DETERMINANTS OF COMMUNITY'S PARTICIPATION IN CENTERS FOR DISEASE CONTROL AND PREVENTION'S CLINICAL TRIALS IN KAREMO DIVISION, KENYA

BY

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DECLARATION

This research project report is my original work and has not been submitted for an award in any other Institution or University.

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DEDICATION

I dedicate this work to my mother Pacifica Juma Obiero and Farida Robi Chacha.

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ABBREVIATIONS AND ACROYNMS

HIV: Human Immunodeficiency Virus

CDC: Centre for Disease Control and Prevention

AIDS: Acquired Immunodefiency Syndrome

ART: Antiretroviral Therapy

PMSA: Primary Metropolitan Statistical Area

FOBT: Faecal Occult Blood Testing

RCT: Randomized Control Trial

HAART: Highly Active Anti-retroviral Therapy

MSM: Men who have Sex with Men

PRs: Prevalence Ratios

NME: New Molecular Entities

CDER: Center for Drug Evaluation and Research

TSUS: Tuskegee Study of Untreated Syphilis

CTs: Controlled Trials

FDA: Food and Drug Administration

AP: Associated Press

CI: Confidence Interval

NIAID: National Institute of Allergy and Infectious Diseases

STDs: Sexually Transmitted Diseases

ABSTRACT

Any research organization's study has solely depended on community's full participation for both quantity and quality data collection which are normally used for analysis. The purpose of this study was to investigate the determinants of community's participation in clinical trials conducted by Center for Diseases Control and Prevention in Karemo Division in Western Kenya. In the world, participation in clinical trials have been found to depend on a number of determinants such as demographics characteristics of the community, socio-economic status of the community, patient's trust in health care provider, information to the community and community's perception among others. The study had the following objectives: To determine the level at which community's demographic characteristics influence community's participation in Centers for Diseases Control and Prevention clinical trials, to determine the extent at which socio-economic status of the community influence their participation in Centers for Diseases Control and Prevention clinical trials, to examine how patient's trust in health care provider influence community's participation in Centers for Diseases Control and Prevention clinical trials, to investigate information as an influence on community's participation in Centers for Diseases Control and Prevention clinical trials and finally to explore community's perception as an influence on community's participation in Centers for Diseases Control and Prevention clinical trials. The research questions were: How do demographic characteristics of the community influence community's participation in Centers for Diseases Control and Prevention clinical trials? To what extent does socio-economic status of the community determine participation in Centers for Diseases Control and Prevention clinical trials? How do patient's trusts in health care provider determine community's participation in Centers for Diseases Control and Prevention clinical trials research? How is information a determinant on community's participation in Centers for Diseases Control and Prevention? How does perception determine community's participation in Centers for Diseases Control and Prevention clinical trials? In the significance of the study, it is hoped that the findings shall be of use to both Centers for Diseases Control and the community in enhancing community's participation in clinical trials. The theory that the study was anchored on is the theory of planned behavior. Descriptive (quantitative) survey research design was used, the target population was parents from Karemo Division and the sample size was 379 participants. The sample selection was by use of simple random sampling where 3600 names were fed into the computer and excel used to select the first 364 participants as 15 were Centers for Diseases Control staffs where purposive sampling was employed for they were few in number. The study used questionnaires to collect data through face-to-face interviews and by self administration by the respondents and these data was entered and analyzed using SPSS for Windows version 12.0 to generate frequencies and percentages. The analyzed data was interpreted and discussed. Through the findings, the study concluded that majority of participants were married primary and secondary school leavers. The study did recommend that more emphasis need to be put on health education in partnership with the ministry of health to religions such as Legio Maria on health seeking behavior. The study suggested the following areas for further studies: Need for a comparative study to look at determinants of community's participation in Centers for Diseases Control and Prevention epidemiological studies and community's participation in International Emerging Infectious diseases.

CHAPTER ONE

INTRODUCTION

1.1 Background of the Study

In the world, participation in clinical trials have been found to depend on a number of determinants such as demographics characteristics of the community, socio-economic status of the community, patient's trust in health care provider, information to the community and community's perception among others. It is through active participation that a research organization can collect both quality and quantity data for purposes of analysis in order to have a problem which can be health related, societal or economical sorted out (Stratford *et al*., 2003).

From a study done in the United States of America the questions of how and to what extent education as a demographic factor can and should influence community participation did preoccupy philosophers, theorists, and social scientists for hundreds of years. From Plato and Aristotle to America's prominent educational leaders – Thomas Jefferson, John Dewey, Horace Mann, W. E. B. Dubois – education has been recognized for its role in preparing community to be socially engaged citizens in any research (Giroux, 2009). The original missions of colleges and universities expressed this essential public purpose, and community returns to education continued to offer a central justification for public policy promoting equal access to schooling.1 Community participation was broadly defined as involvement with voluntary participation in research projects including clinical trials. Community participation confers societal rewards by way of a vibrant democracy and well-functioning neighborhoods; it is linked to individual rewards by way of job networks, occupational advancement, and physical and mental well-being (Durkheim 1933; Putnam 2000; Wilson 2000).

A prominent tradition of clinical, social and political research did seek to identify factors that influence community participation (Wilson 2000). This work has taken on renewed interest at a time when many forms of community involvement appear to be declining (Putnam, 2000). Numerous studies have found education to be a key correlate if not determinant of community participation, with the more educated more participatory than the less educated (Almond and Verba 1963; Brehm and Rahn 1997; Dee 2004; Freeman 1997; Gesthuizen, vander Meer, and Scheepers 2008; Hauser 2000; Huang, vanden Brink, and Groot 2008; McPherson and Rotolo 1996; Nie, Junn, and Stehlik-Barry 1996; Putnam 1995, 2000; Verba and Nie 1972; Verba, Schlozman, and Brady 1995). Putnam (1995) asserts that "education is by far the strongest correlate that he did discover community engagement in all its forms" (p. 672). While some studies recognize the endogeneity problem associated with assessing the causal effect of educational levels on community participation (Dee 2004; Gibson 2001; Hauser 2000), studies did not address a related form of selection bias, i.e., heterogeneous effects by the factors influencing selection 5 into higher education. As individuals differ greatly not only in background attributes but also in how they respond to life events. Given the substantial literature on the relationship between education and community participation, surprisingly little attention was paid to variation in the effect. Estimated effects of college completion on various forms of subsequent volunteer work in community organizations and groups by strata based on the observed probability that an individual completes college and then evaluate the trend in the strata-specific effects in a hierarchical linear model (Brand and Davis 2009).

In America a study conducted on HIV vaccine trial, showed that people participated based on race, education, sex, age and cultural value. The study identified that women did

participate almost 65% as compared to men who were 35%, in further regression analysis, the youths participated in large numbers as compared to the aged for the adults claimed to be busier than the youths. People who were more educated tended to participate more than their counterparts for they were knowledgeable about the study's purpose including its procedures. Concerning cultural practices, those who were more engaged to their culture participated in less than those who not were culture alienated (Ling *et al*., 2009).

According to Ickovics *et al*. (2002), SES is not consistently associated with adherence to therapy among patients infected with HIV and it does not seem to be a major determinant of adherence to antiretroviral treatment. Many available studies suggest a positive trend among factors contributing to patients' socio-economic status and adherence to medical treatment among patients with HIV/AIDS; however such an association cannot be statistically consolidated throughout most of the studies included in our systematic review. It should be emphasized that it appears that there is a confusion regarding the accurate meaning of the term socio-economic status and thus it has been assessed in various ways. Future studies may further explain the different impact of socio-economic status to adherence to treatment between patients infected with HIV and patients suffering from other chronic diseases.

In recent years, response rates to social surveys and clinical trials, where participation is voluntary, have fallen. Research organizations have therefore increased their efforts to gain public co-operation by a variety of means, including providing respondent incentives. Incentives may be given prior to the research taking place, regardless of participation, or retained as a reward for those who complete the survey. They may take the form of a monetary or non-monetary gift (Lynn, 2009).

Although there is no 'gold standard' for the assessment of medication adherence, pharmacy-refill adherence or other easily accessible methods should be considered as an alternative to CD4 count monitoring for identification of patients at risk of virological failure, especially in low-income countries. It represents a simple, inexpensive and accurate method that correlates with virological response to treatment. Data from pharmacy refill charts should be made available to health-care workers to help identifying patients at greatest risk of treatment failure. It is still difficult to pinpoint determinants of non-adherence to Anti Retroviral Treatment in lower-income countries; for example, our study indicates that the role of economic status is more complicated than may previously have been thought. Preventing treatment discontinuation by enhancing adherence counseling for a higher-risk population may not be effective: all previous studies failed to clearly demonstrate a specific group that would benefit from such intervention. Developing strategies should rather focus on improving adherence follow-up by simple and inexpensive measurement. Finally, more studies in resource-limited countries are urgently needed to understand the underlying reasons for late initiation of antiretroviral therapy and for high attrition rates before initiating ART, which account for a large number of early losses to follow-up and deaths in lower-income countries (Rosen *et al*., 2007).

According to Ellis *et al*. (2001), study done in Kenya showed that providing HIV-infected patients and their providers with information about HIV clinical trials at the site where they receive care may increase participation rates in HIV clinical trials. This is because physicians may increase overall accrual to trials and reduce disparities in participation among select groups of patients with HIV.

Misconception arises when there is mistrust in the trial organizations, in that respondents do personal inferences about the main aim of some trials and feel that they are

"treated as guinea pigs." Also, they feel that there is always a possibility of placebo administration that will not benefit them in any way, indicating that mistrust is a main factor influencing participants' refusal to participate (Campbell *et al*., 2007).

In CDC based projects in Karemo Division, there have been a number of determinants on participation in the various projects. These determinants have led to higher withdrawal and refusal rates in both participants and potential participants. They include demographics, socioeconomic status, and patient's trust in health care provider, information and community's perception.

1.2 Statement of the Problem

Participation is a source of concern in all studies that involve an active recruitment process. However, despite repeated calls for standardization in the reporting of the steps taken to recruit a study population, including the response rates at each step; most studies provide no information on participation. When reported, data are usually limited to basic demographic characteristics, such as age, sex, and sometimes race. Among the few studies that have provided greater detail about differences between participants and nonparticipants, the factors that influence participation vary from study to study and often depend on the topic, setting, and target population (Adams *et al*., 1990). Moreover, the approaches used in previous studies to assess participation bias, which include reassessment of nonparticipants, comparison of either early vs. late respondents or difficult to recruit vs. easier to recruit participants, and evaluation of partial participants, might have missed the hard-core nonparticipants by design. Furthermore, given evidence indicating a temporal decline in participation rates in the medical field, contemporary data are specifically lacking (Jacomb *et al*., 2002).

According to CDC records, in the year 2007 out of the 1308 subjects enrolled in the Rotavirus CDC clinical trials, 34 withdrew from the study after dose 1, 55 never received their dose 2 implying that only 1219 went up to dose 3. In the year 2009 out of the enrolled 1620 subjects in the malaria vaccine study, 71 subjects missed their dose 2, out of the 1549 who received their dose 2, 1435 participants received their last dose 3. Refusal and withdrawal rate of both potential participants and participants from clinical trials conducted by CDC in Karemo Division, Western Kenya has been at a rate that at times can influence the clinical trial findings. If this trend continues then it implies that in the future there will be few participants to enroll into the study, therefore the research is being done to establish the determinants of community's participation in CDC clinical trials in Karemo Division.

1.3 The Purpose of the Study

The purpose of the study was to establish the determinants of community's participation in CDC clinical trials carried out in Karemo Division, Kenya.

1.4 Objectives of the Study

The study was guided by five objectives which were to:

1. Determine the level at which demographic characteristics of the community influence their participation in Centers for Diseases Control and Prevention clinical trials in Karemo Division.
2. Investigate the extent at which socio-economic status influence community participation in Centers for Diseases Control and Prevention clinical trials in Karemo Division.

3. Explore how patient's trust in health care provider influence community participation in Centers for Diseases Control and Prevention clinical trials in Karemo Division.

4. Examine the extent at which information can influence community participation in Centers for Diseases Control and Prevention clinical trials in Karemo Division.

5. Explore perception as an influence on community's participation in Centers for Diseases Control and Prevention clinical trials in Karemo Division.

1.5 Research Questions

This study sought to answer the following research questions;

1. At what level does demographic characteristic of the community influence participation in Centers for Diseases Control and Prevention clinical trials?

2. To what extent does socio-economic status determine participation in Centers for Diseases Control and Prevention clinical trials in Karemo Division?

3. How do patient's trust in health care provider determines participation in Centers for Diseases Control and Prevention clinical trials research in Karemo Division?

4. Does information as a determinant influence community's participation in Centers for Diseases Control and Prevention in Karemo Division?

5. How does perception determine community's participation in Centers for Diseases Control and Prevention clinical trials in Karemo Division?

1.6 Significance of the Study

It is hoped that the study findings would be helpful to the HOD in the Government in case they shall be carrying out any research in any of the sectors. The use of incentives in line to economic background, education level of the participants and dissemination of results has always compromised the quality and quantity of research.

In the past Centers for Diseases Control and Prevention have been mobilizing participants for purposes of sensitization and awareness creation to participate in the various studies within areas that it works. The result of this study might be useful to CDC in establishing the best ways to ensure minimal refusal and withdrawal rates of participants in their research studies.

The report might also be shared with the community members and other Non Governmental Organization (NGOs), for this would ensure full community participation in the projects as CDC and the NGOs will also have credible results from the collected quality and quantity data.

Lastly, it is hoped that the study will help the Researcher to identify the knowledge gaps in the research through participation of participants in a study and promote the skills of the Researcher in research project and report writing.

1.7 Basic assumptions of the Study

The study was guided by several assumptions. The first was that parents have higher influence on their minors' participation in CDC clinical trials. Secondly, the study assumed that the report might be used to generalize the effectives of CDC projects in terms of community mobilization, sensitization and awareness creation.

The study also assumed that the people to be interviewed gave their honest opinion during the survey and were well conversant with CDC existence plus its operations in the region.

1.8 Limitations of the Study

The research project was carried out in Karemo Division in Western Kenya, the main limitation especially on those who were already in the study might have been fear of being withdrawn from the study by the staffs or project if they give any negative information about them. The second one was that accessing some parts of the study area might have been difficult due to poor infrastructure. The limitations were addressed as follows, participants were assured of confidentiality on the information that they did give during interviews and motorcycles were used to access places that vehicles were not able to reach.

1.9 De-Limitations of the Study

This study was delimited to Karemo Division in Siaya County, Karemo Division which has an approximate area of 239.8 square kilometers and comprises of 171 Villages with a population of around 85000 with 370 people per square kilometer (HDSS, 2009). In Kenya, Karemo Division was chosen because in CDC clinical trials conducted in the region there have been refusal and withdrawal cases of both potential participants and participants by their parents from the very studies. The organization also has its major operations in Nyanza province especially in Karemo Division where clinical trials are going on, with an estimate of 05 projects in operation. The study was also de-limited on the views given by parents in support of giving their children for clinical trials.

1.10 Definition of Significant Terms Used in the Study

Community's participation is the ability of parents to allow their children to be recruited, enrolled and followed-up for certain duration for safety purposes in CDC clinical trials.

Demographics characteristics of the community are the physical characteristics of a population such as age, sex, marital status, family size, education.

Socio-economic Status of the community is an individual's or group's position within a hierarchical social structure.

Patient's trust is the reliance on the confidence and surety of a participant to the health care provider.

Information to the community is how the community gets news on CDC development plans about their studies and how they interpret or misinterpret the same for their consumption.

Community's perception is the process of attaining awareness or understanding of sensory information.

1.11 Organization of the Study

The study was organized into five chapters: chapter one which is the introduction, includes, the background of the study, statement of the problem, purpose of the study, objectives of the study, research questions, significance of the study, basic assumptions of the study, limitations of the study, delimitations of the study, definitions of significant terms. Chapter two, in which literature review of the independent variables such as demographic characteristics of the community, socio-economic status of the community, patient's trust to the health care provider, information to the community and the community' perception are done, the chapter

also contain the theoretical framework and the conceptual framework. Chapter three where research methodology is captured, with the following components, introduction, research design, target population, sample size and sample selection, research instrument, pilot testing, reliability of the instrument data collection procedures, data analysis techniques and ethical considerations. Chapter four comprises of data analysis, interpretation and discussion as chapter five contains summary of findings, conclusions, recommendations suggestions for further studies and contribution to body of knowledge.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter reviews literature related to the study under the following themes:

Socio-economic status as a determinant on participation, demographics as a determinant on participation, information as a determinant on participation, perception as a determinant on participation, patients' trust in health providers in clinical trials

2.2 Demographic as a determinant of community's participation

The demographic determinants to be reviewed are race/ethnic groups, age, sex and educational level.

A study conducted in Latin America on Detroit and Vicinity Street Finder, where six hundred and seventy-two households were selected from the 1069 occupied census tracts in the Detroit PMSA. A total of 42 households were coded as ineligible for the mail survey portion of the study. The proportion of households coded as ineligible for the mail survey within the City of Detroit and suburban areas was about 6% for each. Among the 284 households initially identified for the telephone survey, nine percent had telephone numbers that were not for the selected household, 12% were disconnected numbers, 2% had respondents that did not speak English, in 1% the respondent was too sick to participate, and in 1% the respondent did not meet eligibility criteria. Eligible households that were not reached after four telephone attempts were coded as refusals. One hundred ninety-eight individuals participated in this study for a total response rate of 36%. Of these, 91 were African American, 88 whites, and 19 were from other racial/ethnic groups. Overall, the most frequent mode of response was the long version of the

mail questionnaire followed by the telephone interview and the short version of the mail questionnaire. Data on response rates are provided for all participants, however only African Americans and Whites are included in the analyses. African American respondents were on the average, younger than whites and more frequently female. The two race groups had similar education and income distributions. This included respondents who did not answer the race/ethnicity question (Rand, 1996).

The study results indicated that African Americans and whites differ in their willingness to participate in medical research. Racial differences in the willingness to participate in a medical research are primarily due to the lower level of trust of medical research among African Americans. African American respondents were also somewhat less willing to participate if they attribute high importance to the race of the doctor when seeking routine medical care, believed that minorities bear most of the risks of medical research, and if their knowledge of the Tuskegee Study resulted in less trust in medical researchers (Bresser, 1997).

According to Kronborg (2004), in a study titled Randomized Study of Biennial Screening with Faecal Occult Blood Test, which was conducted to identify determinants of participation in colorectal cancer screening with faecal occult blood testing, results from the UK RCT, pilot programmes and surveys of screening activities showed an increased participation with increased age. Those activities that include the oldest age groups, 70 years or more, mostly show a drop for that group. The Danish RCT show a decreased participation with increased age. The North American data universally show an increase in the screening uptake with increasing age.

According Klabunde *et al*. (1992), a study in the U.S on Factors influencing enrollment in clinical trials for cancer treatment, age was a significant factor for clinical trial participation, with younger patients more likely to enroll. This is consistent with what has been shown

repeatedly in the literature for other disease sites.57–59 Despite the increasing number of older people in the population and the greater frequency of malignant disease in this age group, 60 substantial under-representation of patients age _ 65 years in cancer treatment trials has been demonstrated. Both older patients and their physicians may choose standard treatments because of the perceived increased toxicity of experimental treatments in this patient population. In a survey of American oncologists, 50% felt that some patients were not suitable for clinical trials based on age alone. There was little data to support the possibility that fit, older patients may not be able to tolerate or benefit from treatment in clinical trials.

Giovanazzi *et al*. (1994), in a study titled Treatment tolerance of elderly cancer patients entered onto Phase II clinical trials, showed that there was no significant difference between elderly patients and younger patients for several clinical trial end points, such as treatment delays and toxicities. Those authors concluded that elderly patients should not be denied access to cancer clinical trials based on age alone. Since that publication, several cooperative groups have designed studies to specifically address the older population. This aspect is particularly relevant among patients with glioblastoma multiform.

A study done on Influence of Tumor Type, Disease Status and Patient Age on Self Reported Interest Regarding Participation in Cancer Clinical Trials by Judy et al. in 2002 showed that the proportion of patients (or their families) who expressed interest in learning about clinical trials ranged from as low as 21% (endometrial and cervix cancer aged > 80; n=178) to as high as 85% (recurrent ovarian cancer patients, aged 51-60; n=842). Patients >80 years old, regardless of sex, tumor type, or disease status, were substantially less likely to desire such information. Patients with self-declared more “serious conditions” (e.g., metastatic breast [71%;n=5,444], recurrent prostate cancer [70%; n=4,121]), and those with cancers widely know n to have a poor

prognosis (e.g., non-small cell lung cancer [75%; n=23,298]), were more likely to request data on trials, than those with an overall more "favorable" prognosis (e.g., newly diagnosed prostate cancer [46%; n=21,348]). There were no observed differences in interest between men and women with similar conditions. It was found out that, major differences in self-expressed interest regarding availability of clinical trials were observed. Particularly notable were the reduced interest among the very elderly, and the increased interest by patients with the most serious cancer-related conditions (Judy *et al*., 2002).

In a study titled Recruitment of HIV/AIDS treatment-naïve patients to clinical trials in the highly active antiretroviral therapy era: influence of gender, sexual orientation and race done in the USA, women, racial/ethnic minorities and persons who acquire HIV infection through heterosexual intercourse represent an increasing proportion of HIV-infected persons, and yet are frequently underrepresented in clinical trials. We assessed the demographic predictors of trial participation in antiretroviral-naïve patients. Methods Patients were characterized as trial participants if highly active antiretroviral therapy (HAART) was initiated within a clinical trial. Prevalence ratios (PRs) were obtained using binomial regression. Results Between 1996 and 2006, 30% of 738 treatment-naïve patients initiated HAART in a clinical trial. Trial participation rates for men who have sex with men (MSM), heterosexual men, and women were respectively 36.5, 29.6 and 24.3%. After adjustment for other factors, heterosexual men appeared less likely to participate in trials compared with MSM [PR 0.79, 95% confidence interval (CI) 0.57, 1.11], while women were as likely to participate as MSM (PR 0.97, 95% CI 0.68, 1.39). The participation rate in Black patients (25.9%) was lower compared with non-Black patients (37.5%) (adjusted PR 0.80, 95% CI 0.60, 1.06). In the conclusions, the study established that in

clinical setting, gender did not appear to impact participation in HIV treatment trials, but Black patients were slightly less likely to participate in these trials. Considering the substantial proportion of HIV-infected patients who are Black, future trials need to consider strategies to incorporate such underrepresented populations (Menezes *et al*., 2010).

According to Menezes et al. (2010), in clinical trial data submitted to the Food and Drug Admission for a study done in the U.S for New Molecular Entities (NMEs) for adult, non-sex specific indications between January 2006 and December 2007 review. Electronic data available on phase 1 trial were evaluated for proposed indications, sex of participants, and doses tested. Therapeutic doses were obtained from the approved labeling. The FDA approved 34 NMEs in 2006–2007. Data for 352 phase 1 trial of 30 NMEs were obtained. Data for 1 NME was not available electronically, 2 did not include new phase 1 data, and 1 provided only summary demographic data. All NMEs reviewed were for drugs used to treat conditions occurring in both men and women. Overall 120 (34.1%) trials had only male participants while 232 (65.9%) trials also enrolled female participants. 30.6% (3106/10,134) of participants were women. 149/352 (42.3%) of trials included safety and tolerability testing above the highest approved dose. In those trials, 32.5% (1628/5011) of the participants were women. An evaluation of trial start date illustrated the number of trials that enrolled women ($p = 0.01$) and the number of female participants ($p < 0.001$) has increased over time. The findings revealed that female subjects have traditionally been underrepresented in phase 1 trials. The number trials enrolling women and the number of women participating in phase 1 trials has increased since 2001, however, women are still underrepresented especially the married ones.

A survey done in Zimbabwe on the Relationship of sex and Clinical pain to experimental pain response by Fillingim *et al*. in 1999 showed that education is a key component of healthcare because it initiates discussion and understanding of information that impacts the way care is provided. The historical exclusion of women from clinical trials has disabled the process of information sharing within healthcare by limiting the availability and downplaying the relevancy of sex-specific information. It is essential that pharmacists, nurses, and doctors integrate new sex-specific drug information as it becomes available through clinical research. Healthcare systems should facilitate this process by providing access to research databases, posting critical drug information updates, and developing clinician education campaigns that share emerging data that may impact the provision of care to both men and women. Healthcare systems are also in a position to collect and review hospital- or clinic-specific data to identify any gender-related differences in evaluating and treating clinical conditions, such as pain (Fillingim *et al*., 1999).

In a clinical trial done Uganda on women's health by CDER in 2004, it was generalized that, female patients and their families need information about the potential sex-related risk factors that may result from a particular drug regimen. The database of drug-specific effects in women is limited; however, women should be given general information on how sex hormones and female biology have the potential to impact the effectiveness of drugs (CDER, 2004).

According to Shamrakov *et al*. (2009), in a study carried out in Toronto on Control Trials, where 101 questionnaires were completed out of 112 administered (90% response rate). 76% of patients self-reported as knowledgeable about clinical trials. Patients' education level correlated to their perceived knowledge of clinical trials: 37.5% of patients with a less than grade

9, 59.4% with a high school, and 90.2% with a university background identified themselves as knowing what Control Trials (CTs) are. All patients scored poorly on details and held common misconceptions of CTs (e.g. knowing little about placebos and experimental drug testing). Overall, 27% of patients had been previously enrolled in CTs. Of the 34% of patients who had been previously approached, 79% had agreed to participate. The majority were willing to participate or unsure of participating in CTs. A minority stated they will never participate in a trial. Patients also identified concern about lack of hospital resources about CTs and a desire to have a doctor present when learning about CTs. Patients with less education identified a greater desire for a doctor's presence than those with more education. The study findings revealed that lack of staff recruitment, low patient awareness, and lack of availability of trial facilities as potential barriers to participation. Targeted information to patients with different education levels may be appropriate, given variable knowledge about CTs. Education and counseling regarding placebos and experimental drugs should be targeted towards all patients to reduce barriers to patient participation, diminish myths, and increase understanding and interest. In response, this institution will design a brochure for all patients describing clinical trials, providing a glossary of terms, and offering a list of key resources in order to improve awareness and trial recruitment.

In a study known as Synergistic associations between hookworm and other helminth species in a rural community in Brazil by Fleming et al. in 2006. An informational video was produced in Toronto to explain the work of the research team and the first planned hookworm vaccine trial, using a pedagogical method based on analogies. Seventy-two adults living in a rural community of Minas Gerais were administered a structured questionnaire that assessed their knowledge of hookworm, of research and of the planned hookworm vaccine trial, as well as their attitudes and perceptions about the researchers and participation in future vaccine trials. The

questionnaire was administered before being shown the educational video and two months after and the results compared. After viewing the video, significant improvements in knowledge related to hookworm infection and its health impact were observed: using a composite score combining related questions for which correct answers were assigned a value of 1 and incorrect answers a value of 0, participants had a mean score of 0.76 post-video compared to 0.68 pre-video ($p = 0.0001$). Similar improvements were seen in understanding the purpose of vaccination and the possible adverse effects of an experimental vaccine. Although 100% of participants expressed a positive opinion of the researchers even before viewing the film and over 90% said that they would participate in a hookworm vaccine trial, an increase in the number who expressed fear of being vaccinated with a novel vaccine was seen after viewing the video (51.4% post-video versus 29.2% pre-video). Increases were also seen in the proportion who thought that participation in a vaccine trial would be inconvenient or disrupt their daily activities (Fleming *et al*., 2006).

In a Randomized, placebo-controlled, double-blind trial of the *Na*-ASP-2 hookworm vaccine in unexposed adults study done by Bethony et al. in 2008, it was discovered that even in rural, resource-limited populations, educational tools can be specially designed that significantly improve understanding and therefore the likelihood of obtaining truly informed consent for participation in clinical research. The observed changes in the knowledge and perceptions of the research participants about hookworm infection and the experimental hookworm vaccine demonstrate that the video intervention was successful in increasing understanding and that the subjects acquired knowledge pertinent to the planned research (Bethony *et al*., 2008).

In a study done in Europe known as Metaanalysis of radiation therapy with and without adjuvant chemotherapy for malignant gliomas in adults by Fine et al. in 1993 where one hundred fifty-one of 708 patients (21.3%) participated in a clinical trial, which was higher than the participation reported typically for patients with other types of primary malignancies. In univariate analysis, race, histology, and first craniotomy were significant between the two groups, with Caucasian patients and patients with glioblastoma histology showing higher participation rates. In a multivariate logistic regression model, significant predictors included young age and glioblastoma multiform histology. It was concluded that percentage of participation among the patients in the current study was greater than among patients with other primary tumor sites. Therefore it was advised that strategies should be implemented to improve recruitment to neuro-oncology trials, especially in elderly and minority populations (Fine *et al*., 1993).

Studies set up in USA and Canada on Audio-visual presentation of information for informed consent for participation in clinical trials carried out by Ryan et al. in 2008 which included 4 trials involving data from 511 people. Three were randomized controlled trials (RCTs) and the fourth a quasi-randomized trial. Their quality was mixed and results should be interpreted with caution. Considerable uncertainty remains about the effects of audio-visual interventions, compared with standard forms of information provision (such as written or oral information normally used in the particular setting), for use in the process of obtaining informed consent for clinical trials. Audio-visual interventions did not consistently increase participants' levels of knowledge/understanding (assessed in four studies), although one study showed better retention of knowledge amongst intervention recipients. An audio-visual intervention may transiently increase people's willingness to participate in trials (one study), but this was not

sustained at two to four weeks post-intervention. Perceived worth of the trial did not appear to be influenced by an audio-visual intervention (one study), but another study suggested that the quality of information disclosed may be enhanced by an audio-visual intervention. Many relevant outcomes including harms were not measured. The heterogeneity in results may reflect the differences in intervention design, content and delivery, the populations studied and the diverse methods of outcome assessment in included studies. The value of audio-visual interventions for people considering participating in clinical trials remains unclear. Evidence is mixed as to whether audio-visual interventions enhance people's knowledge of the trial they are considering entering, and/or the health condition the trial is designed to address; one study showed improved retention of knowledge amongst intervention recipients. The intervention may also have small positive effects on the quality of information disclosed, and may increase willingness to participate in the short-term; however the evidence is weak. There were no data for several primary outcomes, including harms. In the absence of clear results, triallists should continue to explore innovative methods of providing information to potential trial participants (Ryan *et al*., 2008).

2.3 Socio economic status as a determinant of community's participation

Socio-economic status creates barriers to research participation, for both social and logistical reasons. For example, homelessness, lack of transportation, and lack of fluency in English can preclude reliable participation in a clinical trial in the U.S. In a study of Asians, 79 elderly Asian immigrants from Taiwan, China, or Hong Kong were compared with 58 Asian American older adults regarding their responses to hypothetical clinical research situations. The study showed that the immigrant group was more likely to be influenced by a request from a

son/daughter, landlord, physician, or advertisement ($P < 0.001$) and by a monetary incentive ($P = 0.05$) than the Asian Americans to participate in a clinical study. In other words, the power of persuasion was markedly different in people with the same ethnicity but different cultural influences. The authors conclude that "acculturation or assimilation into American society may build resistance to pressure to participate in research. The findings also suggested that elderly Asian immigrants may need additional protections to achieve truly informed consent" (Brugge *et al*., 2005).

A clinical trial conducted in Asia titled Representation of American blacks in clinical trials of new drugs by Svensson in 1989 revealed that susceptibility to persuasion is an important issue in clinical trial recruitment, especially as cultures differ in familism which is family-centered decision making process, their reverence for authority such as including views of physicians as authoritative figures and adoption of a "wait and see" attitude for some community members do believe that in clinical trials they are used as guinea pigs. Therefore they normally wait to see the drug's positive effect in other people, for them to try it (Svensson, 1989).

In this systematic review in a study conducted in the U.S on Determinants of compliance with antiretroviral therapy in patients with human immunodeficiency virus by Sing et al. in 1996, it was found that socio-economic status was not consistently associated with adherence to HIV drug which was on trial among HIV infected patients. Since there was no study directly examining the association between socio-economic status and adherence in patients with HIV/AIDS, we evaluated the available data regarding the possible association between the major separate determinants of socio-economic status (income, education, occupation) and adherence. Although someone would have expected a clear association between socio-economic status and adherence to the clinical trial based on data from studies on patients with chronic diseases other

than HIV/AIDS infection, the evidence from the available studies does not fully support the existence of such an association in this patient population. However, a positive trend of association between levels of various socio-economic status components and levels of adherence to antiretroviral treatment is present among many of the studies. By taking a close look at the data presented, it is noteworthy that among the reviewed studies that examined some of the main components of socio-economic status, most did not find a statistically significant association between these factors and adherence to antiretroviral treatment. It should be emphasized that a statistically significant association between income and education, two main determinants of socio-economic status, and adherence was found in only half and less than a third of the studies that examined income and education, respectively (Sing *et al*., 1996).

The existence of a possible association between income and adherence to clinical trial in HIV/AIDS patients was examined in 14 of the reviewed studies. Among the 7 studies in which income was found to be significantly associated with adherence, 4 concluded that the cost of antiretroviral treatment and/or poor living conditions were factors preventing patients from complying with treatment. If this financial obstacle was overcome, adherence was expected to reach considerably higher levels (Laniece *et al*., 2003). In the remaining 3 studies, among patients having the economic ability to receive their medication, there was an association between the annual income and adherence (Golin *et al*., 2002). It was presumed by the authors of one of the studies that patients with a higher level of income differ to those of lower/middle income, in terms of behavioural characteristics and hierarchy at the decision-making process, thus affecting their adherence to antiretroviral treatment (Kleeberger *et al*., 2001).

In India, in a study titled Determinants of subject compliance within an experimental anti-HIV drug protocol, it was found that perceived economic support by a significant other had

a direct association with levels of adherence to antiretroviral treatment (Morse *et al*., 1991). Such findings agree to the general idea linking stratification of income to disparities in health status and the will to adhere, placing the lower income patients on a deprivation scope, while allowing for higher income patients to adjust according to relative social status, possibly being influenced by other socio-economic status factors such as education and occupational status. The existence of a possible association between level of education and adherence to treatment in HIV/AIDS patients was examined in 13 of the reviewed studies. Among the 13 studies that considered education as a probable factor affecting adherence to antiretroviral treatment, only 4 original studies proved a statistically significant positive association. Education, providing the basis of a stable future for each person, as well as altering the criteria used during the decision-making process and the knowledge to access health resources and information on disease and treatment, is a powerful implement and could possibly be influenced by policies targeted to enhance adherence among HIV patients, religion was found to be have less impact on participation (Goldman *et al*., 2000).

2.4 Patient's trust in the health provider as a determinant of community's participation

According to Rosen *et al*. (2007), many studies in the world have shown that Health disparities related to the provision of, and access to, healthcare in the United States are well documented across racial and ethnic groups. One are of particular interest to health disparities researchers has been solid organ transplantation. Both provider and patient behaviors are implicated as contributing to ethnic variance of medical care in kidney transplantation. A pilot study that was conducted explored the perceptions of trust among patients in the kidney transplant process at the Warren Magnuson Clinical Center at the National Institutes of Health

and at Walter Reed Army Medical Center. Army Medical Center. Seven dimensions contributing to trust were identified in the literature: competence, vaccine safety, dosage, compassion, control, communication and confidentiality which did enhance participation. Face-to-face interviews to explore these five dimensions will include questions regarding demographic variables, the Trust in Physician Scale; the Trust in Nurse Scale, and the Patient Trust Scale.

According to Schneider *et al*. (2004), in a study done in America titled Better physician-patient relationships, 115 patients were enrolled, (56% had previously enrolled in a clinical trial; 50% of whom were currently enrolled in a trial); 92% would consider participating in a future clinical trial. Increased patient trust in the provider was associated with increased willingness to participate in a trial. After the intervention, 94% indicated that they would be willing to be contacted about a clinical trial for which they may be eligible and 85% preferred to be contacted by their primary physician. They concluded that patients' trust in their provider may predict willingness to participate in clinical trial. Response dispersion for deliverer and receiver uptake was clustered at the endpoints, indicating that most participants in the study either strongly would or strongly would not engage in patient delivered partner therapy, with very few individuals responding in the moderately. A large majority of participants expressed willingness to engage in patient-delivery: 83% expressed some level of willingness (_0 on _3–3 scale) and 45.8% expressed strong willingness (3 on the _3–3 scale). Willingness to engage in partner-use was also high, although less so than willingness to deliver, with 69.4% expressing some willingness to receive/use and 27.9% expressing strong willingness. This difference between delivery and use uptake was significant (t (505) _ 4.627, *P* _ 0.000) indicating that participants are more willing to engage in patient delivered partner therapy delivery than they are to engage

in patient delivered partner therapy use. Attitude and perceived norm were also statistically significantly higher among deliverers than receivers.

According to Allen *et al*. (2002), in a study conducted in Spain titled HIV Cost and Services Utilization Consortium, 62 percent of HIV-infected adults participating in medication trials were white, whereas only 49 percent of all those receiving care for HIV infection were white. At that time, whites accounted for 44 percent of the patients with AIDS whose cases had been reported to the CDC. Distribution of Race or Ethnic Group (Panel A) and Sex (Panel B) of Adult Patients with Human Immunodeficiency Virus (HIV) or the Acquired Immunodeficiency Syndrome (AIDS) in Population-Based Samples, Research Studies, and Access to Experimental Medications between 1996 and 1998.). Blacks accounted for 23 percent of the adults participating in treatment trials but for 33 percent of those receiving care for HIV infection and 37 percent of patients with reported AIDS cases. The percentage of trial participants who were white was similar to the 63 percent in published, peer-reviewed HIV studies and higher than the 54 percent of ACTG enrollees. These data suggest that whites were over represented in clinical trials related to HIV. The proportions of women in the various research and clinical groups were similar.

2.5 Information as a determinant of community's participation

On December 14 and 15 the Associated Press touched off a media firestorm with stories charging that side effects of single-dose nevirapine (to prevent mothers with HIV from infecting their babies during childbirth) had been covered up. The next day it reported on the August 2003 death of a woman in a U.S. clinical trial of continued treatment with nevirapine (not single

dose), due to a rare liver failure probably caused by the drug, after an abnormal blood-test result was not noticed in time. Later the AP quoted responses -- one comparing nevirapine's distribution in Africa to the notorious Tuskegee Experiment, another charging that Africans were treated like guinea pigs. There never was any evidence of a significant risk of side effects from only a single dose of nevirapine. There is a risk of HIV drug resistance, but this is well known to all AIDS doctors and experts and has never been covered up. Every day about 1,800 babies are born with HIV, mostly to women who have no treatment options either for themselves or to prevent the infection of their child. There is no reason to doubt that single-dose nevirapines works, and could prevent about half of these infections. Because of the resistance problem, single-dose nevirapine is not the first choice -- but sometimes it is the only choice possible. The brief media storm that still threatens the lives of thousands of children grew out of a bitter dispute between two officials of the U.S. National Institutes of Health -- Jonathan M. Fishbein, M.D., a physician with clinical-trials monitoring expertise, and his supervisor, Edmund Tramont, M.D., director of the Division of AIDS (DAIDS) at the U.S. National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH. The falling out happened rapidly; Dr. Fishbein was hired by NIH in July of 2003, and notified in February 2004 that he would be fired. Dr. Fishbein sought whistleblower status and released documents to Congress that he said showed "scientific and professional misconduct" at NIAID. The AP published selected internal NIAID emails, memos and reports (see links to these documents below). Dr. Fishbein, still a Federal employee today (earning about $178,000 a year, according to a December 29 story in *The Washington Post*), set up a Web site, http://www.honestdoctor.org, which alleges wrongdoing by NIAID officials and provides documents that had been released elsewhere; he "did not provide

non-public documents to the Associated Press," according to a statement from his attorney, Stephen M. Kohn (Glazer, 2004).

According to BeLue *et al*. (2006), focus groups were conducted among African American participants by gender. A total of 67 African American participated in the focus groups. All focus groups were audio-taped and transcribed verbatim. Data analysis was performed by combining the key elements of grounded theory and content analysis with the assistance of the qualitative software. The result showed that different themes emerged for men versus women due to misinformation. The business and economics of research were important to male participants. The researcher–participant relationship emerged as one of the strongest themes related to potential female participation in research. Focus group results did indicate that African American men and women present different preferences, beliefs and barriers to participation. Men expressed the desire to know information on funding issues, financial benefit and impact of the research. Women expressed the desire to be treated respectfully and as an individual as opposed to just a study subject. Integrating gender preferences into researcher–participant interactions, advertisement, informed consent delivery and advertisement of research studies may lead to increased participation rates. Discussing and presenting relevant information on clinical research funding mechanisms, and the business of clinical research with potential participants may be helpful in building trust with the researcher and the research team. Creating a process for information exchange and methods to minimize the power imbalance between the researcher and participant may also build trust and help participants feel more comfortable to participate in research.

In the Tuskegee Study of Untreated Syphilis done on prisoners in America by Brandon et al. in 2006, it was not true that "approximately two-fifths of both black and white participants" indicated that they had heard of the Tuskegee Study of Untreated Syphilis (TSUS), but it was 25% and 74%, respectively—results markedly different than what others have reported. Miscalculations similar to the ones described, if applied to other areas, could cause numerous health disparities to vanish literally on paper when they still exist to the disadvantage of the black community. It was true that there was little difference between these black and white respondents in detailed knowledge about TSUS—most answered incorrectly the author-selected questions. The authors exaggerated that "nearly twice as many black respondents believed that Tuskegee study research investigators infected the study participants with syphilis" (75.3% vs. 52.8%) this did lead to participants' intention to withdraw from the study (Brandon *et al*., 2009).

2.6 Community's perception as a determinant of community's participation

In a study done in the U.S.A by Strauss et al. 2001 titled Willingness to volunteer in future preventive HIV vaccine trials, which examined perceived risks, benefits, and desired information related to willingness to volunteer in preventive HIV vaccine trials.

Purposive sampling was used to select 90 participants among injecting drug users (Philadelphia, PA, U.S.A.); gay men (San Francisco, CA, U.S.A.); and black Americans (Durham, NC, U.S. A qualitative interview guide did elicit perceived benefits, risks, and desired information relating to trial participation. Themes were developed from the transcribed texts and from free lists. The result stated willingness to volunteer in a preventive HIV vaccine trial was similar across the three communities. Eight perceived benefits were reported, including self-benefits, altruism, and stopping the spread of AIDS. Seven perceived risks were reported, including negative side

effects and vaccine safety issues, contracting HIV from the vaccine, and social stigmatization. Participants voiced the desire for eight types of information about issues relating to trust and confidentiality in the research process, health complications and later assistance, and vaccine trial methodology. It was concluded that many benefits as well as risks of preventive HIV vaccine trial participation were cited. Scientists conducting preventive HIV vaccine trials need to address community perceptions of risks and provide information about the research if trial enrollment is to be diverse and successful (Strauss *et al*., 2001).

Research done in South Africa by Buchbinder et al. in 2004 on Determinants of enrollment in a preventive HIV vaccine trial, showed that both adults and adolescents have concerns regarding perceived stigma or perceived negative social consequences stemming from participation in HIV-related research. According to Buchbinder *et al*. (2004), concerns regarding what family and friends would think if they knew about their participation in HIV-related research were expressed, and concerns regarding the social consequences of vaccine-induced seropositivity (i.e., the false-positive HIV test that can occur as a result of participating in HIV vaccine trials) made many people not to participate in any trial. According to Newman et al. (2006), the stigma associated with testing positive for sexually transmitted diseases (STDs), in general, has been identified in both adults and adolescents as a significant barrier to individuals seeking prompt and appropriate diagnosis and treatment for STDs.

According to Fortenberry (1997), a study done on Health care seeking behaviors relation to sexually transmitted diseases among adolescents in the U.S, revealed that those with higher levels of STD-related stigma were more likely to delay seeking STD services. According to Fortenberry *et al*. (2002), in two studies on adolescents' willingness to receive a hypothetical HIV vaccine, those perceiving oneself to not belong to a traditionally identified risk group, when simply being associated with such groups can be stigmatizing, were less willing to accept HIV vaccination. The result agrees with Liau *et al*. (1998), who found out that perceived stigma or

negative social consequences, side effects after vaccination associated with being a participant in clinical trial especially HIV-related research may be a significant barrier to participation in such researches.

2.7Theoretical Framework

The study is anchored on the theory of planned behavior which was proposed by Icek Ajzen in 1985 through his article "From intentions to actions: A theory of planned behavior." The theory was developed from the theory of reasoned action, which was proposed by Martin Fishbein together with Icek Ajzen in 1975 which was grounded in various theories of attitude such as learning theories, expectancy–value theories, consistency theories, and attribution theory. According to the theory of reasoned action, if people evaluated the suggested behavior as positive (attitude), and if they think their significant others wanted them to perform the behavior (subjective norm), this results in a higher intention (motivation) and they are more likely to do so. A high correlation of attitudes and subjective norms to behavioral intention, and subsequently to behavior has been confirmed in many studies. A counterargument against the high relationship between behavioral intention and actual behavior has also been proposed as results of some studies do not show that behavioral intention always leads to actual behavior because of circumstantial limitations. Namely, since behavioral intention cannot be the exclusive determinant of behavior where an individual's control over the behavior is incomplete, Ajzen introduced the theory of planned behavior by adding a new component, "perceived behavioral control." By this, he extended the theory of reasoned action to cover non-volitional behaviors for predicting behavioral intention and actual behavior of the community towards any scientific research. The theory admits that community's participation is influenced by factors such as

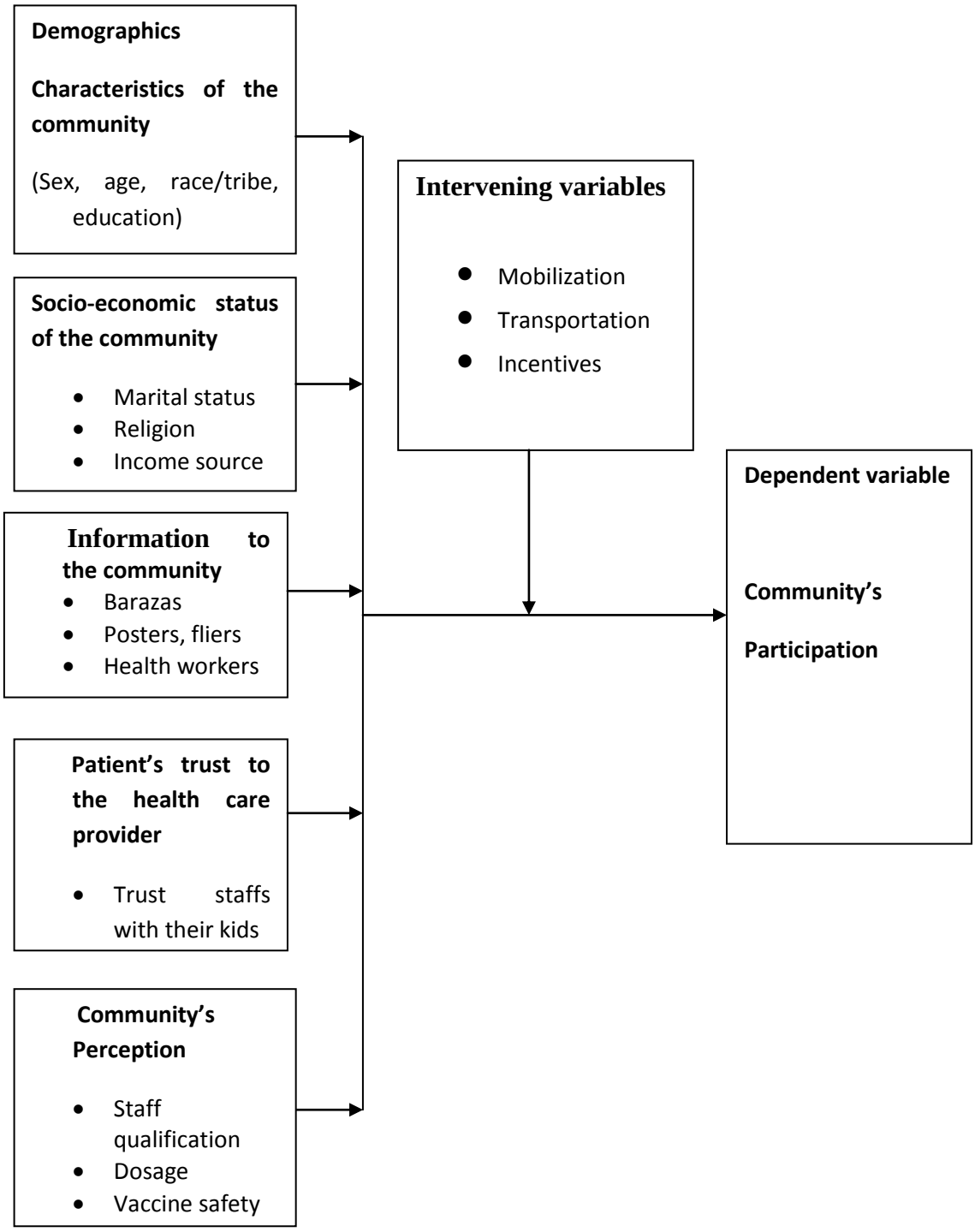
demographic characteristics of a community, their socio-economic status, community's perception (attitude) among others (Sheppard *et al*., 1988). Based on the theory, to increase the participation of Community members, there is need for CDC to ensure that the determinants of community's participation need to be addressed to the latter to ensure maximum community's participation and retention of the participants. This can be achieved through both continued mobilization of the community, consenting and re-consenting of the participants.

2.8 Conceptual Framework

This study was guided by the following conceptual framework.

Figure: 2.1Conceptual framework

Independent variables



In this study, the independent variables are demographics characteristics of the community, socio-economic status of the community, information to the community and community's perception as community's participation is the dependent variable. The other factors that make participants rush to participate in a study are incentives, transportation/transport reimbursement and mobilization which are the considered intervening variables towards community participation in CDC projects.

2.9 Summary of literature review

The literature was viewed to gain more understanding on determinants of community's participation in clinical trials. Various studies done in different parts of the world did find that, demographic characteristics of the community such as age, sex and educational level, socio-economic status such as occupation, marital status and religion, information to the community or participants, patient's trust to the health care provider and community's perception are determinants of community's participation in any clinical trial. The key gaps identified was that besides the enormous studies done highlighting on determinants of participation in clinical trial, still there is no adequate information on determinants of community's participation in vaccine trials done in Sub Saharan region and specifically in children. The little information on community's participation in vaccine trials in the sub Saharan region (Kenya) therefore forms the basis for the justification of this topic under investigation.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

This chapter discussed in detail how the data was obtained, processed, analyzed and interpreted to fulfill the research objectives. The methodology elements herein included the research design to be applied; target population; sampling design and procedures; the types of data; research instruments; as well as data processing and analysis techniques. Details of these are as discussed in the succeeding sections.

3.2 Research Design

The research used descriptive survey research design. The descriptive survey design generally entails investigating populations by selecting samples to analyze and discover occurrences. For the purposes of this study, the survey provided a description and explanation of a sample of the both potential participants and participants from Karemo. Although surveys can be a cost-effective type of research, survey research design also has a number of limitations.

According to Kothari (1990), descriptive design are best suited for this kind of study where sample size is small and also structured questionnaires are used, but he recommended that to obtain data free from errors, introduced by those who are responsible from collecting them, it is necessary to closely supervise those who collect data. When descriptive design is used, inferences can be made, but not at the level of cause and effect and ruling out rival hypotheses, like one can do with experimental or quasi-experimental research. Additionally, lack of the temporal element does not allow studying changes over time, as would be beneficial for this

specific study. However, a well-conducted survey can provide a description of sample that is representative of the general population and show the phenomena that are currently happening in such a population. Other potential study limitations included: social desirability bias, recall bias, selection and sampling biases and researcher bias. It is also important to use this kind of design because at a glance, you would be able to know what is in the whole population and based on the nature of data and the resources that was available, the descriptive survey design was the best.

3.3 Target Population

According to Household Demographic Surveillance system (2009), the annual birth rate in Karemo Division is 3600. Therefore the target populations were parents from the Division and the number interviewed was 364 in the 172 villages and the 15 Centers for Disease Control and Prevention field supervisors and community interviewers who do carryout home follow ups for the enrolled participants.

3.4 Sample Size and Sample Selection

In this section sample size and sample selection was discussed.

3.4.1 Sample Size

According to Mugenda and Mugenda (1999), a sample size must be large enough to represent the salient characteristics of the accessible population. Generally the sample size depends on factors such as the number of variables in the study, the type of research design, the method of data analysis and the size of accessible population.

The sample size was picked with the help of Cochran (1963) Table as shown in appendix IV on page 85. In the table from the sample of 4000, which was near 3600 of the target

population, appropriate sample size was 364. A total of 379 respondents participated in this survey, whereby 364 were the community members as the remaining 15 were CDC staffs. All participants gave consent to be in the study.

3.4.2 Sample Selection

The selection was as per the general households provided by CDC DSS data base for Karemo Division which has been programmed, therefore the sample selection exercise was not a difficult task. Simple random sampling technique was employed where a computer was used to generate a series of random numbers. A list of all the respondents village wise was keyed in an excel sheet. A function =RAND () was used to generate random numbers between 0 and 1. Then, sort both columns the list of names and the random number by the random numbers. This rearranged the list in random order from the lowest to the highest random number. Then, the first 02 names in the first 02 households in this sorted list was selected per household per village totaling to 364 respondents, since they all did meet the eligibility criteria. The study resorted to simple random sampling, since it was easy to use the generated results of the random numbers very quickly and not prone to bias.

The study also applied the purposive method in selecting the 15 CDC staff respondents, since they were few to be subjected to a random sampling method. In this study the power of the study (precision) was considered for a sample to have any statistical significance. In this study the confidence level was 95% and error of margin 5% but the already calculated figures on the table on appendix IV in page 85 was used.

3.5 Research Instrument

The study used closed questionnaires as instrument for data collection. The researcher developed the questionnaires to measure the determinants of community's participation in clinical trials in the Centers for Disease Control and Prevention projects and the effect they have created in terms of project implementation. Questionnaires are commonly used to obtain information from a given population; each item in the questionnaire was developed to address specific objectives and research questions. A standardized questionnaire was developed with closed-ended questions, comprising a list of all possible alternatives from which respondents selected answers that best suits them.

The study had two research instruments namely questionnaire for CDC staff and questionnaire for the household who were legible, the questionnaire had four sections. The questionnaire for the household was divided into five sections namely demographic characteristics of the community, socio-economic status, information about CDC clinical trials, perception of the community about CDC clinical trials and patient's trust in health care provider. The questionnaire for the CDC staffs was composed of four sections namely, demographic characteristics of the staff, information about CDC clinical trials, ratings of CDC clinical trials community entry, participant/patient's trust to the staffs and the community's perception.

3.5.1 Pilot testing

According to Nachmias and Nachmias (1996), pilot-testing is an important step in the research process because it reveals vague questions and unclear instructions in the instruments. It also captures important comments and suggestions from the respondents that enable the researcher to improve efficiency of instruments, adjust strategies and approaches to maximize response rate.

Pre-testing and practical interviewing exercises was conducted by the researcher together with the Research assistants in the neighboring Boro Division. A total of 37 interviews was done which was 10% of the total sample size of the targeted population. The filled questionnaires was collected and checked if well answered, any necessary correction was done. After two weeks the same people were given questionnaires to fill once again.

The data from the pilot testing was not included in the final analysis, but, was only used to make the research instrument better.

3.5.2 Validity of the instrument

Validity can be defined as the accuracy and meaningfulness of inferences, which are based on the research results. In this study pilot-testing was used as an important step in making the instrument valid for the purposes of the study. During the pilot testing vague questions and unclear instructions were revealed. Important comments and suggestions were also captured from the respondents that enabled the researcher to improve efficiency of instruments, adjust strategies and approaches to maximize response rate. The responses from different participants were analyzed to come up with a generalized position which did stand the validity test.

The researcher made sure that the questionnaire captured all the intended respondents who also answered all the intended questions. The questions were simplified by the researcher which made all the respondents to comprehend to all the questions. The researcher did use a survey method which usually lessens bias hence the researcher was assured of collecting valid data from the respondents to be interviewed.

3.5.3 Reliability of the instrument

Reliability is a measure of the degree to which a research instrument yields consistent results or data after repeated trials. It is influenced by random error. As random error increases, reliability decreases. Random error is defined as the deviation from a true measurement due to factors that have not been addressed by the researcher. Errors may arise from inaccurate coding, fatigue and bias (Mugenda and Mugenda, 1999).

The reliability of a research instrument concerns the extent to which the instrument yields the same results on repeated trials. Although unreliability is always present to a certain extent, there will generally be a good deal of consistency in the results of a quality instrument gathered at different times. According to Cook et al, (2007), the tendency toward consistency found in repeated measurements is referred to as reliability.

To measure reliability the researcher employed the test-retest method which involved selecting 37 respondents from Boro division and administered the same instrument twice to the same group of participants after some two weeks time lapse. The following procedure was used: selection of an appropriate group of participants, administer the questionnaire to the group, keeping all the initial conditions constant and interview the participants again the second time after one week and finally analyze the two different results. The results generated were similar this showed that the instrument was reliable for data collection.

3.5.4 Data collection procedures

First and foremost the Researcher prepared the research instrument which was a questionnaire. The questionnaires were of two types of respondents namely: Centers for Disease Control and Prevention and the participants. The research permit was obtained from the Ministry

of higher Education under the Department of National Council For Science and Technology, which gave an authentication for the study to take place. After the permit had been acquired, the researcher was assisted by three research assistants had a pre test of the two instruments in the neighboring Boro division to make the instruments clearer for the actual data collection in Karemo Division. After the pilot testing preliminary results was analyzed, after which a rough idea of how the field would be like was obtained. The Researcher had a training session for the three assistants to go through the research instrument, so as to get an insight of what each and every question was intended for.

The research assistants had a copy of the permit letter of authorization from the Siaya District Headquarters detailing the kind of research they will be involved in. This letter came in handy whenever the Research assistants were to approach a potential participant for participation in the study. After the consent had been given by the potential participants, the research assistants were in a position to go ahead with the interview by asking questions face-to-face for those who could not administer the questionnaires themselves, but for the CDC staff they were given the questionnaires to administer by themselves with little guidance from the Researcher. The data collection exercise took exactly two weeks due to time that was taken to trace the randomized respondents from home if not found within the health facilities.

3.6 Data analysis techniques

The analysis employed descriptive statistics, including frequencies and percentage distribution to examine the relation between independent and dependent variables individually.

Descriptive statistics, including frequency and percentage was generated for age, sex, level of education and used to analyze the socio-demographic characteristics of the sample. Statistical

significance of the association between the dependent and independent variables were interpreted using the computation of an index that measured this relationship.

Before the data was entered into the database, a code book was created to describe each and every variable to be used in the analysis and a data clerk was engaged to enter the data into the database to be ready for analysis and the exercise took one week to complete.

3.7 Ethical considerations

For participation in this study, the subjects were not required to give any samples so it posed minimal risk to the participant. The participants were required to give a verbal consent since; this study did not pose any risk to them. All participants were required to undergo a standard informed consent procedure consistent with international recommendations Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO, 2007). During consenting the Interviewer described the purpose of the study, the possible benefits and risks of participation and the contact person in case of a query.

All the participants were assured of total confidentiality and the information they gave was to be used for research purposes only. They were also assured that their names were not to appear anywhere. The importance of maintaining confidentiality was also emphasized to the research assistants.

This study did not have any risk to the participant since; the kinds of questions asked were not personal therefore they did not face any discomfort or anxiety when responding to questions. There was no direct benefit to the participant, but the results would be used to make them better engaged and useful to the research institution.

CHAPTER FOUR

DATA ANALYSIS, PRESENTATION, INTERPRATATION AND DISCUSSIONS

4.1 Introduction

This chapter presents study findings which have been discussed in line with the objectives.

4.2 Questionnaire response rate

A total of 379 questionnaires were sent to be administered and 374 questionnaires were returned for analysis yielding a response rate of 98.7%. Response rate was achieved as a result of good training of the field assistants. Both field assistants and the community were taught on the importance and purpose of the study. This percentage was enough to continue with the study since according to Necamaya (1996), response return rate of more than 75% is enough for the study to continue.

4.3 General information on community's participation in CDC's clinical trials

The study sought to find the general information on community's participation in CDC's clinical trials in Karemo Division and a question was asked to know whether the respondents have had a chance to participate in CDC clinical trials, frequency of participation and reasons for not participating. The information was important because it helped to know why potential participants did refuse to be in the trials therefore the CDC can have other approaches to the community during mobilization. The results were as shown in tables 4.1 and 4.2.

Table 4.1: Community participation in CDC clinical trials

Child ever participated in CDC clinical trial	Frequency	Percent
Yes	251	70.11
No	107	29.89
Total	**358**	**100**

Table 4.1 shows that majority 251 (70.11%) of the respondents have had their children participate in CDC clinical trials, 107 (29.89%) have not participated in these clinical trials due to either lack of chance or misconception.

This statistics is similar to BeLue *et al*. (2006) where focus groups were conducted among African American participants by gender. A total of 67 African American participated in the focus groups. All focus groups were audio-taped and transcribed verbatim. Data analysis was performed by combining the key elements of grounded theory and content analysis with the assistance of the qualitative software. The result showed that different themes emerged for men versus women due to misinformation. The business and economics of research were important to male participants. Focus group results did indicate that African American men and women present different preferences, beliefs and barriers to participation.

Table 4.2: Reason for not participating in CDC clinical trials

Not participating in CDC clinical trial	Frequency	Percent
Never wanted	35	35.00
Never had chance	65	65.00
Total	**100**	**100**

Table 4.2 shows that of the 29.89% who did not participate in CDC clinical trials have not done so because they never wanted 35 (35.00%) due to misinformation or poor perception and because they have not had a chance 65 (65.00%) to participate in these clinical trials.

The statistics is similar to Buchbinder *et al*. in 2004, where concerns regarding what family and friends would think if they knew about their participation in HIV-related research were expressed, and concerns regarding the social consequences of vaccine-induced seropositivity (i.e., the false-positive HIV test that can occur as a result of participating in HIV vaccine trials) made many people not to participate in any trial.

4.4 Demographics characteristics of the community and their participation in CDC's clinical trials.

This section covers the results, interpretation and discussions on demographic characteristics of the community which include age, gender and level of education of the respondents.

4.4.1 Age group of the respondents on participation in CDC clinical trials

To answer this, the respondent were asked to indicate their age and results were cross tabulated by their responses on whether or not they have participated in clinical trials as shown in table 4.3.

Table 4.3: Age category and community participation in CDC clinical trials

	YES		NO	
Age bracket	**Frequency**	**Percent**	**Frequency**	**Percent**
≤ 19 years	18	7.17	11	10.28
20-29 years	150	59.76	52	48.60
30-39 years	71	28.27	32	29.91
40-49 years	10	3.98	7	6.54
≥ 50 years	2	0.80	5	4.67
Total	**251**	**100**	**107**	**100**

Table 4.3 shows that majority of CDC clinical trials participants are in the age bracket of 20-29 years that is 59.76% followed by 30-39 age brackets. This implies that most participants who participate in the trials are of mature age of 20 years and above and can tell the importance of participation.

The statistics is similar to Kronborg (2004), in a study conducted to identify determinants of participation in colorectal cancer screening with faecal occult blood testing, results from the UK RCT, pilot programmes and surveys of screening activities showed an increased participation with increased age.

4.4.2 Gender of the respondents on participation in CDC's clinical trials

To answer this question, the respondent were asked to indicate their gender and results were cross tabulated by their responses on whether or not they have participated in CDC clinical trials as shown in table 4.4.

Table 4.4: Gender of the respondents and community participation in CDC clinical trials

	YES		NO	
Gender	**Frequency**	**Percent**	**Frequency**	**Percent**
Male	23	9.16	32	29.91
Female	228	90.84	75	70.09
Total	**251**	**100**	**107**	**100**

Table 4.4 shows that majority of participants in CDC trials were females at 90.84% as male were 9.16%, for females are normally the ones who take the children to clinics.

This statistics is similar to a study done by Menezes *et al.* in (2010) in the U.S for New Molecular Entities, where overall 120 (34.1%) trials had only male participants while 232 (65.9%) trials also enrolled female participants. 30.6% (3106/10,134) of participants were women.

4.4.3 Education level of the respondents and their participation in CDC's clinical trials

To answer the question on education of respondents, they were asked to indicate their educational level and results were cross tabulated by their responses on whether or not they have participated in CDC clinical trials as shown in table 4.5.

Table 4.5: Level of education of the respondents and community participation in CDC clinical trials

	YES		NO	
Education level	**Frequency**	**Percent**	**Frequency**	**Percent**
None	8	3.19	4	3.74
Primary	193	76.89	63	58.89
Secondary	49	19.52	27	25.23
Tertiary	1	0.40	3	2.80
University	0	0.00	10	9.36
Total	**251**	**100**	**107**	**100**

Table 4.5 shows that 76.89% and 19.52% of the respondents who did participate in CDC clinical trials had gone to school up to primary and secondary level respectively. This is because they have an understanding on research importance.

The statistics differ slightly with Shamrakov *et al*. (2009), in a study carried out in Toronto, where 101 questionnaires were completed out of 112 administered (90% response rate). 76% of patients self-reported as knowledgeable about clinical trials. Patients' education level correlated to their perceived knowledge of clinical trials: 37.5% of patients with a less than grade 9, 59.4% with a high school, and 90.2% with a university background identified themselves as knowing what Control Trials (CTs) are. This is because the statistics shows that those with tertiary and university education did participate the least.

4.5 Socio-economic status of the community and their participation in CDC's clinical trials

This section covers marital status, religion and source of income of the community which were used as indicators to community participation in CDC clinical trials.

4.5.1 Marital status of the respondents and their participation in CDC's clinical trials

This section was answered by asking the participants to indicate their marital status and the results were cross tabulated by their responses on whether or not they have participated in CDC clinical trials as shown in table 4.6.

Table 4.6: Marital status of the respondents and community participation in CDC clinical trials

	YES		NO	
Marital status	**Frequency**	**Percent**	**Frequency**	**Percent**
Single	35	13.94	18	16.82
Married	192	76.49	79	73.83
Widowed	21	8.37	10	9.35
Divorced	0	0.00	3	2.80
Total	**251**	**100**	**107**	**100**

Table 4.6 shows that the majority of the participants (76.49) were married followed by the single parents who were 13.94%.

This statistics disagrees with Menezes *et al*. in (2010) in clinical trial data submitted to the Food and Drug Admission for a study done in the U.S for New Molecular Entities (NMEs) for adults that in overall 120 (34.1%) trials had only male participants while 232 (65.9%) trials also enrolled female participants. 30.6% (3106/10,134) of participants were women. 149/352 (42.3%) of trials included safety and tolerability testing above the highest approved dose. In those trials, 32.5% (1628/5011) of the participants were women. An evaluation of trial start date illustrated the number of trials that enrolled women ($p = 0.01$) and the number of female participants ($p < 0.001$) has increased over time. The findings revealed that female subjects have traditionally been underrepresented in phase 1 trials. The number trials enrolling women and the

number of women participating in phase 1 trials has increased since 2001, however, women are still underrepresented especially the married ones.

4.5.2 Religion of the respondents and their participation in CDC's clinical trials

This section addresses the religious believe of the respondents involved in the study and its impact on participation in CDC clinical trials. Therefore the respondents were asked to indicate their religion and the results were cross tabulated as shown in the table 4.7.

Table 4.7: Religion of the respondents and community participation in CDC clinical trials

	YES		NO	
Religion	**Frequency**	**Percent**	**Frequency**	**Percent**
Catholic	73	29.67	34	31.78
Protestant	146	59.35	55	51.40
Legio Maria	26	10.57	15	14.02
Muslim	1	0.41	2	1.89
Other	0	0.00	1	0.93
Total	**246**	**100**	**107**	**100**

Table 4.7 shows that majority of the respondents (59.35%) who have participated in the trials were Protestants as legio Laria though a large denomination after Catholics had few participants. This was because the Legio Maria does not believe in taking children to the hospital.

This statistics disagrees with Goldman *et al*. 2000, who found out that religion was found to be have less impact on participation.

4.5.3 Occupation of the respondents and their participation in CDC's clinical trials

The respondents were asked to indicate their occupation and the results were as cross tabulated in table 4.8.

Table 4.8: Occupation of the respondents and their participation in CDC clinical trials

	YES		NO	
Occupation	**Frequency**	**Percent**	**Frequency**	**Percent**
Peasant farmer	144	57.37	40	38.10
Large scale farmer	1	0.40	1	0.95
Employed	12	4.78	22	20.95
Small scale business	79	31.47	33	31.43
Large scale business	1	0.40	1	0.95
Other	14	5.58	8	7.62
Total	**251**	**100**	**105**	**100**

Table 4.8 indicates that 57.37% of respondents who have participated in CDC trials were peasant farmers followed by small scale business as the minority were large scale farmers and business men. This might be because of the incentives and transport reimbursement that they do get as compensation for their time.

This result agrees with Morse *et al*. (1991) who found out that perceived economic support by a significant other was found to have a direct association with levels of adherence to antiretroviral treatment, in another of the reviewed studies. Such findings agree to the general idea linking stratification of income to disparities in health status and the will to adhere, placing the lower income patients on a deprivation scope, while allowing for higher income patients to adjust according to relative social status, possibly being influenced by other socio-economic status factors such as education and occupational status.

4.6 Information about CDC's clinical trials

This section seeks to present the extent to which information to the community about CDC clinical trials determines participation in CDC clinical trials in Karemo Division.

4.6.1 Whether the respondents have heard of CDC clinical trials and their participation in CDC's clinical trials.

In order to answer this, the respondents were asked to check their relevant answer whether or not they had participated in the trials and the results were cross tabulated as shown in table 4.9.

Table 4.9: Whether respondents have heard about CDC clinical trials and their participation in the trials

Heard of CDC	YES		NO	
	Frequency	Percent	Frequency	Percent
Yes	251	100	96	89.72
No	0	0	11	10.28
Total	**251**	**100**	**107**	**100**

Table 4.9 shows that most community members (100%) who have participated in the trials have heard of CDC clinical trials.

The statistics agrees with Fleming *et al*., 2006 where an informational video was produced in Toronto to explain the work of the research team and the first planned hookworm vaccine trial, using a pedagogical method based on analogies. Seventy-two adults living in a rural community of Minas Gerais were administered a structured questionnaire that assessed their knowledge of hookworm, of research and of the planned hookworm vaccine trial, as well as their attitudes and perceptions about the researchers and participation in future vaccine trials. The questionnaire was administered before being shown the educational video and two months after and the results compared. After viewing the video, significant improvements in knowledge related to hookworm infection and its health impact were observed.

Table 4.10: Community's sources of information about CDC clinical trials

Source of information	Frequency	Percent
Chiefs baraza	75	12.54
Radio	21	3.51
Posters, brochures, fliers	53	8.86
Newspapers and magazines	8	1.34
TV	3	0.50
Health workers	252	42.14
Family	81	13.55
Friends, peers	95	15.89
Religious leaders	8	1.34
Teachers	2	0.33
Total	**598**	**100**

Table 4.11: CDC staff opinion on sources of information about CDC clinical trials to the community

Source of information	Frequency	Percent
Chiefs baraza	14	31.11
Radio	2	4.44
Posters, brochures, fliers	6	13.33
Newspapers and magazines	2	4.44
TV	3	6.67
Health workers	7	15.56
Family	3	6.67
Friends, peers	3	6.67
Religious leaders	3	6.67
Teachers	2	4.44
Total	**45**	**100**

Table 4.10 shows that many people (42.14%) of the community did hear about the CDC trials from the community health workers followed by chiefs' barazas. This indicates that the community health workers are the best strategy for community.

Table 4.11 shows that majority of CDC staff (31.14%) believe that chiefs' barazas is the leading source of information to the community followed by health care workers.

Table 4.12: Staff rating of CDC clinical trials community entry

Function	Excellent	Good	Average	Poor
Introducing the study to the community	1 (6.67%)	10(66.67%)	4(26.67%)	-
Defaulter tracing	1 (6.67%)	4 (26.67%)	8(53.33%)	2(13.33%)
Community mobilization	2(13.33%)	5 (33.33%)	8(53.33%)	-
Health promotion/education	1 (6.67%)	7 (46.67%)	4(26.67%)	3(20.00%)

Table 4.12 shows the CDC staff rating of the institution in terms of community entry strategy, defaulter tracing, community mobilization and health education.

4.6.2 The extent to which information influence participation in CDC clinical trials

To know the extent at which in information did influence participation in CDC clinical trials, the respondents who did participate in the trials were asked to answer the question on the extent of information influence to their participation and the result is as shown in table 4.13.

Table 4.13: Information influence on participation in CDC clinical trials and community participation in CDC clinical trials

The extent to information influence	Frequency	Percent
Large	169	47.61
Moderate	65	18.31
Low	10	2.82
No extent	9	2.54
N/A	102	28.73
Total	**355**	**100**

Table 4.13 shows that most participants (47.61%) are largely influenced by the information about CDC clinical trials.

The statistics agrees with Fleming *et al*., 2006 where an informational video was produced in Toronto to explain the work of the research team and the first planned hookworm vaccine trial, using a pedagogical method based on analogies. Seventy-two adults living in a rural community of Minas Gerais were administered a structured questionnaire that assessed their knowledge of hookworm, of research and of the planned hookworm vaccine trial, as well as their attitudes and perceptions about the researchers and participation in future vaccine trials. The questionnaire was administered before being shown the educational video and two months after and the results compared. After viewing the video, significant improvements in knowledge related to hookworm infection and its health impact were observed.

Table 4.14: CDC staff opinion on the extent to which the information influence parents participation in clinical trials

Influence of information	Frequency	Percent
Large	5	33.33
Moderate	8	53.34
Low	2	13.33
Total	**15**	**100**

Table 4.14 shows the opinion of the CDC staff on the extent to which the information influences the parents' participation in clinical trials which did show that majority of the participants (53.34%) was moderately influenced by the information. This shows that the kind of information that the community get might make them to participate in the study, not to participate or withdraw after being enrolled in any clinical trial.

The statistics is similar to Brandon *et al*., (2009) in the Tuskegee Study of Untreated Syphilis done on prisoners in America, it was not true that "approximately two-fifths of both black and white participants" indicated that they had heard of the Tuskegee Study of Untreated Syphilis (TSUS), but it was 25% and 74%, respectively—results markedly different than what others have reported. Miscalculations similar to the ones described, if applied to other areas, could cause numerous health disparities to vanish literally on paper when they still exist to the disadvantage of the black community. It was true that there was little difference between these black and white respondents in detailed knowledge about TSUS—most answered incorrectly the author-selected questions. The authors exaggerated that "nearly twice as many black respondents believed that Tuskegee study research investigators infected the study participants with syphilis" (75.3% vs. 52.8%) this did lead to participants' intention to withdraw from the study.

4.7 The perception of the community on qualification of health care providers/CDC staff, dosage, vaccine safety and their participation in CDC's clinical trials

This section seeks to present the perception of the community about qualifications of CDC staffs, dosage, vaccine safety and their participation in CDC clinical trials.

4.7.1 The influence of CDC staff qualification to conduct clinical trials and participation in CDC's clinical trials

To know how staffs qualification did influence community's participation in CDC clinical trials, the respondents were asked to answer the question on staff qualification and the result were and the result were cross tabulated as shown in table 4.15.

Table 4.15: Results on CDC staff qualification to conduct clinical trials

Staff	**YES**		**NO**	
Qualification	**Frequency**	**Percent**	**Frequency**	**Percent**
Yes	248	99.20	2	66.67
No	2	0.80	1	33.33
Total	**250**	**100**	**3**	**100**

Table 4.15 shows that most respondents (99.20%) believed that CDC staffs were qualified to conduct the trials this made them participate actively in the trial.

The result agrees with Rosen *et al*. 2007, in a pilot study that was conducted that explored the perceptions of trust among patients in the kidney transplant process at the Warren Magnuson Clinical Center at the National Institutes of Health and at Walter Reed Army Medical Center. Seven dimensions contributing to trust were identified in the literature: competence, compassion, vaccine safety, dosage, control, communication and confidentiality which did enhance participation.

Table 4.16: Do parents believe you are the best

Parents believe you are the best	Frequency	Percent
Yes	13	86.67
No	2	13.33
Total	**15**	**100**

Table 4.16 shows that majority of CDC staffs (86.67%) believed that they were the best.

The result agrees with Rosen *et al*. 2007, in a pilot study that was conducted that explored the perceptions of trust among patients in the kidney transplant process at the Warren Magnuson Clinical Center at the National Institutes of Health and at Walter Reed Army Medical Center. Seven dimensions contributing to trust were identified in the literature: competence, vaccine safety, dosage, compassion, control, communication and confidentiality which did enhance participation.

4.7.2: Whether parents are convinced if the vaccines are safe

To answer this question, CDC staff were asked to indicate their opinion on whether parents were convinced that the vaccines were safe or not and the results were as shown in table 4.17.

Table 4.17: Response on vaccine safety

Opinion	Frequency	Percent
Yes	6	40.00
No	9	60.00
Total	**15**	**100**

Table 4.17 shows that majority of CDC staff 9 (60%) believed that the parents are not convinced that the vaccines are safe for their children.

The result did agree with Rosen *et al*. 2007, in a pilot study that was conducted that explored the perceptions of trust among patients in the kidney transplant process at

the Warren Magnuson Clinical Center at the National Institutes of Health and at Walter Reed Army Medical Center. Seven dimensions contributing to trust were identified in the literature: competence, vaccine safety, dosage, compassion, control, communication and confidentiality which did enhance participation.

4.8 The community's trust on CDC staff with their children

This section seeks to present the community's trust on CDC staffs with their children and their participation in CDC clinical trials.

4.8.1 The influence of community's trust to CDC staffs with their children

To answer this question, respondents were asked to indicate their stand on trust to CDC staff with their children and the result was cross tabulated as shown in table 4.18.

Table 4.18: Whether the respondents trust CDC staff with their children and community's participation in CDC clinical trials

Trust	**YES**		**NO**	
	Frequency	**Percent**	**Frequency**	**Percent**
Yes	248	99.20	2	66.67
No	2	0.80	1	33.33
Total	**250**	**100**	**3**	**100**

Table 4.18 shows that majority of participants (99.20%) who participated in the trials trusted CDC staff with their children.

The statistics agrees with Schneider *et al*. (2004), in a study conducted in America about patients trust to health care providers, they concluded that patients' trust in their provider may predict willingness to participate in clinical trial.

4.8.2 The influence of the respondents' opinion on whether the dosage procedure is recommendable and its influence on participation of CDC's clinical trials

To answer this question, the respondents' opinion on whether the dosage procedure is recommendable was sought and the result was as shown in table 4.19.

Table 4.19: The response on whether the dosage procedure is recommendable

whether the dosage procedure is recommendable	Frequency	Percent
Yes	235	92.89
No	18	7.11
Total	**253**	**100**

Table 4.19 shows that majority of participants (92.89%) agreed that the dosage procedure was recommendable.

The result did agree with Rosen *et al*. 2007, in a pilot study that was conducted that explored the perceptions of trust among patients in the kidney transplant process at the Warren Magnuson Clinical Center at the National Institutes of Health and at Walter Reed Army Medical Center. Seven dimensions contributing to trust were identified in the literature: competence, vaccine safety, dosage, compassion, control, communication and confidentiality which did enhance participation.

4.8.3 The respondents' opinion on whether their child is normally given the right dose and its influence on participation of CDC's clinical trials

This section presents the respondents opinion on whether their child is given the right dose and the result is as shown in table 4.20.

Table 4.20: The respondents' opinion on whether their children are given the right dose

Child given the right dose	Frequency	Percent
Yes	220	87.65
No	31	12.35
Total	**251**	**100**

Table 4.20 shows that most of the respondents 220 (87.65%) believe that their children are given the right dose as opposed to 31 (12.35%) who do not believe that their children are given the right dose.

The result did agree with Rosen *et al*. 2007, in a pilot study that was conducted that explored the perceptions of trust among patients in the kidney transplant process at the Warren Magnuson Clinical Center at the National Institutes of Health and at Walter Reed Army Medical Center. Seven dimensions contributing to trust were identified in the literature: competence, vaccine safety, dosage, compassion, control, communication and confidentiality which did enhance participation.

4.8.4 The influence of the respondents' opinion on whether their children suffer any side effects and its influence on participation of CDC's clinical trials

This section presents the respondents opinion on whether their child suffer side effects and the result is as shown in table 4.21.

Table 4.21: The respondents' opinion on whether their children suffer side effects

Child suffer side effects	Frequency	Percent
Yes	94	37.60
No	156	62.40
Total	**250**	**100**

Table 4.21 shows that 62.40% of participants had their children suffer from no side effects as quite a good number 37.40% were for the opinion that their children did suffer from side effects. This normally happens when children become sick immediately they receive the vaccine.

The result agrees with Liau *et al*. (1998), who found out that perceived stigma or negative social consequences, side effects after vaccination associated with being a participant in clinical trial especially HIV-related research may be a significant barrier to participation in such researches.

4.8.5 Whether the respondents had tried to pull their child out of a study and its influence on participation of CDC's clinical trials

This section presents the respondents opinion on whether they tried to pull their children from the study or not, result is as shown in table 4.22.

Table 4.22: Opinion on whether respondents' tried to pull their children from the study

Tried to pull their child from the study	Frequency	Percent
Yes	32	12.75
No	219	87.25
Total	**251**	**100**

Table 4.22 shows that most 219 (87.25%) of the respondents have not tried to pull their children out of the studies while only 32 (12.75%) have tried to pull their children out of the clinical trials.

The statistics agrees with a study conducted by Brandon *et al*. (2009), on Tuskegee Study of Untreated Syphilis done on prisoners in America, as it was not true that "approximately two-fifths of both black and white participants" indicated that they had heard of the Tuskegee Study of Untreated Syphilis (TSUS), but it was 25% and 74%,

respectively—results markedly different than what others have reported. It was true that there was little difference between these black and white respondents in detailed knowledge about TSUS—most answered incorrectly the author-selected questions. The authors exaggerated that "nearly twice as many black respondents believed that Tuskegee study research investigators infected the study participants with syphilis" (75.3% vs. 52.8%) this did lead to participants' intention to withdraw from the study.

4.8.6: Whether parents have ever complained about stigmatization

The staff's opinion on whether the participants have ever complained to them about stigmatization was asked and the result is as shown in table 4.23.

Table 4.23: Stigmatization complain response

Stigmatization	Frequency	Percent
Yes	9	60.00
No	6	40.00
Total	**15**	**100**

Table 4.23 shows that many staff reported that 9 (60%) of the parents have ever complained to them about stigmatization while 6 (40%) of the parents have never complained about stigmatization. This might have been associated with the fact that the community mistakes those in CDC trials or studies to be having HIV/AIDS.

The statistics agrees with Fortenberry *et al*. (2002), in two studies on adolescents' willingness to receive a hypothetical HIV vaccine, those perceiving oneself to not belong to a traditionally identified risk group, when simply being associated with such groups can be stigmatizing, were less willing to accept HIV vaccination.

CHAPTER FIVE

SUMMARY OF FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter discusses in detail summary of the findings, conclusions, recommendations, recommendations for further studies and contribution to the body of knowledge.

5.2 Summary of Findings

The objectives of this study were to determine the level at which demographic characteristics of the community influence their participation in CDC clinical trials, to investigate the extent at which socio-economic status influence community's participation in CDC clinical trials, to explore how patient's trust in health care provider influence community's participation in CDC clinical trials, to examine the extent at which information can influence community's participation in CDC clinical trials and to explore how community's perception influence their participation CDC clinical trials in Karemo Division, Western Kenya.

The first objective was to determine the level at which demographic characteristics of the community influence their participation in CDC clinical trials. This study reveals that majority of the respondents (parents) who were 59.76 % of those have participated in the trials, were females in the age bracket of 20-29 years with the highest education level achieved being at the primary level for they are the ones that normally takes their children to the clinic.

The second objective was to investigate the extent at which socio-economic status influence community's participation in CDC clinical trials. The study findings

did show that majority of participants were married Protestants (75.77%) and their main source of income was peasant farming (51.54%) followed by small scale business.

The third objective was to explore how patient's trust in health care provider influence community's participation in CDC clinical trials. It was found out that majority of the parents (99.2% of the respondents) who did participate in the trials trusted CDC staffs with their children.

The second last objective was to examine the extent at which information can influence community's participation in CDC clinical trials. The study discovered that majority of the participants heard about CDC clinical trials from the health care workers. While majority of CDC staffs believed that the participants heard about CDC clinical trials from the chiefs' barazas. On the part of the parents (66.53%), the information had large influence on their participation in the trials. Whereas on the other side, 53.33% of CDC staffs believed that information had moderate influence on parents' participation in clinical trials.

The last objective was to explore the perception as an influence on community's participation in CDC clinical trials. It was discovered that majority of the parents (respondents) that is 99.20% believed that CDC staffs were qualified to conduct clinical trials.

5.3 Conclusions

In relation to the first objective, which was to determine the level at which demographic characteristics of the community influence their participation in Centers for Diseases Control and Prevention in CDC clinical trials, it was concluded that in terms of age majority of respondents were mature therefore they do easily understand the trials. In terms of gender many participants are always female for they are the ones who normally accompany their children to the clinics. On educational level, majority of participants are always primary and secondary school leavers as those from colleges and universities participate the least.

Concerning the second objective which was to investigate the extent at which socio-economic status influence community's participation in Centers for Diseases Control and Prevention in clinical trials, it was concluded that religion wise, majority of participants are protestants. Majorities are married and their main source of income is peasant farming.

The third objective was to explore how patient's trust in health care provider influence community's participation in Centers for Diseases Control and Prevention clinical trials it was concluded that community's trust on the health care providers with their children influence their participation in the trials.

Fourth objective was to examine the extent at which information can influence community participation in Centers for Diseases Control and Prevention clinical trials it was concluded that information to the community do have large influence on their participation which did depend on the source.

Concerning the fifth objective which was to explore perception as an influence on community's participation in Centers for Diseases Control and Prevention clinical trials it was concluded that community's perception in terms of qualification of the staffs, vaccine safety and dosage procedure do influence participation in CDC clinical trials.

5.4 Recommendations

Having looked at the theoretical framework, the conceptual framework alongside the literature review and the study findings, the following recommendations are made. First, information to the community has major in influence on participation, it is only that the middle class and the rich do not get this information for they tend to be busy with their income activities, therefore do not have time to attend the barazas. Therefore CDC should employ door to door mobilization alongside the chiefs' barazas and the community health workers. Secondly, more emphasis need to put on health education in partnership with the ministry of health to religions such as legio maria that do not believe in taking their children to the hospital. Finally I recommend that the community need to be enlightened more on the importance of participation in any given research by both the Government and the concerned Non Governmental Organizations.

5.4.1 Suggestions for further studies

This study did not explore certain areas that were equally important. Such areas were left out because the scope and limitation of this study warranted and also due to a limitation in time and other resources. In view of this the study recommends the following areas for further research. There is need for a comparative study to look at

determinants of community's participation in CDC epidemiological studies, community's participation in International Emerging Infectious diseases.

5.5 Contribution to the body of knowledge

Objective	**Knowledge**
Determine level at which demographic characteristics of the community influence their participation CDC clinical trials.	- In terms of age, gender and level of education, it was found out that majority of participants are females who are of mature age. The highest level of education was primary and secondary level.
Investigate the extent at which socio-economic status influences community's participation.	-It was discovered that majority of participants were married protestants and their main source of income was peasant farming.
Explore how patient's trust in health care provider influences participation.	-Participant's trust in health care provider especially with their children was a major contribution to participation.
Examine the extent at which information can influence community's participation.	-Information has a large influence on community's participation.
Explore perception as an influence on community's participation.	- Opinion on qualification of the health care provider influences participation.

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APPENDIX I : LETTER OF TRANSMITALL

UNIVERSITY OF NAIROBI

P.O BOX 30197-00100

NAIROBI, KENYA

10TH APRIL 2011

TO,

MR/MRS/MISS……

Dear sir/madam,

RE : DETERMINANTS OF COMMUNITY'S PARTICIPATION IN CDC'S CLINICAL TRIALS IN KAREMO DIVISION, WESTERN KENYA

I am a student at the University of Nairobi pursuing a Masters of Arts Degree in Project Planning and Management. Currently I am carrying out the above study in your Division as part of the requirements for the fulfillment of Masters of Arts Degree.

The purpose of this letter is to kindly request you to participate in the study by completing the attached questionaires. All the information collected will be treated as strictly confidential as your cooperation and support in this study will be highly appreciated.

Yours faithfully'

V.O.O

Vincent Otieno Obiero

APPENDIX II : QUESTIONNAIRE FOR THE HOUSEHOLDS

Determinants Of Community's Participation in CDC Clinical Trials. The case of Karemo Division, Western Kenya.

Instructions:

1. Do not write your name on this form. It is an anonymous survey

2. Read through all the options before you make a choice.

3. Tick in the box ( ) the answer you think is correct or is your point of view.

4. Other questions might have more than one answer circle all that are of your choice.

SECTION A: DEMOGRAPHIC CHARACTERISTICS QUESTIONS

1. How old are you?

19 years and below ( )

20-29 years ( )

30-39 years ( )

40-49 years ( )

50 years and above ( )

2. What is your gender? Male ( ) Female ( )

3. What is your level of education?

None ( )

Primary ( )

Secondary ( )

Tertiary ( )

University ( )

4. Has your child ever participated in any CDC clinical trial? Yes ( ) No ( )

5. If yes, how many times?

Once ( )

Twice ( )

Thrice ( )

6. If no why?

Never wanted ( )
Never had chance ( )

7. If never wanted why?

Never wanted to be used as guinea pig ( )

Against tradition and culture ( )

Rumors ( )

Stigmatization ( )

SECTION B: SOCIO- ECONOMIC STATUS

8. What is your marital status?

Single ( )

Married ( )

Widowed ( )

Divorced ( )

9. Which is your religion?

Catholic ( )

Protestant ( )

Legio Maria ( )

Muslim ( )

10. What do you do for a living?

Peasant farmer ( )

Large scale farmer ( )

Employed ( )

Small-scale Business ( )

Large-scale Business ( )

Other (Please Specify):_____

SECTION C: INFORMATION ABOUT CDC CLINICAL (VACCINE) TRIALS

11. Have you heard of CDC clinical trials? Yes ( ) No ( )

12. If yes, where did you hear about CDC Clinical trials? *(Please tick all that apply.)*

At a chief's baraza in the village ( )

Radio ( )

Posters, brochures, fliers ( )

Newspapers and magazines ( )

TV ( )

Health workers ( )

Family ( )

Friends, peers ( )

Religious leaders ( )

Teachers ( )

Other (please explain): _____

13. To what extent did the information influence you to allow your child to participate in clinical trials? If the answer is N/A do not answer questions in section D.

Large ( )

Moderate ( )

Low ( )

No extent ( )

N/A ( )

SECTION D: PATIENT/PARTICIPANT'S TRUST IN HEALTH CARE

PROVIDER/CDC STAFF

14.To your own opinion, do you think staffs handling your children are qualified to conduct clinical trials? Yes ( ) No ( )

15.Do you trust them with your child? Yes ( ) No ( )

16. Do you think the procedure used during dosage is recommendable? Yes ( ) No ( )

17.Do you think the child is normally given the right dose? Yes ( ) No ( )

18. Did your child suffer from any side effect? Yes ( ) No ( )

19. Is there a time you tried to pull your child from the study? Yes ( ) No ( )

APPENDIX III: QUESTIONNAIRE FOR CDC STAFF

Determinants Of Community's Participation in CDC Clinical Trials. The case of Karemo Division, Western Kenya.

Instructions:

1. Do not write your name on this form. It is an anonymous survey

2. Read through all the options before you make a choice

3. Tick the box ( ) that has the answer you think is correct or is your point of view.

4. Other questions might have more than one answer circle all that are of your choice.

SECTION A: DEMOGRAPHIC CHARACTERISTICS QUESTIONS

1. How old are you?

18-25 years ( )

25-30 years ( )

30years and above ( )

2. What is your gender? Male ( ) Female ( )

3. What is your level of education?

Secondary ( )

Tertiary ( )

University ( )

4. What is your current position in the organization?

Community Interviewer ( )

Nurse ( )

Clinician ( )

Supervisor ( )

Study Coordinator ( )

5. Do you have any training in clinical trials? Yes ( ) No ( )

SECTION B: INFORMATION ABOUT CDC CLINICAL (VACCINE) TRIALS

6. Do you think the community is aware of CDC clinical trials? Yes ( ) No ( )

7. If yes, where do you think they hear about Clinical trials? *(Please tick all that apply.)*

At chief's baraza in the village ( )

Radio ( )

Posters, brochures, fliers ( )

Newspapers and magazines ( )

TV ( )

Health workers/ CDC staffs ( )

Family ( )

Friends, peers ( )

Religious leaders ( )

Teachers ( )

Other (please explain): _____

8. To what extent do you think the information influence parents to allow their children to participate in clinical trials?

Large ( )

Moderate ( )

Low ( )

No extent ( )

SECTION C

9. Based on the above answers, kindly rate the CDC clinical trials Community entry by using the following ranking (Excellent-1, Good-2, Average-3 and Poor -4)

Function	Excellent	Good	Average	Poor	Don't know
Introducing the study to the community					
Defaulter tracing					
Community mobilization					
Health promotion/education					
Other (specify):					

SECTION D: PATIENT/PARTICIPANT'S TRUST IN HEALTH CARE PROVIDER/CDC STAFF

10. Do you think the parents believe that you are the best? Yes ( ) No ( )

11.Do you think that the parents are always convinced that the vaccines are effective? Yes ( ) No ( )

12.To what level do you think parents' culture and tradition influence participation of their of their children in a study?

Large ( )

Moderate ( )

Low ( )

No extent ( )

13. Have a parent ever complained to you of stigmatization? Yes ( ) No ( )

APPENDIX IV: Sample selection table Source: Cochran, 1963

Sample size table for ±5%, ±7% and ±10% Precision Levels Where Confidence Level is 95% and P=.5.			
Size of	Sample Size (n) for Precision (e) of:		
Population	±5%	±7%	±10%
500	122	145	83
600	240	152	86
700	255	158	88
800	267	163	89
900	277	166	90
1000	286	169	91
2000	333	185	95
3000	353	191	97
4000	**364**	**194**	**98**
5000	370	196	98
6000	375	197	98
7000	378	198	99
8000	381	199	99

APPENDIX V: / PARTICIPANT ASSENT/CONSENT INFORMATION

Participant Information and Assent/consent Form

The following information will tell you about the study and your part in it. Please listen

Carefully and pay much attention. Feel free to ask any questions.

Voluntary Participation

You may choose to not be in this study. You can leave the study at any time. You will not get into any trouble or lose any benefits. We will need permission from you and before you can take part in this study.

Background

In any society, there are problems that need to be addressed so that the community can have a solution to their problems. Some of these problems can be solved amicably with the help of research in any community which will be able to find the root cause and offer solutions based on the findings. Again the Government can conduct a research in any given part of the country or use any research institution's findings to offer any help to the affected population. It is through this that any Institution or nation can budget for its people without management by crisis.

Reason for the Study

We are doing a study to find out how factors like community's demographic characteristics (age, sex, race/tribe, and education), socio-economic status, information and participant/patient's trust in health care provider can influence community's participation in CDC clinical trials.

Procedures to be followed

If you agree to take part in this study, you will get a list of questions about determinants of community's participation to answer. Remember that this is NOT a test or examination.

Study Eligibility

All randomly selected residents of Karemo Division community members that have participated are participating or have not participated in any CDC clinical trials. This shall involve parents who have their kids or have had their kids in any clinical trial.

Risks and Benefits to You

There will be no risks or benefits from participating in this study.

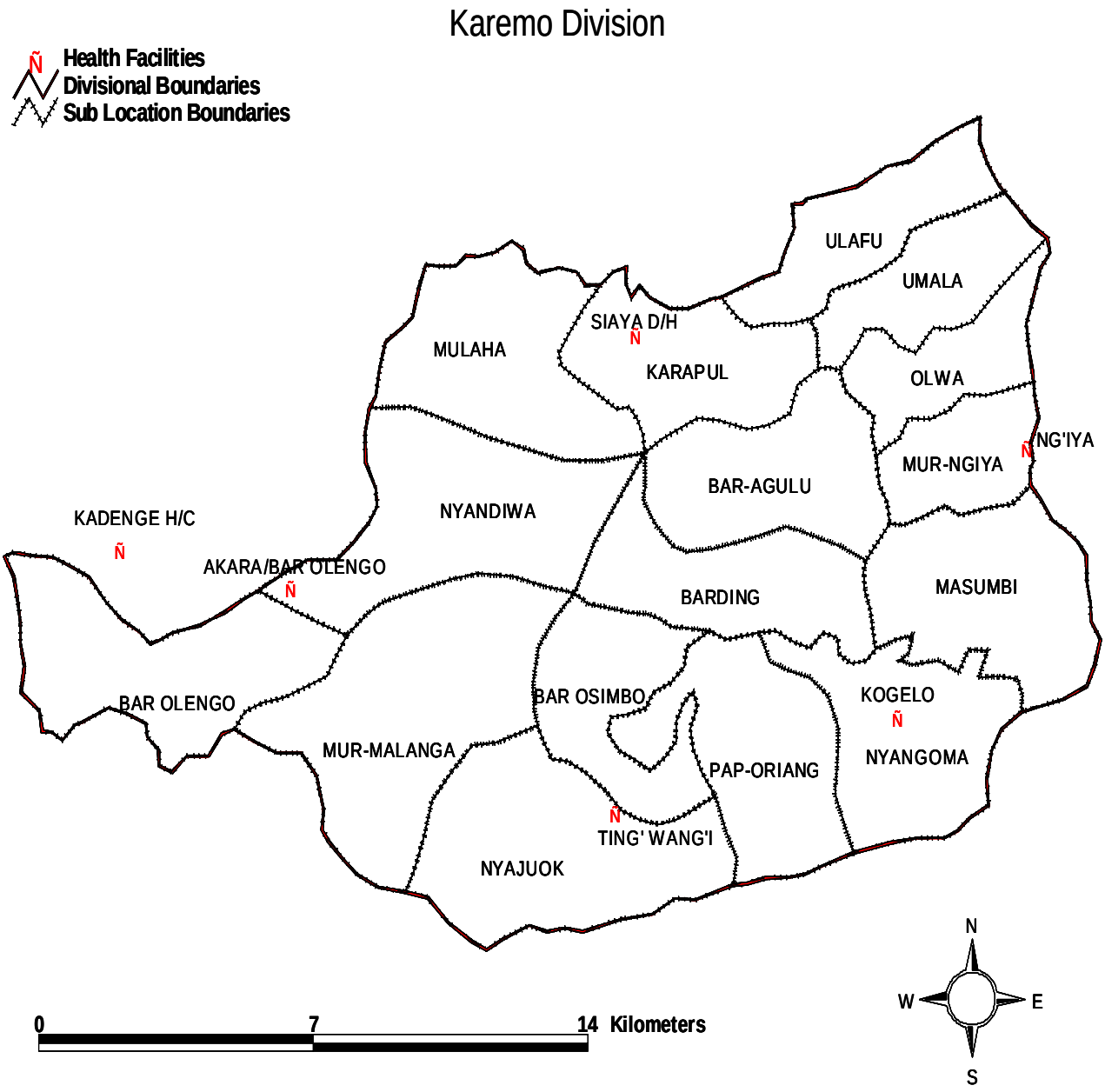
Compensation

No money will be paid for taking part in this study.

Privacy

We will keep all records strictly private. Nobody but the researchers in this study will see your records and your name will not be in any publication written from this study.

APPENDIX VI: MAP OF KAREMO DIVISION



APPENDIX VII: RESEARCH AUTHORIZATION

REPUBLIC OF KENYA

NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

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

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

Our Ref: **NCST/RRI/12/1/SS-011/977/4**

Date: **20th July, 2011**

Vincent Otieno Obiero
University of Nairobi
P. O. Box 30197 - 00100
NAIROBI

RE: RESEARCH AUTHORIZATION

Following your application for authority to carry out research on **"Determinants of community's participation in centre for diseases control and prevention's clinical trials in Karemo Division, Kenya"** I am pleased to inform you that you have been authorized to undertake research **in Siaya District** for a period ending ***31st August 2011.***

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

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

DR. M. K. RUGUTT, Ph.D, HSC
DEPUTY COUNCIL SECRETARY

Copy to:

The District Commissioner
Siaya District

The District Education Officer
Siaya District

APPENDIX VIII: RESEARCH CLEARANCE PERMIT

PAGE 2

THIS IS TO CERTIFY THAT:

Prof./Dr./Mr./Mrs./Miss. VINCENT OTIENO OBIERO

of (Address) UNIVERSITY OF NAIROBI P.O BOX 30197,NAIROBI

has been permitted to conduct research in .....

.....Location,

SIAYA .....District,

NYANZA .....Province,

on the topic. DETERMINANTS OF COMMUNITY PARTICIPATION IN CENTRE FOR DISEASES CONTROL AND PREVENTIONs CLINICAL TRIALS IN KAREMO DIVISION, KENYA

for a period ending 31st AUGUST 20 11

1. You must report to the District Commissioner and the District Education Officer of the area before embarking on your research. Failure to do that may lead to the cancellation of your permit
2. Government Officers will not be interviewed with-out prior appointment.
3. No questionnaire will be used unless it has been approved.
4. Excavation, filming and collection of biological specimens are subject to further permission from the relevant Government Ministries.
5. You are required to submit at least two(2)/four(4) bound copies of your final report for Kenyans and non-Kenyans respectively.
6. The Government of Kenya reserves the right to modify the conditions of this permit including its cancellation without notice

GPK6055t3mt10/2011

PAGE 3

NCST/RRI/12/1/SSo11/977

Research Permit No.....

Date of issue 20th JULY 2011

Fee received KSHS1000

Applicant's Signature

Secretary National Council for Science and Technology

REPUBLIC OF KENYA

RESEARCH CLEARANCE PERMIT

(CONDITIONS—see back page)