO HEALTH CARE SERVICES POST MEDICAL RESEARCH: A CASE OF A MALARIA VACCINE TRIAL IN KILIFI COUNTY, KENYA

BY

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DECLARATION

This Research Project Report is my original work and has not been submitted for any award in this University or any other institution of higher learning.

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This Research project has been submitted for examination with our approval as the university supervisors

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DEDICATION

I dedicate this work to my colleague Francis Kombe, who ensured I had enough time for my studies by always offering to stay late until I was through with my work.

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ABBREVIATIONS AND ACRONYMS

ANC:	Anti-Natal Care
CHWs:	Community Health Workers
CIOMS:	Council for International Organisations of Medical Sciences
FGD:	Focus Group Discussion
HF:	Health Facility
IDI:	In-depth interview
KWTRP:	KEMRI Wellcome Trust Research Programme
PHO:	Public Health Officer

WHO GCP: World Health Organization Good Clinical Practice

ABSTRACT

Health care is acknowledged as one of the basic rights of every human being. Different strategies have been recognized to ensure improvement in health care. Some of the strategies employed by different governments include medical research to enhance the search of appropriate interventions. However, despite the strategies put in place, studies have shown that uptake of the developed interventions has been way below expectations. Empirical findings have identified different factors that could determine uptake of the services to the targeted population. These factors include knowledge, attitude and cultural values and beliefs in relation to the health problem and recommended service; affordability, accessibility, perceived quality of care as well as the attitudes of health care services providers; distance from health care facility, household income, authoritative sources of information among others. Medical research projects conducted in Health Facilities (HF) especially in developing countries often provide support in form of construction or expansion of facility buildings, hire additional staff and provide improved quality of care (ambulatory services, skilled staff) and these could benefit all facility users. In resource poor settings, studies have shown that individuals join health research to utilize health care services, often provided for free in studies especially in context of vast unmet health needs. Consequently, exit of research projects have the potential to impact negatively on the healthcare services uptake when project resources and services are removed. Little is known about the potential effects when research projects are withdrawn especially on the access and utilization of health care services, hence the need for more empirical work. This project, focussed on the determinants of access and utilization of health care services after the exit of a Malaria vaccine trial, which was carried out by Kenya Medical Research Institute/Wellcome Trust Research Programme (KWTRP) in Kilifi County. Objectives of the study were to establish how economic factors, quality of care and cultural values and beliefs determined access and utilization of health care services post medical research. The study was carried out in Madamani community which had participated in the malaria vaccine trial. It involved a sample of 22 respondents who took part in In-depth interviews, Focus Group Discussions and filling questionnaires. It employed a descriptive survey research design. The study identified economic factors, quality of care, severity of illness as well as cultural values and beliefs as key determinants for access and utilization to health care services after the exit of a trial.

CHAPTER ONE

INTRODUCTION

1.1 Background of the study

Health improvement has been recognized as one of the important goals within the Millennium Development Goals. 189 countries signed for these 8 important goals and strive to ensure they are achieved using recognized strategies, (United Nations 2000). One of the strategies widely used is medical research, such as clinical trials, to help develop health care policies which are responsive to the health needs of the community. These efforts have however not always translated to the envisioned level of improvement (WHO 2012; Turin 2010).

In developed countries, various factors that could influence the access and utilization of health care services have been identified. These include knowledge, attitude and beliefs in relation to the health problem, affordability, accessibility, availability and perceived quality of care as well as the attitudes of health care services providers. Where these are favourable, an increase in uptake of the services has been registered (Rajendra; Lee & Binns 2013; and Simkhada et al 2008). In other studies in Africa, similar factors have been identified, depending on who the service targets. However, other factors have also been shown to have great influence on the uptake in this setting. Aspects such as cultural values and beliefs surrounding the health problem and the recommended service, quality of care, household income, authoritative sources of information, maternal/husband level of education, knowledge about the disease or condition and domestic gender power relations (Twaha et al 2007; Ditekemena et al 2012). In addition, distance from health care facility, maternal and child age, household head occupation and past experiences on the kind of disease targeted influence uptake of these services locally (Otieno et al 2011).

Medical research and clinical trials are recognized as the corner stone of development of medicines and improved healthcare. Clinical trials are one form of health research projects, conducted within health facilities to test new or proven treatment interventions. The need for improved health care has necessitated the increase in funding for medical research and especially transnational research with the aim of meeting the goal of developing superior diagnostic, prophylaxis and therapeutic measures to counter the debilitating impact of diseases in developing countries (Tindana 2007; Experts in clinical

trials 2011; Zong 2008; Farmer 2002). To achieve this, participation of volunteers is paramount (Godskesen et al 2014; Williams, Entwistle, Haddow, Wells 2014).

Internationally funded research projects close on a regular basis and this have the potential to impact negatively on the health outcomes especially on the trial participants when project resources and services are removed (Stephenson et al 2008). However, the exit of trials is usually a neglected area when compared to the amount of resources (time, finances and personnel) directed towards recruitment and other active phases of a trial. It is paramount for researchers/trial staff to recognize they have an ethical responsibility to ensure appropriate support for those who have been research participants when studies come to an end. These responsibilities are created by virtue of the fact that researchers have entered into a relationship with the research participants and the host community that cannot simply be waved away because it is inconvenient (Willson, Elkan & Cox 2007; Cox, Wilson, Arthur, Elkan & Armstrong 2005; Ashcroft 2005; Dinnet et al 2004; Greenwood & Hausdorff 2003). Although there is a consensus that trial subjects should not be worse off than they would have been had they not participated in the study, the current contentious issue is on how much they, or the community from which they come, should subsequently be 'rewarded' for having taken part in the trial (Greenwood & Hausdorff 2003).

Clinical trials (CTs) are often conducted in weak public health systems in Africa and this requires CTs to invest substantially to meet both international and local standards of care. Clinical trial inputs have the potential to benefit local health facilities (HF) through construction or expansion of HF and improved quality of care including strengthening ambulatory services, skilled staff and support with essential drugs (Angwenyi 2014; Cutts et al 2006, Liheluka et al 2013, Tinto et al 2014; Marchettia et al 2012; Idoko et al 2013). In resource poor settings, studies have shown that individuals join health research to access health care services provided in studies especially in context of vast unmet health needs. In fact, long-term research projects that offer basic medical care and treatment to their study participants have the potential to become de facto primary health care providers (Cox 2000; Cox et al 2005). There is evidence that when projects withdraw, it could affect communities and individuals involved through for instance instilling fear of being abandoned due to decreased contact from research teams or the services provided by research organizations (Cox 2000; Cox et al 2005). In addition, the limited access to health care to patients in the developing world makes it unlikely that the improved services will be sustainable after study comes to an end (Zong 2008). Thus this suggests

the potential negative impact on health outcomes when research projects are concluded (Stephenson et al 2008).

Ethical guidelines have been put in place which among other important research concerns, also address the need to consider the period after clinical trials are concluded. The guidelines include World Health Organization guidelines on good clinical practice (WHO GCP), World Medical Association's Declaration of Helsinki, Guidelines of the Council for International Organisations of Medical Sciences (CIOMS guidelines), UK Nuffield Council on Bioethics among others. These generally agree that the ethical responsibilities of research investigators, sponsors, and participants in a clinical trial do not end on its completion. However the precise nature of the responsibilities is still under debate and there is need for more empirical work to examine the potential impact on health care services once clinical trials conclude.

This project focuses on a Malaria vaccine trial, which was carried out by Kenya Medical Research Institute/Wellcome Trust Research Programme (KWTRP) in Kilifi County. The study intends to do a descriptive social science study on one of the rural health facilities to help in exploring the determinants of access and utilization of health care services after the end of the malaria vaccine trial.

1.2 Statement of the problem

Internationally funded research projects close regularly (Stephenson et al, 2008). End of trials, especially large multicentre clinical trials, is a complex process. However, most resources, including staff, support, time and information is usually directed at the stage of trial recruitment and implementation with little attention given to the trial conclusion (Willson, Elkan & Cox 2007; Cox et al 2005; Dinnet et al 2004). To many research participants, research provides access to otherwise scarce health care services, as the trials tend to improve the standard of care for research participants particularly in resource poor settings where there is limited or even no access to health care (Angwenyi et al 2014; Mfutso-Bengo et al 2008; Stephenson et al 2008; Zong 2008; Cutts et al; Liheluka et al 2013; Masiye et al, 2008). Therefore the removal clinical trial and the services they provide have the potential to impact on facilities and communities. An understanding of the determinants of access and utilization of health care services, both real and perceived, after the end of a clinical trial could provide imperative evidence useful in establishing relevant support systems for research study participants and the community. The proposed study intended to do a descriptive social science study on one

of the rural health facilities to help in exploring the determinants of access and utilization of health care services after the conclusion of medical research project.

1.3 Purpose of the study

The purpose of this study was to identify the determinants of access and utilization of health care services post medical research in Kilifi County.

1.4 Research objectives

The objectives of this study were:

- i. To establish whether economic factors determines access and utilization of health care services post medical research
- ii. To find out whether quality of care at health facilities determines access and utilization of health care services post medical research
- iii. To assess whether cultural values and beliefs determines access and utilization of health care services post medical research

1.5 Research questions

The study was guided by the following research questions:

- i. How does economic factors determine access and utilization of health care services post medical research
- ii. How does quality of care at health facilities determine access and utilization of health care services post medical research?
- iii. How do cultural values and beliefs determine access and utilization of health care services post medical research?

1.6 Significance of the study

End of a medical research project has been a neglected area in many trials as more effort and resources are usually focused on participants' recruitment and participation stages. In addition, there is scarce evidence on the access and utilization of health care services when medical research project conclude. In addition, this study provides a platform for community members to give their perception on the determinants of access and utilization of health care services after a trial comes to an end. These findings could be useful in establishing relevant support systems for communities and facilities involved in trials.

1.7 Basic assumptions of the study

The study assumed that bias would be controlled during the In-depth Interviews (IDIs) and Focus Group Discussion (FGD) in that the participants gave their honest views.

1.8 Limitations of the study

- i. Generalization of the results might be limited since this work only involved one facility. However the issues generated might be generalizable to other similar settings
- The interviewer/moderator being a KWTRP staff asking for information on KWTRP might introduce potential bias of views provided by the participants. However having the 'insider' knowledge about the trial under study provided enable the interviewer to probe for.

1.9 Delimitations of the study

The study only focuses on Madamani sub location which is within the Ganze Sub County where the trial was carried out.

1.10 Definitions of Significant Terms Used in the Study

Access: Right to use health care services

Clinical Trial: This is a type of research that involves comparing 2 different health measures or interventions against each other to see which one is best.

Cultural values and beliefs: Characteristics of a particular group of people, defined by assumptions and convictions that are held to be true, by an individual or a group, regarding concepts, events, people, and things.

Economic factors: Factors relating to income of household and cost of services.

Health care services: Services aimed at diagnosis, treatment, and prevention of diseases provided by professional health care providers.

Medical research: Finding better ways of treating and preventing illnesses for the benefit of everyone in the future.

Quality of care: Perception of the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. This includes number of skilled staff, availability of services and waiting time

Utilization: Uptake of health care services.

1.11 Organization of the study

Chapter One outlines the Background of the study, Statement of the Problem, Purpose of the study, Objectives of the study, The research Questions, Research Hypothesis, Basic assumptions of the study, significance of the study, Delimitation of the study, Limitations of the Study and Definition of significant terms as used in the Study.

Chapter Two explains the related literature written by different Authors on the factors influencing access and utilization of health care services post medical research and the Conceptual framework.

Chapter Three presents the design, the methodology of the study, the target population, the sampling size and procedure, methods of data validity and reliability of research instruments, operationalisation definition of variables and the methods of data analysis to be employed in the study.

Chapter Four presents the data presentation, analysis and interpretation using tables, graphs and quotes.

Chapter Five provides the discussion of findings, discussions, conclusions, recommendations and suggestions for further research.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter explains related literature written by different authors on the factors influencing access and utilization of health care services post medical research and the conceptual framework used for this study.

2.2 Uptake of health care services

Health care is acknowledged as one of the basic rights of every human being (United Nations). It is against this backdrop that governments have put in place measures towards health care improvement to their citizens. In Kenya several government health reforms exist to address these including removal of user fee, provision of free maternity, national health insurance fund, and medical research. Despite these efforts, it is noted that the expected outcome seems to be a moving target; the employed efforts have not translated to the expected uptake of the health care services, (WHO 2012, Turin 2010).

2.3 Determinants of access and utilization of health care services

Various studies have tried to understand the different access and utilization of these services. Literature provides the following factors based on diverse health needs.

2.3.1 Economic factors

Empirical studies have identified economic factors as important in determining the uptake of health care services. Economic factors encompass household income, household socioeconomic status, and health care cost including transportation, insurance or at point of care charges and time (Rajendra et al 2013; Simkhada et al 2008). In all these studies, higher household income, higher socio economic status and low cost of services was found to be positively associated with facility use while the opposite remaining to be true. Financial constraint and low socioeconomic status on the other hand is seen to be the most important factor in suboptimal use of health care services. The costs of the service including transportation and necessary laboratory tests were major factors prohibiting service utilization, (Charlotte 2014; Rajendra et al 2013; Twaha et al 2007; Abubakar et al 2013).

2.3.2 Quality of health care service

The perceived quality of health care services in the health facility by those who are supposed to seek health care service has also been noted to have an impact on the usage of the service. The quality of the service is characterised by availability of the service, perceived quality of medication, attitudes of service providers (Simkhada et al 2008). Studies have shown that poor relationships between patients and healthcare providers, and rude and unfriendly attitudes of nurses, as reasons why patients prefer not to be referred to some hospitals (Simakadha et al 2008). In contexts where health services providers are often overworked, stressed, and have to work in an infrastructure with severely limited resources, the quality of services is usually compromised and being friendly is considered an additional burden (Ditekemena et al 2012; Simkhada et al 2008; Twaha et al 2007). In addition, Ditekemena et al 2012 noted that where the service is not available or where services are not proposed by health providers, then uptake of the service is usually low.

2.3.3 Cultural values and beliefs

Traditional beliefs, cultural standards and customs about an illness or condition requiring care play a great role in influencing uptake of health care services by different communities (Simkhada et al 2008; Ditekemena et al 2012). A study in Nepal found cultural values and beliefs had a significant negative impact on the use of maternal health services (Rajendra et al 2013). In this study, they reported that among this community there was a belief that the household deity would be angry if they went against the tradition of delivering in an animal shed by opting to deliver in health care facility. In another study focussing on Anti-Natal Care (ANC), reason for not attending ANC at first trimester was the fear associated with the local belief that the early period of pregnancy was most vulnerable to witchcraft. There was a fear that blood could be used for bewitching women if it came into the wrong hands.

Certain cultural standards also contribute to negative perceptions towards uptake of services for instance gender roles and stereotyping. For instance, in Kenya, men who accompanied their wives to ANC services were perceived as being dominated by their wives. Frequently men perceive that ANC services are designed and reserved for women, thus are embarrassed to find themselves in such "female" places. Some women feel uncomfortable being seen with their male partner attending ANC clinics (Ditekemena et al 2012). In cervical cancer studies, some authors reported that men were reluctant to

participate in women's reproductive health issues (Simkhada et al 2008; Twaha et al 2007).

Cultural values and beliefs are also expressed through the availability of alternative sources of medicine. Traditional healers are perceived in some cultures to be more powerful and that are preferred and trusted more than other ways of health care (Ditekemena et al 2012). In other studies, the role of traditional medicine and healers was perceived to act as a barrier in uptake of health care services (Charlotte et al 2014; Abubakar et al 2013). Twaha (2007) and Abubakar (2013) also identified sources of authority of health knowledge as an important cultural factor in the uptake of health care services. These are very powerful in some cultures and could impact on the successful implementation of health measures.

Cultural values and beliefs however vary depending on the ethnicity and religion and the kind of service being sought. Therefore, the relative importance of these factors should be examined in the changing context of culture, values and the health system (Rajendra et al 2013)

2.3.4 Other determinants of access and utilization of health care services

Other determinants of access and utilization of health care services in Africa have been described by several authors to include: literacy levels among caregivers or patients; knowledge about the disease or condition; gender and power relations among households; maternal and child age; and the household head's occupation and availability of time for caregivers to take their sick children to hospital (Mutyaba et al 2007; Ditekemena et al 2012, Otieno et al 2011).

2.4 Uptake of health care services in clinical trials

Relatively large resources are normally made available to research programmes operating in resource constrained environments so as to meet the required standard for conducting research. In this case, research plays a very important role that is viewed to complement the overburdened national health systems where there is limited or poor access to health care in developing world (Angwenyi et al 2014; Mfutso-Bengo et al 2008; Stephenson et al 2008; Zong 2008; Cutts 2006; Liheluka et al 2013; Masiye et al 2008). Some of the reasons why research participants in resource poor settings enrol in research include the anticipation for extra treatment, an opportunity to prolong life and hope for a miracle or

cure (Cox 2000; Molyneux, Peshu, K. Marsh 2004; Apateerapong & Ananworanich 2003; Mfutso-Bengo et al 2008; Masiye et al 2008).

Despite the healthcare benefits accrued from research projects, internationally funded research projects close on a regular basis (Stephenson et al 2008; McNeece & Arnold 2002). According to Cox 2000 & Cox et al 2005, the removal of research projects could potentially instil fear of being abandoned due to decreased contact from research teams or the services provided by research organizations. The management of trial conclusion is a neglected area as most resources, including staff, support, time and information is usually directed at the stage of trial recruitment and implementation, with little attention given to the conclusion and exit of trials. It is paramount to recognize that trial staff have an ethical responsibility to ensure appropriate support for those who have been research participants when the study comes to an end (Willson, Elkan & Cox 2007; Cox et al 2005; Armstrong 2005, Dinnet et al 2004).

Establishment of post trial support services for research study participants that are feasible requires an understanding of how project closure could have an impact - both real and perceived - on study participants' uptake of health care services (Stephenson et al 2008). Studies have recognized that making transition plans and budgeting for mechanisms from the start of the project and the actual marking of the end of a trial reduces the negative impact on participants of project closure (Wilson, Elkan & Cox 2007, Nuffield Council on Bioethics, 2005; Stephenson et al 2008). An elaborate exit strategy enables participants to deal with the anxieties associated with conclusion of research projects, identifies any prevailing concerns and expectations and how they will be handled, and identify ways in which existing research-community relations could be sustained.

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2.5 Conceptual framework

Figure 2.1 presents the conceptual framework consisting of independent variables,





2.5.1 Economic factors

These are factors related to costs incurred when one seeks for services for the under five child. This may include consultation fees, costs for diagnostic tests, costs for medication, costs when being referred to superior HFs, transport costs, costs for meals among others. These are important determinants in accessing HC services form health facilities. High costs act as deterrent when accessing care.

2.5.2 Quality of health care services

This includes aspects such as perceived quality of medication, health worker's attitude, availability of care and waiting time. When these are favourable, then it encourages people to access and utilize health care services.

2.5.3 Cultural values and beliefs

This is related to characteristics of a particular group of people, defined by assumptions and convictions that are held to be true, by an individual or a group, regarding concepts, events, people, and things. It includes traditional beliefs and norms of a particular community. This is shown by aspects such as availability of alternative medicine, religious beliefs/spiritual and decision makers

2.5.4 End of medical research project

When a research project comes to an end, support received through the project ceases as it withdraws or stops providing the resources (such as supplies, staff, information, facility improvement, equipments etc) available during the study. For developing world, the provision of those services may not be sustainable since integrating these services in the routine health system may not be realistic. Thus the end of provision of these services may affect community's utilization of health care services.

2.6 Identified gaps in literature

Available literature has provided data that identifies some of the factors influencing access and utilization of health care services in normal circumstances, and the potential contribution of medical research in supporting health service delivery. However there is limited empirical work on the potential impact of health service delivery and uptake upon conclusion and removal of medical research projects. This study therefore aims to generate more evidence that could provide useful information to advice on how to handle end of medical research.

2.7 Summary of literature

Improvement of health care services has been a goal of governments. Various strategies are normally put in place to ensure achievement of this important goal. Medical research and clinical trials which is one of the recognized strategies has been employed by many governments. It has been acknowledged that despite the government efforts, uptake of the services has not been optimal. Various factors have been identified to affect the uptake which includes quality of health care services, economic factors, cultural values and beliefs among others. In developing world, medical research projects provide to otherwise scarce healthcare services especially since there is limited or even no access to healthcare. As such, those who participate in research enjoy better healthcare which may not be sustainable after the exit of the project and it is not clear how the exit of these studies contribute towards the factors influencing access and utilization of health care services post trial by focusing on a case of Malaria vaccine trial which was conducted in Kilifi County.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

This chapter presents the design, and the methodology of the study. It also describes the Target population, the Sampling procedure, Methods of data collection, validity and reliability of research instruments, operational definition of variables, and the methods of data analysis to be employed in the study.

3.2 Research design

This study adopted a descriptive survey research design which is used to obtain information concerning the current status of a phenomenon and to describe "what exists" with respect to variables or conditions in a situation. It is done in a natural and unchanged environment without introducing influences in any way. Descriptive studies are usually the best methods for collecting information that will demonstrate relationships and describe the situation as it exists (Labaree 2014, Shuttleworth 2008, Key 2002 & Nebeker). Therefore, it can be used when collecting information about peoples' perceptions, habits or any of the variety of social issues. This design is chosen because the researcher will be dealing with people whose perception can be well described upon interviewing and discussions analysed before any conclusions could be made.

3.3 Target population

The study targeted the community that participated in the recently concluded Malaria vaccine trial. The study was carried out in Ganze Sub County in three sites. A total of 904 children and infants were included in the trial which was conducted from 2009 to January 2014. This study focused on the Madamani community, which forms one of the three sites that participated in the recently concluded Malaria vaccine trial. The area is within Madamani and Mwahera sub location. The site was purposively selected based on a number of participants recruited from the area, it being the first site where recruitment started and there being a lot of community engagement activities during the early phases of the trial.

3.4 Sample Size and Sampling procedure

The study employed purposive sampling technique in selecting the site and the participants, to allow for diversity in the choice of respondents, with sufficient experience in the phenomenon under investigation (Green & Thorogood 2009). The sampling criteria employed included age, gender, level of interaction with the malaria vaccine study, location of residence from Madamani dispensary and for health providers, type of cadre and work experience were also considered.

The participants selected included female parents/guardians of research participants and non-study children below the age of 5 years selected from different villages in Madamani location. Study only focussed on female parents since they are predominantly responsible for health care needs of children, hence more likely to visit HF than male parents. Others were health care providers including health facility in-charge (nurse), public health officer (PHO) and community health workers (CHWs).

Category	Data collection method	Numbers involved
Parents/guardians to study	IDI (Pilot)	1 participant
participants	1 Focus group discussion	8 participants
	(FGD) with female parents	
Parents/guardians to non-	1 Focus group discussion	7 participants
participants	(FGD) with female parents	
Health providers	6 In-depth interviews (IDIs)	1 nurse in-charge
		1 PHO
		4 CHWs

Table 3.1. Sample size

3.5 Data collection approach

The study used a mixed method approach employing both quantitative and qualitative data collection techniques. The quantitative data was collected from existing health facility records to describe what had been happening since the end of the trial in terms of utilization and delivery of health care services, in terms of selected services. In particular, the study intended to find out how many under five year old patients were attended to at the health facility 3 months prior and 3 months post end of the trial; to determine whether there was any effect in health care delivery and utilization. In addition a structured questionnaire was administered to parents of children under-five years who used the study facility in the last 12 months. The qualitative data was used to explore views of various stakeholders on the effect of the end of the trial on utilization of health care

services at the health facility. This data was collected using in-depth interviews and focus group discussions.

3.6 Data collection techniques

The study employed the following data collection techniques:

3.6.1 Audit of health facility records

This was used to collect the quantitative data from the health facility records. It helped in describing what had been happening since the end of medical research project in terms of utilization of health care services. In particular the method enabled finding out the number of patients that were attended to at the health facility; 3 months prior to exit, 3 months of exit phase and 3 months post end of the trial (n=9 months). The data of interest collected included vaccination, growth monitoring and treatment for malaria for children below the age of five years who were attended to at the health facility within the 9 month period of interest.

3.6.2 Questionnaires

Questionnaires are a useful tool that allows uniformity in the way questions are asked, to provide generalized information about a certain phenomenon under study. For this study questionnaires were used to gather quantitative data showing: important factors that parents consider before accessing health care; health care costs incurred during the last clinic visit; explore persons who are consulted or are involved in decision making regarding health care for under-five year olds. This tool was administered to mothers of children under-five years who were invited to participate in focus group discussion (n=2, with 15 participating mothers). The data was collected prior to the FGD to avoid any influence from the other group members which is possible in such discussions. The tool was structured and had sections with open ended responses to allow respondents to elicit or elaborate their responses.

3.6.3 In-depth interviews

This was employed in collecting qualitative data necessary in exploring views of the health workers, and a parent to trial participant on the effects of the exit of the trial on access and utilization of health care services, factors influencing access and utilization health care services at the health facility after the exit of a trial and on recommendations on appropriate exit of medical research project.

3.6.4 Focus group discussions

This was used to collect qualitative data from the parents/guardians to study participants and parents/guardians to non-participants, to explore effects of the exit of the trial on access and utilization of health care services, the factors influencing access and utilization health care services at the health facility after the exit of a trial and recommendations on appropriate exit of medical research project.

3.7 Validity of the research instrument

Validity is the degree to which results obtained from the analysis of the data actually represent the phenomenon under study (Mugenda and Mugenda 2003). It is concerned with establishing whether the research instruments content is measuring what is intended (Orodho 2005). The researcher ensured validity of the research instruments through a series of activities; during tool development, the tool was piloted among colleagues to ensure that the questions asked were appropriate and generated desired responses; the questionnaire, FGD and IDI guide were translated to Kiswahili and piloted among community members; feedback from the pilot activity and from supervisors were used to amend the tool that were administered in the study. All the inputs were included in the instruments before actual data collection.

3.8 Reliability of the research instrument

Reliability is a measure of the degree to which a research instrument yields consistent results or data after repeated trials (Mugenda and Mugenda 2003). Therefore when testing the reliability of an instrument, an instrument should produce consistent results when administered several times on the same group. For this descriptive study I strived to interview till a point of data saturation (where no new information was obtained) and probing respondents during interviews it enabled us to get as much detail as possible. During interviews, I took note of emerging issues and had the opportunity to ask in subsequent interviews, if these issues were also felt. All the tools developed covered similar themes and this allowed me to check for whether there were any similarities or differences in the pattern of responses by different respondents.

3.9 Data presentation and analysis technique

The interviews and FGDs were conducted in the language preferred by respondents (Kiswahili, Giriama, and English). The interviews were audio taped, transcribed and translated into English. Qualitative data analysis was done using a thematic approach to explore common themes emerging from the data and topic guides. This involved reading a few interview transcripts to develop the coding framework. Thereafter the coding framework developed was applied to code all qualitative data. Qualitative data was managed using MS word and qualitative software (NVivo 8). All quantitative data was managed using MS Excel to generate descriptive frequencies. The data will be presented in tables and descriptive form based on the identified themes.

3.10 Operationalisation definition of Variables

Variable	Indicator	Scale
Dependent variable Uptake of health care services	• Services offered at health facility for under five, Services accessed by under five	Nominal
	• Number of under-five served at health facility before and after the end of the medical research project	Ratio
Independent variables		
Economic factors	• Cost of service (e.g. consultation fees, diagnostic tests, medication referrals, transport, meals)	Nominal
Quality of health care services	 Perceived quality of medication Heath worker's attitude Availability of care Waiting time 	Nominal
Traditional norms and values	Alternative medicineReligious beliefs/spiritualDecision making	Nominal
Moderating variable End of medical research project	• Existence of services offered by research project	Nominal

 Table 3.2: Operationalisation definition of variables

CHAPTER FOUR

DATA ANALYSIS, PRESENTATION AND INTERPRETATION

4.1 Introduction

This chapter presents the data analysis, presentation and interpretation with respect to the determinants of access and utilization of health care services post medical research. It includes information on the response rate, demographic characteristics of the respondents as well and finally presents the data. This being a qualitative descriptive study in providing answers to research questions, the researcher has included some of the 'rich' quotes from the participants which highlight and elaborate the findings.

4.2 Response rate

Twenty three respondents were invited to participate in the project. 22 participants turned out and gave written consent to participate in the discussions or interviews. Response rate was therefore 96%. 15 out of 16 invited respondents filled in the questionnaires which gave a response rate of 94%.

Description	Target	Respondents valid	Response
	Respondents	for analysis	rate (%)
Parents to study participants	9	9	100
Parents to non-study participants	8	7	88
Health care providers	6	6	100
TOTAL	23	22	96

Table 4.1: Study sample description

4.3 Demographic characteristics of participants

The study was keen to include participants who had stayed in the area for more than 12 months and had observed or experienced what was happening during the trial and after. Table 4.2 gives details of the demographic characteristics of the participants involved in this study.

Demographic characteristic	Category	Ν	(%)
Age (in years)	20-30	6	(27)
	30-40	14	(64)
	40-50	2	(9)
Gender	Male	2	(9)
	Female	20	(91)
Education level	None	2	(9)
	Primary	18	(82)
	Secondary	0	(0)
	Tertiary	2	(9)
Occupation	Farming	19	(86)
	Business	1	(5)
	Employed	2	(9)

 Table 4.2: Respondents Demographic Characteristics

More than 90% of the respondents were between 20-40 years old. Females were the majority since they were purposefully selected as they normally carry the responsibility of seeking health care services for their under 5 children from the health facilities. Most of the FGD respondents had some primary level schooling while those who had tertiary level education were mostly health facility staff.

4.4 Results from audit of health facility records

An audit report of health facility records was done to know the actual changes as per the health records at the Madamani dispensary, where children access care. This was so as to see the trends of utilization of health care services towards the end of the trial, during the exit of the trial and after the exit of the trial. This helped to assess whether there were any notable changes. The data collected was on the under fives and focused on the vaccination, growth monitoring and malaria since the study was on malaria.

Below is the data obtained from health facility records which helped come up with the trends in utilization of health care for the community within a 9 month period. The data is for the period 3 months before exit of the project (August 2013 to October 2013); 3 months period during the exit phase (November 2013 to January 2014); and 3 months after the trial had fully exited from the community (February 2014 to April 2014).

Indicators of	Pre-exit phase		Trial exit phase		Post-trial exit phase				
interest	Aug 2013	Sep 2013	Oct 2013	Nov 2013	Dec 2013	Jan 2014	Feb 2014	March 2014	April 2014
Vaccination	138	94	49	169	45	173	124	56	30
Growth monitoring	24	13	17	14	1	25	7	12	8
Diagnosis and treatment for malaria	2	2	1	1	1	2	7	3	2

Table 4.3: Uptake of services at health facility

Table 4.3 demonstrates utilization of health services at Madamani dispensary. The trend did not show any clear relationship between the exit of the trial and access to health care which seemed to come out strongly in the qualitative data. This could be due to the fact that community especially the parents to former trial participants received continuous health education which could have encouraged them to still access care even after the removal of the trial benefits, which is supported by the quantitative data collected during this project.

4.5 Results from the In-depth Interviews (IDIs) and Focus Group Discussion (FGDs) on effects of exit of trial on health care access and utilization

Some of the noticeable changes included those that affected the quality of services such as reduced staff, since the trial staff had been removed from the facility, which led to increased workload, congestion and delays in accessing services.

"initially ...most of the under 5's were being handled there because they were the ones in the project....because even those who were not in the study...had been brought to hospital and his sibling or even the mother who has brought him also is unwell they are seen by the study clinicians and then takes the drugs from the facility, but at least that would have reduced the workload. But currently, everyone flocks at the facility so workload has increased and staff are the same." (IDI03_male, health facility staff)

... [During the trial] we were used to being attended quickly but now we are not happy about queuing [for health services] because we were used to being attended to quickly. Now it's slow because there are few staff at the dispensary. (IDI07_Mother of a former trial participant) Availability of services was also affected due to the exit of the trial which sometimes used to support the hospital with drugs when supplies from the Ministry of Health were out of stock and there were delays in supply.

"...there was a time we had no drugs at all at the dispensary. After a short time, KEMRI vehicle arrived and was full of different drugs. We were lucky because of that. Those who belonged to KEMRI project and those not of KEMRI [project] were helped. But now there is no help, if there isn't [any drugs], then there isn't...When you go to Kilifi [district hospital] you are given boxes of Panadol to bring. So what will a patient whose illness doesn't require Panadol do?" (IDI02_female, CHW)

Another change included increase in cost of accessing services especially transport due to the removal of project vehicles to provide transport which was perceived to be a benefit. For former study participants, they reported they would now have to incur other costs such as registration fees and purchase of drugs, which were readily available during the trial period.

"If the child has been prescribed injections you have to pay, and also you have pay for transport cost to your home. You now have to get a motor bike. You cannot carry a five year child on your back from home to here." (P3, FGD 01_mother of former trial participants)

In addition, there were positive changes where for instance the facility was able to use some of the rooms constructed by the research project and equipment including seats, cabinets, and medical equipment brought by the trial to facilitate with provision of services to all health facility users:

"...At least we have been left with a room... you [KEMRI] also made us a place where could administer our vaccines, before we would use the dressing room so at least now there is a place where ... you [KEMRI] partitioned for us to do vaccination there. And also you [KEMRI] put for us cabinets because initially the cabinet were full but now there are many storage cabinets...and they are not like the government ones which... (laughing) are old and made of metal and if you put many files, opening becomes a problem." (IDI03_male, health facility staff).

Another change that was observed was health facility staff attitude. The respondents felt that health workers at the health facility have been able to retain good patient-provider relationship due to the interactions and trainings offered by research project staff, even after the trial came to an end.

I think our staff those who were here [facility] have learnt a lot from KEMRI staff... Because they [KEMRI] would not exchange with clients...and clients compare services [offered]...The client could tell you openly you are doing this to us because people from KEMRI have left. So even if you were harsh you will have to change and be like them [KEMRI]... (IDI03_male, health facility staff).

4.6 Study outcome in relation to the study objectives

4.6.1 Objective one

To establish whether economic factors determines access and utilization of health care services post medical research

Economic factors looked at the aspects in relation to costs incurred when accessing services. The results from both qualitative and quantitative tools showed that economic factors seemed to play a critical role in deciding on uptake of health care for under-fives.

Outcome of the questionnaires showed that cost of services influenced community members to a great extent with 75% saying that they consider it before making decision to access care in the health facility. Distance was also considered as it mostly determined the costs of services as most of those coming from places further from the hospital incurred transport costs. This was considered by 88% of the community respondents as shown in table 4.4.

Factor considered	Frequency	%
Cost of service	12	75
Distance	14	88

Table 4.4: Cost of care

Respondents were also asked to state the cost they incurred while seeking health care for their children from January 2014. The cost incurred by most parents (80% of the respondents) was the registration fees which majority of the respondents stated they paid between 20-30 shillings, while the least cost incurred was for diagnostic tests which was 50 shillings. About 60% of the parents stated they incured transport cost which ranged between 50 to 200 shillings which was the highest in terma of amount.

Cost incurred	Frequency	%
Registration	12	80
Consultation	0	0
Book	11	73
Drug bottle	10	67
Test	1	7
Drugs	6	40
Food	8	53
Transport	9	60
Others	2	13

 Table 4.5: Cost incurred during the visit.

Results showed that those who normally pay the costs for services for their under five children are either parents; 40% mothers and 40% fathers. It was interesting to note that people could still access services on credit, as reported by 7% of the respondents.

Who paid	Frequency	%
Mother	6	40
Father	6	40
Neighbour	2	13
Credit	1	7

 Table 4.6: Those who paid the cost in the family
 Image: Cost of the cost of the

Results from qualitative data; interviews and group discussions showed that the study benefits which included free health care provided to study participants (that is free transport to health facility, free treatment, tests, waiver of any medical cost, provision of meals during facility visits), encouraged trial participants to access care from the health facilities. This was mentioned by 9 out of 15 respondents. The removal of transport assistance came out strongly compared to other health related cost. These acted as a potential deterrent to some of the parents from accessing care.

"Other parents are now reluctant to take their children to hospital because they are used to being picked by a car and now there are no cars." (P6, FGD 01_Mother to non-trial participant)

It was also clear that the experience they had during the trial helped parents to consider the health of their children as a priority and thus after the study, they still maintained the same vigor in seeking care for their children. And this is also strengthened by the fact that the dispensary offer services on credit for those who may not have money at the time. "Based on my understanding after the training, even if you don't have money you have to get money on credit because if you delay your child with such conditions, then you are going to incur more expenses. So you have to decide, even if the cost is high but if I delay the child from seeking care, the cost will be higher."(IDI07_Mother of former study participant)

"[at the moment] if they [patients] come and we give services and always tell them money is not a priority, you will just be treated and go and then next time when they come, they come and pay back. So you just treat them and allow them to go even if they haven't paid." (IDI01_female, health provider)

4.6.2 Objective two

To find out whether quality of care at health facilities determines the access and utilization of health care services post medical research

Different aspects of quality of care were used as indicators to determine how they affect decision to accessing care for the under fives. From the quantitative data; questionnaires, 93% of the respondents indicated that availability of staff was a an important factor that they considered while the least considered was staff attitude and availability of services as shown in table 4.7.

Factor considered	Frequency	%
Availability of staff	14	93
Availability services	10	67
Hours of service	13	84
Staff attitude	10	67

Table 4.7: Quality of care

From the qualitative data, availability of services was noted to be an important factor community members (FGDs) consider when deciding on whether to seek health care at a facility. These services included availability of drugs, diagnostic tests, health education among others.

"If it's at night time I know I may not get the drugs so I have to go to a place I can get the drugs." (P2_FGD01 Mothers to trial participants)

This was a bit different from the views of the health providers (IDIs) where 4 out of 6 felt that patients would only know whether the services are available or not only upon arrival

at the facility. If services are not available such as malaria tests and medication for common ailments, then they are referred to other facilities or local chemist where they can pay for them.

"...but it is only that because a person cannot know which drug I will get, which drug I will miss ... so I don't think that they consider this so much... so they will come here and maybe if you tell her this drug is not available you cannot tell her to go to Vitengeni, you will tell her to go buy in Matanomane ... So I don't think they mostly consider factors on drugs." (IDI03_Male health provider)

Attitude of health provider was seen to be one of the most critical factors in utilization of care from health facilities according to the health providers. As a health provider put it,

"Staff kindness because staff are different ... They [community members] will tell you if I see this person I don't feel like I am getting treatment. So there are those who are willing to be handled by a subordinate than the qualified person...because whether you are qualified or not the drugs are the same and sometimes we usually say faith also can help a sick person to recover. So a person tells you that if you get this person while you are still explaining they tell you to go and take drugs." (IDI03 _Male health provider)

However, to the participants (FGD), the general view is that health workers at the particular health facility were serving them well and this could be the reason this never came up as a factor to consider to them.

Time spent at the health facility is also a factor that is considered. This came from 5 participants from FGDs. For most however, they put this in mind to help them plan well on when they will be back home. For others, this discouraged them from accessing care from the facilities. They preferred going to a private facility rather than a government hospital to avoid the long queue.

"You take time but when you leave home you in fact tell them that you are coming to the hospital but you can't know the time you will be back, because when you reach the hospital there are others who have also come with sick children. And you can't be allowed to be treated first; the first one must be attended first, so for you at home they must know that you are not sure the time you are going to come back." (P6_FGD01_Mother to former trial participant) "You get some deep thought for example if you have come all the way from home and there is only one doctor, all the patients are attended by one doctor, your colleagues are already there, you know others may think of going to a private clinic where you can be attended to and just go home as opposed to going there and waste time. One will rush to where she will get the services quickly because she just want to go back home therefore, you can think of going to a private clinic so that you can return back home quickly, that is something you can think of." (P5_FGD02_Mother to non study participant)

Quality of medication did not come up as a factor that determines their uptake of care. However, most mentioned it in terms of treating after ascertaining illness through test. Although they appreciated the trial for always treating after conducting relevant tests, it did not come out as a deterrent to them accessing care currently.

"They think if KEMRI project was still around, my child would be tested, she will be tested the level of blood and when they given drugs, I will be sure they have been given the right drugs." (IDI04_Female CHW)

4.6.3 Objective three

To assess whether cultural values and beliefs determines the uptake of health care services post medical research

Under this objective, the study tried to look at availability of alternative medicine, religious beliefs and decision makers in deciding on health care uptake for the underfives.

Questionnaires only focused on the decision makers where the respondents were asked to state the people they consult before deciding to visit heath facility. Table 4.8 shows the outcome where 53% of the respondents (who were mothers) said that they consult the fathers.

Who was consulted	Frequency	%	
None	5	33	
Child's father	7	53	
Mother in law	1	7	
Others	2	13	

Table 4.8: Those consulted

Results from the qualitative data (IDIs and FGDs) brought up information in relation to all the identified indicators.

On alternative medicine, only one of the community health workers mentioned that some community members still practice the use herbal medicine to treat febrile illnesses together with other biomedical interventions.

"Sometimes they wake up and feel it is serious, but sometimes it may be fever and you say this is only fever or flu. So she goes to the shop and buys drugs, or boils neem tree leaves and washes her and for those who are older like 5 years, they give them a spoon (of the boiled neem tree leaves)" (IDI05_Female, CHW).

Although not to a great extent, this suggests that alternative medicine determines the uptake of health care services from health facilities.

Religious beliefs/spiritual was perceived to play a role in the uptake of health care services. This came from the FGDs. Some respondents mentioned that there are a few people in their community who still visit traditional healers for serious illnesses like severe malaria. During these visits, they are given charms for protection against illnesses believed to be caused by witchcraft or other supernatural powers. A few mentioned that some parents opt to pray for their children before accessing care or when it is late in the night, with the hope for recovery.

"For some of the children who were in the study their mothers were asked, 'why do you make your children wear charms', they would say this was meant for protection. But with the constant awareness and education they were given, this practise has reduced and they are not that many." (IDI07_Mother to a former study participant)

The respondents in FGDs stated that both male and female parents were key decision makers with regards to seeking health care for their under-five year old children especially if both parents are available. Mother in-laws were at times also consulted. However, some respondents felt that mothers were the ultimate authority on matters relating to health care for their children, since they were the main carers when the father was away and looked after the child's needs including health care. Fathers were mainly consulted especially with decisions that had financial implications.

"I am alone here and the child's father stays far...I don't have to wait for the child's illness to be more serious...I will just act...even if the child father was here, he will also tell me to take the child to the hospital. So most of the time it is me who decides." (IDI07_Mother to former study participant)

4.6.4 Emerging factors

Other factors which had not been considered under the stated objectives also came up.

Severity of illness came up in the questionnaires where 67% of the respondents said they consider it before accessing care as shown in table 4.9.

Table 4.9: Emerging factors

Factor considered	Frequency	%
Severity of illness	10	67

This also came out strongly from the IDIs and FGDs as a factor being considered before making a decision to access care from health care facility. From both the community and health provider perspectives, it was felt that people normally consider the condition of the child before making the decision. So for perceived severe illnesses, the parent will not hesitate to bring the child to hospital while they may decide to observe the child for days if the illness is perceived to be manageable, prior to seeking care at the facility. Very few, only 2 parents out of the 22 respondents stated they would seek health care services promptly regardless of the child's condition.

"We were told not to allow a child to stay with an illness...we should not just be observing when we see the child's condition is not good. We should try to know what the child is suffering from but not to observe the child since this makes the illness penetrate in the child ... it is not possible to know since we don't have any tools to do tests ... we should not just give the child some drug when we don't know the type of disease the child has."(IDI07Mother to trial participant)

CHAPTER FIVE

SUMMARY OF FINDINGS, DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter presents summary of findings as per the objectives of the study. A brief discussion of the findings then follows showing that most of the findings of the study were in agreement with literature review. This section goes forward to provide conclusions and recommendations of this study.

5.2 Summary of findings

Factors of	Specific indicators of	Impact on access and utilization post-medical research		
influence	interest	Most important	Moderate	Least important
Economic factors	Cost of services - Transport service, - Fees i.e. registration, tests, drugs - Meals	An important factor as described in both qualitative and quantitative data. Could be a potential deterrent especially when considering the cost of transport.		
Quality of health care services	Waiting time	An important factor as some parents would now have to consider going to the nearest health facility or buy drugs from local shops.		
	Availability of care	An important factor for mothers as described in both questionnaires and FGD data.	According to health workers, this is of moderate importance i.e. parents would only know of the availability of drugs once they arrive at the facility	
	Health workers attitude	Important factor as described in questionnaire and health workers IDIs.		Was not considered important in FGDs, since the good

Table 5.1 Summary of the findings.

Factors of	Specific indicators of	Impact on access and utilization post-medical research			
influence	interest	Most important	Moderate	Least	
				important attitude of health workers observed during the trial seemed to have been maintained even after the	
	Perceived quality of medication			trial ended. Did not come up as a factor in all data sets	
Cultural values and	Decision making	Mostly mentioned in discussion with parents i.e. role of fathers as important decision makers		Mother in law	
beliefs	Religious beliefs/spiritual		Came up in FGDs where some still visit traditional healers, while some pray for their children before accessing care from facility		
	Alternative medicine		nom raenty	Mentioned only once in FGD where some still use Neem tree leaves to cure febrile illnesses	
Other emerging factors	Severity of illnesses	Came up as a strong factor in FGDs with parents and IDIs with health providers.			

It is important to note that some factors came as important from parents as compared to health workers, for instance health workers attitudes and availability of services. In addition, some factors came very strongly in the questionnaires while these were not considered as such in the qualitative data, for instance health workers attitude. This could have been due to the nature of the data collection tools since the questionnaires were closed ended. Audit of health facility records showed that there was no relationship between the exit of the malaria vaccine trial to the uptake of selected health care services offered at the health facility. However qualitative data suggest that there was a possibility of negative impacts on access and utilization of health care services once research conclude and exit from communities.

5.3 Discussions

Exit of medical research projects and in particular clinical trials is an important though neglected area in medical research as most resources are normally focussed on project implementation. Trial existence in a particular area usually raises the standard of care for participants and subsequently entire participating community especially in developing world. As stated by Stephenson et al 2008, this study confirms that trial exit has the potential to impact negatively on the health outcomes especially on the trial participants when project resources and services are removed. The exit contributes to reduced staff; which subsequently leads to increased workload, congestion, and delays in accessing services, increased costs of accessing services, unavailability of services which were offered by trial among others. However, audit of facility records did not show any clear relationship between the exit of the trial and access to health care. This could be due to the fact that community especially the parents to former trial participants received continuous health education which could have encouraged them to still access care even after the removal of the trial benefits thus sustaining their positive attitude in seeking care.

In terms of the determinants of access and utilization of health care services, this study identified different factors as contributing to it. These included economic, cultural values and beliefs and quality of care.

The study confirmed some aspects of economic factors to be determining access of health care services. Both quantitative and qualitative data strongly indicated economic factor as an important factor. The cost of care did feature and it was mostly in form of costs such cost of transport, medicine and registration fees, where transport was paramount as it was higher for many people bearing in mind the vastness of the health facility coverage. This seems to support the study by Rajendra et al 2013 which identified cost of health care including transport costs as a key factor in accessing health care. Other costs did not feature and this might have been probably due to the fact that there were no deliberate efforts to seek information on them.

Quality of health care services featured in terms of staff attitude, availability of services, and waiting time. This did support studies by Simkhada et al 2008 2012 and Ditekemena et al 2012 which also identified similar factors. Thus when they are not favourable, they deter people from accessing care. In terms of quality of medication, this came up in relation to medication being provided after tests to ascertain the illness. The tests encouraged parents to take their children to hospital rather than accessing care from alternative places.

On cultural values and beliefs, male parents were noted to be the major decision makers while seeking health care services for the under-fives. The study identified traditional healers and religion being important factors determining access and utilization of health care services. It agreed with charlotte et al 2014 and Abubakar et al 1023 studies that these acts as barriers to accessing care although this was as a reported case; done by other community members but not the respondents. Charms from traditional healers and the role of prayers for religion were pointed out, as alternative approaches used in when a child was sick. In this study, it was noted that religion did not act as a barrier to access care per se, but that it was an additional support for the parents. Use of alternative medicines which included herbs was also mentioned especially in treating febrile illnesses. However, this seemed to deter people from accessing care from health care facilities although not to a great extent.

Although not included in the objectives, severity of illness came out as a very important factor while deciding to seek health care. Majority of the respondents said that they would observe the child first when illness is less severe while will be prompt in seeking care if the child's condition is perceived to be severe.

5.4 Conclusions of the study

The study identified similar factors as those already mentioned in existing literature; economic factors, quality of care and cultural values and beliefs. Exit of medical research projects did not seem to have an impact on the factors as compared to those identified in normal life situation. However, the study confirmed that the participating community's experiences on the benefits when participating in the studies increase their importance as they compare their experiences before and after the exit of the project. Therefore, studies tend to have the potential of impacting on access of health care services by participating communities due to the removal of benefits brought about by research project.

5.5 Recommendations

The following recommendations are made based on the research findings.

Economic factors determine access and utilization of health care services post medical research. To reduce this impact, government should ensure implementation of removal of user fees health policy in primary level facilities. The other way can be bringing services closer to the community by scaling up outreaches as well as putting up more primary level facilities to reduce transport costs so as to encourage access and utilization of recommended care.

On quality of care, staff attitude seemed to have been affected positively by the interaction with trial staff and trainings provided during the trial. This ceased to be a factor considered when accessing care after the exit of the trail. Whenever possible, trials should be integrated in existing government health care facilities to encourage interaction of trial and government staff and as well as include the government staff in training as it leads to improved and sustained positive attitudes of health providers.

On cultural values and beliefs, fathers were identified to be very key in making decisions regarding access of care for the under fives. To help improve the uptake of care for under fives, it would be important to put up measures to encourage fathers to make health care access for their under fives a priority.

5.6 Suggestion for further studies

This study focused on determinants of access and utilization of health care services postmedical research. It is evident from this study that there are major effects when a research exits from the community in low income settings, which impact on the livelihoods of communities. This study therefore recommends a study to be carried out on the socioeconomic impacts upon the removal of research projects.

5.7 Contribution to body of knowledge

The study brought in new knowledge on an area where no literature was accessed on the topic. This brought in important insights which may need to be explored further.

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APPENDICES

Appendix 1: Letter of transmittal

Betty M. Kalama University of Nairobi-Mombasa campus July 2014

To whom it may concern.

Dear Sir/Madam,

RE: PERMISSION FOR DATA COLLECTION

I am a student of the University of Nairobi pursuing Master of Arts in Project Planning and Management. The purpose of this letter is to seek your permission and participation when carrying out data collection for my Research Project.

My Research Title is 'Factors influencing access and utilization of health care services post medical research: A case of Malaria vaccine trial in Ganze County'.

The information I shall gather is purely for academic purposes and will be treated with utmost confidentiality.

Your assistance will be highly appreciated.

Yours Faithfully,

Betty M. Kalama

Reg. No: L50/82199/2012

Appendix 2: Questionnaire

SECTION 1: RESPONDENT DETAILS

PARTICIPANT	EDUCATION	AGE (DOB)	GENDER	MAIN OCCUPATION

SECTION 2: ACCESS AND UTILIZATION OF HEALTH CARE SERVICES

- How many of your children were involved in the KEMRI malaria vaccine project? None/1, 2, 3, etc
- 2. Am interested to know the kind of services you accessed at Madamani dispensary for your under five year old child since January this year.
 - a. What services were you seeking at the facility for that particular child (tick appropriately)

i.	Regular check-up (e.g. growth monitoring)	
ii.	Febrile condition (e.g. fevers, coughs etc)	
iii.	Vaccination	
iv.	Malaria	
v.	Severe/chronic condition (e.g. pneumonia etc)	
vi.	Others (specify)	

 b. During that visit, what costs did you incur to access the services (probe and tick appropriately)

i.	Registration fee	
ii.	Consultation fee/user fee	
iii.	Purchase of book	
iv.	Purchase of medicine bottle	
v.	Diagnostic tests	
vi.	Drugs	
vii.	Transport	
viii.	Food for you and the child	
ix.	Others (specify)	

c. What was the source of the fund? (probe and tick appropriately)

i. Self

ii.	Spouse	
iii.	Other family member (Relative)	
iv.	Borrowed from friends/neighbour	
v.	Others (specify)	

d. For this particular visit, who did you consult prior to accessing health services for that child (probe and tick appropriately):

i.	Nobody	
ii.	Child's father	
iii.	Mother (in law)	
iv.	Father (in law)	
v.	Friend/ Neighbour	
vi.	Others (specify)	

3. What factors would you normally consider prior to accessing health services from a health facility? (Probe for each and tick responses as yes/no)

		Yes	No
i.	Severity of disease		
ii.	Distance and time to the nearest facility		
iii.	Availability of staff during your visit at the facility		
iv.	Number of staff at the facility		
v.	Availability of drugs		
vi.	Availability of diagnostic tests		
vii.	Cost of services		
viii.	Hours of service at the facility		
ix.	Waiting time at the facility before being seen		
х.	Staff attitude towards you and your child		

Appendix 3: Participants FGD Tool Introduction:

As you may be aware, KEMRI carried out a project for the last few years in this community on malaria vaccine which ended in January this year. You are participating in this discussion because your child was involved in the malaria vaccine trial. As I have informed you a few minutes ago, I would like to discuss with you about what used to happen during the project and after the project and to get your views about this study. This is important because it will help us in future planning for studies in the community. This discussion has been divided into 4 sections.

- In this 1st section, I would like you to tell me a little bit about the research project (vaccine trial) that your children were involved in since the time you allowed them to take part in the project? *How long were your children involved in the study, what used to happen to the children during the study (check for-free listing:*
 - Kind of services you used to access (diagnostic services and taking vitals, drugs, vaccines, free treatment, 24 hour access to health care, free referrals to Kilifi Hospital, transport to HF, meals, vaccine schedule).
 - who paid for the services
 - waiting time, staff handling and attitude (pick out any differences between MOH and KEMRI staff for follow up)
 - regular visits to clinic and home visits by FWs
- 2. Now that the trial has ended, what has changed in terms of health care services for the child? Probe for any changes in the following aspects
 - What changes are you experiencing on the kind of services provided in Madamani dispensary since the project ended. (any changes on diagnostic services and taking vitals, drugs etc)
 - What costs do you incur when accessing care from HF (*meals, transport, drugs, tests referrals etc*)
 - i. Who pays for the services
 - How long do you wait before being attended to (time before meeting HW and total time used in the HF)
 - Staff
 - i. How has the number of staff changed in the HF
 - ii. how do the staff handle your child
 - How do community members relate to you as a former trial participants in relation to health care

- Are there any other changes
- a. You have talked about ------ changes, what do you think brought about these changes? (probe for what brought the changes to differentiate from those brought about by the end of the trial and those that would have happened despite the end of the trial)
- b. How do you feel about these changes? (general question)
- 3. We would like to talk about your decisions on seeking health care for your child now that the project has ended
 - a. Where do you seek for health care; and why? (Check for same HF, different HF, alternative medicine)
 - b. Apart from HF, where else do you seek for help when your child needs care (when ill, need preventive services etc)
 - c. What factors do you consider when deciding on seeking health care for your children from hospital(Probe for points below if not mentioned)
 - i. Severity of disease
 - ii. Who is the decision maker
 - iii. Cost of service
 - iv. Availability of service including drugs, staff, tests etc (look out for staff attitude)
 - v. Distance/Time to nearest HF
 - vi. Waiting time before being served by the HW and total time spent at HF
- 4. I would like to get your opinions about how to end projects in the community.
 - How did you know about the end of the study?
 - What suggestions do you have on how to end similar KEMRI projects
 - Do you have any questions about the study or this discussion

Appendix 4: Non-participants FGD tool Introduction:

As you may be aware, KEMRI carried out a study for a few years in this community on malaria vaccine which ended in January this year. You are participating in this discussion because you were present during the study period and after and therefore are familiar with what happened during the study and after. As I have informed you a few minutes ago, I would like to discuss with you about what used to happen during the project and after the project and to get your views about this study. This is important because it will help us in future planning for studies in the community. This discussion has been divided into 4 sections.

- In this 1st section, I would like you to tell me a little bit about the research project (vaccine trial) that some children were involved especially since the time they were allowed to take part in the project. What used to happen to the children during the study (check for-free listing:
 - Kind of services they used to access (diagnostic services and taking vitals, drugs, prevention, free treatment, 24 hour access to health care, free referrals to Kilifi Hospital, transport to HF, meals, vaccine schedule)
 - who paid for the services
 - waiting time, staff handling and attitude (pick out any differences between MOH and KEMRI staff for follow up)
 - regular visits to clinic and home visits by FWs
- 2. Now that the trial has ended, what has changed in terms of health care services for children age 5 years and below? Probe for any changes in the following aspects
 - What changes are you experiencing on the kind of services provided in Madamani dispensary since the project ended. (*any changes on diagnostic services and taking vitals, drugs etc*)
 - What costs do you incur when accessing care from HF (*meals, transport, drugs, tests referrals etc*)
 - i. Who pays for the services
 - How long do you wait before being attended to (time before meeting HW and total time used in the HF)
 - Staff
 - i. How has the number of staff changed in the HF
 - ii. how do the staff handle your child

- How do you relate with community members whose children participated in the project now that the project has ended?
- Are there any other changes
- You have talked about ------ changes, what do you think brought about these changes? (probe for what brought the changes to differentiate from those brought about by the end of the trial and those that would have happened despite the end of the trial)
- How do you feel about these changes after the study came to an end?
- 3. We would like to talk about your decisions on seeking health care for your child now that the project has ended
 - Where do you seek for health care; and why? (Check for same HF, different HF, alternative medicine)
 - Apart from HF, where else do you seek for help when your child needs care (when ill, need preventive services etc)
 - What factors do you consider when deciding on seeking health care for your children from hospital (Probe for points below if not mentioned)
 - i. Severity of disease
 - ii. Who is the decision maker
 - iii. Cost of service
 - iv. Availability of service including drugs, staff, tests etc (look out for staff attitude)
 - v. Distance/Time to nearest HF
- 5. I would like to get your opinions about how to end projects in the community.
 - How did you know about the end of the study?
 - What suggestions do you have on how to end similar KEMRI projects
 - Do you have any questions about the study or this discussion

Appendix 5: IDI Tool

Health care providers

- 1. Get overall views on the changes to access to health care after the exit of the malaria vaccine trial.
- 2. Explore factors that contribute to access to health care for the under five children after the malaria vaccine trial, including challenges that they currently experience.

3. Getting views and opinions on how best to end trials to minimize any negative effects Introduction:

As you may be aware, KEMRI carried out a study for a few years in this community on malaria vaccine which ended in January this year. You are participating in this discussion because you were a health provider during the study period and after and therefore are familiar with what happened during the study and after in terms of health care provision. As I have informed you a few minutes ago, I would like to discuss with you about what used to happen during and after the project and to get your views about this study. This is important because it will help us in planning for future studies in the community. This discussion has been divided into 4 sections.

- 1. Tell me a little bit about how you were involved in the research project (vaccine trial) as a health provider?
 - 5 minutes
 - What kind of support/roles were you playing for the trial?
 - What kind of support were you as a provider and health facility receiving from the trial?
- 2. Now that the trial has ended, what has changed in terms of health care service provision in Madamani Dispensary? Both positive and negative effects
 - 25 minutes
 - Effects on health providers and facility?

Check out for: Number of staff, availability qualified service providers e.g. doctors, workload, availability of drugs/other services, financial support (salary top-ups), transport support (referrals, supplies), infrastructure and equipment

- Effects on study participants?

Check out for: Health care costs (transport, food, user fees, and other medical cost), speed of services (hours of service and availability of providers), availability of specialized services (diagnostic tests), close monitoring (follow-ups) - Effects on general community/facility users in seeking health care at the dispensary?

Check out for: Transport support, availability of drugs and other services, speed of services etc

- Any other changes....
- What changes have been introduced in the health care system since January? (prompt for removal of user fees, free maternal care etc)
- What's your overall feeling about the changes you mentioned?
- 3 Based on the changes/effect on participants mentioned above, as a provider what do you think are the key factors parents/guardians of children would consider NOW prior to accessing health care services in this facility? (Probe for and ask for reasons to be specified)
 - i. Severity of disease
 - ii. Cost of service
 - iii. Availability of service including drugs, staff, tests etc (look out for staff attitude)
 - iv. Distance/Time to nearest HF (linked to transport)
 - v. Any other....
- 6. As we conclude I would like to get your views/suggestions on how to end KEMRI projects in the community/for future similar studies?
 - i. How did you know about the end of the study?
 - ii. What suggestions do you have on how to end similar KEMRI projects
 - iii. Do you have any questions about the study or this discussion