FACTORS INFLUENCING THE CHOICE OF CLINICAL RESEARCH DESIGN AMONG UNIVERSITY STUDENTS: THE CASE OF UNIVERSITY OF NAIROBI, KENYA.

BY

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A RESEARCH PROJECT SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF ARTS IN PROJECT PLANNING AND MANAGEMENT OF THE UNIVERSITY OF NAIROBI

2014

DECLARATION

I declare that this project is my original work and has not been presented for any award in any university.

Sign _____ Date _____

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This research project has been submitted with my approval as the University supervisor.

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DEDICATION

I dedicate this work to my wife Glenah Moraa, my daughter Gwen Nyatuga, my parents Benson Onchiri and Askah Mogotu for their emotional support.

ACKNOWLEDGEMENT

I would like to express my sincere appreciation to my supervisor Prof. Christopher Gakuu. I owe him much for his constant guidance and patience. Also to my lecturers who gave me the knowledge which form the basis of my passion to aim for higher targets in my academics. Thanks to the University of Nairobi for according me the opportunity to pursue my dream.

My fellow classmates have been my greatest challenge given their positive competitiveness. I also wish to acknowledge my wife, daughter, parents and family at large for the moral support they have always granted me. Thanks to Chris my statistician for your kind assistance.

All references have been clearly acknowledged at the end of this write-up. To God, through whom all things are possible, thank you.

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ABBREVIATIONS AND ACRONYMS

AHCs -Academic Health Centers

CI -Confidence Interval

IMPACT -Increase minority participation and awareness of clinical trials

KNH -Kenyatta National Hospital

MMED -Masters of Medicine

MPH -Masters in Public Health

MSCN -Master of Science in Nursing

NIH -National Institute of Health

OR-Odds Ratio

SPSS-Statistical package for social science

UON -University of Nairobi

ABSTRACT

Conducting research in all study designs is important in clinical research. The purpose of the study was to assess the various factors that influence the choice of study designs by postgraduate students of the University of Nairobi. The study assessed how the level of knowledge, availability of resources, students' attitudes and students' mentorship influenced the choice of type of study design.

The study was a cross-sectional survey. Data was collected using self-administered questionnaires administered to 136 post-graduate students in the college of health science. Data was presented using tables, and narratives. Data analysis was done by descriptive, chi-square test and multivariate analysis.

66.2% of the students chose cross-sectional study design. The mean period of training was 8 months with a SD of 3.98. Both length of training and cost of study had an association with choice of design at p= 0.000. The preference of Cross-sectional design was 55.5%. Mentorship influenced 66.3% of respondents in choosing their study design. The choice of cross-sectional design was associated with training that covered all steps of conducting cross-sectional survey and the feeling that one could afford it (p= 0.029 and p=0.001 respectively).

There is need for sufficient training in all study clinical research designs and improved research infrastructure. Hence all stakeholders ought to take appropriate steps to ensure that enough opportunities are created for the choice of all research designs.

CHAPTER ONE
INTRODUCTION

1.1 Background of the study.

There has been limited research on the trends of choice of study designs in clinical research and factors influencing the choices. Gordon, Heft, Dionne, Jeffcott, Alfano, Valachovic and Lipton (2003) outlines objectives of clinical research to include discovery of new knowledge, integrate scientific principles into clinical practice, explore research as a career choice and develop personnel for academic positions in teaching, research and industry.

According to Jeffrey, Timothy and David (2002), when a student is considering a career as a physician-scientist, they must weigh their interest in research against three factors: accumulated debt, a long period of training, and the uncertainty of success.

In a study done in Pakistan on medical students, students' knowledge and attitude towards health research significantly improved with increasing years of education at medical school. This signifies a relatively satisfactory contribution of medical curriculum in developing research skills among medical students through well-structured intensive training. The students were taught theoretical essentials of research methodology, statistics and epidemiology during the first two years of their medical curriculum, followed by extensive community health projects undertaken by groups of students during year 4 and 5. During these projects, students are involved in designing and implementing their research questions, analyzing their data and writing a detailed report of their project (Khan, Khawaja, Waheed, Rauf & Fatmi 2006).

There is need for more involvement in clinical research by third world health care providers despite notable challenges experienced. George, Victoria, Elizabeth and John (2005) states that developing countries need to perform research, particularly on conditions and settings specific to their context, in order to maximize their yield from scarce health-care resources. They however need support to conduct this research and to develop local research capacity. Increased research capacity in developing countries is believed to have beneficial consequences for developed nations, for example in preventing the global spread of infectious agents.

Evidence shows that minority patients are underrepresented in clinical trials globally (Getz & Faden 2008). He further concludes that the development of new drugs and

treatments requires that clinical research studies include representative participants, particularly in light of evidence indicating that minority populations sometimes respond differently to prescription medications. Racial disparities among clinical investigators are often cited as a major reason why minority patients are under-represented in clinical trials. However, there is little to no empirical data to support or refute the prevalence of disparities among clinical investigators.

In addition to the study results indicating that significant racial disparities exist among clinical investigators, Getz and Faden (2008) study results support assertions that physician race influences race of the clinical trial volunteer. The incidence of participation in clinical research among minority physicians is well below that observed among white physicians, more so with regard to U.S. Food & Drug Administration-regulated clinical trials funded by industry. Minority investigators tend to conduct and initiate fewer clinical trials annually and yet minority and white physician interest in participating in clinical research is similarly high. Lastly, minority investigators tend be younger, with more limited clinical research infrastructure and support than their white counterparts.

There is need for the practitioners to get involved in research more than it is currently. This is because; translational research is taking the findings from bench research and clinical trials and studying the safety, efficacy, feasibility, and acceptability of implementing those findings in community-based clinical practice. Family physicians are a natural fit for such clinical translational research. To maintain the vibrancy of family medicine research, there is a need for family physicians to become translational scientists involved in and seeking funding for translational research (Niharika, Laquandra, Mary and Carol 2009).

A study in South Africa concluded that there was currently national plan to provide coordinated support for the training and development of clinical researchers, and grossly insufficient support for research professorships and training fellowships in the clinical research field (Bongani, Amaboo, Peter, Wieland, Gregory, Maureen & Jimmy 2009).There was little incentive for clinicians to train in doctoral programs, resulting in a very small number of the clinical professoriate having doctoral degrees.

The University of Nairobi College of health science offers undergraduate and postgraduate courses in medicine, nursing, pharmacy and dental sciences. These

students progress to pursue various careers on completion of the undergraduate courses. By the time they make a choice on postgraduate studies they already have enough information on available opportunities. The vision, mission and core values of the University demonstrate the importance placed upon research activities within the University.

Kenyatta National Hospital (KNH) was established in 1901 with a bed capacity of 40, now having grown to a bed capacity of 1800. It has 50 wards, 22 outpatient clinics, 22 theatres (16 specialized) and accident and emergency department. Within the KNH complex are the College of Health Sciences (University of Nairobi); Kenya Medical Training College); Kenya Medical Research Institute and National laboratory service (Ministry of Health).

The vision of Kenyatta National Hospital is to be a world class referral hospital in the provision of innovative and specialized healthcare. Its mission is to provide accessible specialized quality healthcare, facilitate medical training, research, and participate in national health planning and policy.

There is a need to look for the solution to encouraging more participation in clinical research by practitioners from all parts of the world regardless of the underlying challenges. Getz & Faden (2008) recommended that new strategies, policies, incentives, and reforms are needed to address racial disparities among clinical investigators. The collaboration between the University of Nairobi and Kenyatta National Hospital provides an ideal environment for the conduct of numerous and high quality clinical research of all designs especially clinical trials by new and experienced researchers. According to Bongani et al (2009) Clinical research in a developing country contributes to health care at all levels by identifying the causes of problems, facilitating diagnosis, improving the efficiency and effectiveness of care, and promoting good policy-making. It also supports the training of competent health professionals of all kinds, and contributes to global knowledge about locally, as well as generally, prevalent diseases in terms of prevention and treatment.

1.2. Statement of the problem

According to Wallen. R. G, Mitchell. A.S, Melnyk. B, Fineout-Overholt. E, Miller-Davis. C, Yates .J and Hastings . C (2010) evidence-based practice is associated with higher quality care and better patient outcomes than care that is steeped in tradition. However, the integration of evidence-based practice implementation into daily

clinical practice remains inconsistent, and the chasm between research and bedside practice remains substantial.

There is a rising demand for evidence based practice in the healthcare sector due to the dynamism in the disease occurrence, diagnostics and treatment regimens in our country, continent and the world at large. This is especially important given that much of what is practiced in Africa is a product of research findings conducted by foreigners either in or outside the continent. Few principal investigators for clinical trials are based in African countries, although it is possible that a proportion of principal investigators were of African origin and working abroad. Publication of trial results continues to be driven by researchers external to the continent. It was difficult to predict how this impact on African collaborating researchers but transfer of skills and knowledge to local researchers must remain a fundamental aim of any trial conducted in Africa (Nandi, Mike, & Jimmy 2005). Most drugs, vaccines, medical devices, and procedures have not been extensively studied in our setting despite the fact that they are in use.

According to Jeffrey et al (2002), physician-scientists perform three kinds of research: basic, disease-oriented, and patient-oriented. A great deal of attention has been paid to the shortage of physician-scientists who perform patient-oriented research.

A manual library assessment of previous studies for most (approximately 97%) students pursuing post graduate studies in the University of Nairobi in the various fields of health research conduct observational research designs. John et al (2000) found out that in randomized and observational studies in health-services research, treatment effects may differ according to research design, but that one method does not give a consistently greater effect than the other.

The study therefore seeks to assess the factors that influence the choice of clinical research design for postgraduate students in the University of Nairobi.

1.3 Purpose of the study

The purpose of this study is to assess the factors that influence the choice of clinical research designs so as to make appropriate recommendations for enhancing all studies.

1.4. Objectives of the study

The study will be guided by the following objectives:

1. To assess how level of knowledge influences the choice of clinical research design among the students of the university of Nairobi
2. To establish how the availability of resources influences the choice of clinical research design among students of the University of Nairobi
3. To assess how students' attitude influences the choice of clinical research design among students of the University of Nairobi
4. To assess how students' mentorship influences the choice of clinical research design among students of the University of Nairobi

1.5. Research questions

The study intends to answer the following questions:

1. How does the level of knowledge influence the choice of clinical research design among the students of the University of Nairobi?
2. To what extent does the availability of resources influences the choice of clinical research design among students of the Nairobi University?
3. How does attitude influence the choice of clinical research design among students of the University of Nairobi?
4. How does mentorship influence the choice of clinical research design among students of the University of Nairobi?

1.6. Hypotheses

Ho1 –Cost of research study does not influence the choice of research study design

Ho2 – Prior training in clinical research does not influence the choice of clinical research design

Ho3 –Mentorship does not influence the choice of clinical research design

1.7. Significance of the study

The study is important in assessing the factors that influence the choice of clinical research design by University of Nairobi post-graduate students. This is because of the rising need for evidence based practice of patient care activities (diagnosis, treatment, drug development) given the global disease burden. Hopefully this will be achieved through sufficient provision of requirements for students and researchers to engage in all types of clinical research designs. This will help in decision making while reviewing curricula and designing career development programs such as mentorship for the students in trying to achieve global standards both in academics and health care practice. This is for the benefit of the government, University of Nairobi, Kenyatta National Hospital, all the students, the patients and the whole society. It is also beneficial to pharmaceutical companies and interested institutions to identify opportunities for funding to conduct clinical research for drugs, vaccines and medical devices.

1.8 Delimitation of the study

The study was conducted in the University of Nairobi post-graduate students doing their final year in the college of health science. The University has a long history in training and possesses a lot of research information. These are students registered for postgraduate courses in medicine, nursing, pharmacy and dental sciences. The choice is mainly because these students are involved in clinical research and have already decided on their study designs.

1.9 Limitations of the Study

Health related research is conducted by a multidisciplinary team who come from different fields. Given that the study will only be done in the college of health science it leaves out other disciplines. The study will not be carried out in the various colleges where all these aspiring professionals are undergoing training. These include data managers, study coordinators, social workers and statisticians.

Some respondents requested to go with questionnaires and fill at their own time but on follow-up they never returned, the researcher had to re-recruit other respondents in order to complete the target sample size.

1.10. Assumptions of the study

The following assumptions were made:

That that the study was conducted within the planned time schedule.

That the respondents understood and answered questions correctly and truthfully.

1.11. Definitions of significant terms

Case series-This is a form of reporting involving a detailed investigation of one or more cases of diseases

Case study- This refers to an in-depth analysis of a single individual or group

Clinical research- This is medical research involving human beings in order to understand the mechanism of disease development, treatment and assess outcomes

Clinical trials-These are research studies that attempt to intervene or alter care or treatment of study participants in a healthcare setting in some way and assess its effectiveness

Cohort study-An observational study in which subjects are selected according to exposure status and followed up to determine the incidence of disease

Cross-sectional- This is a study whereby the exposure and disease are measured together at a single point in time

Experimental design- The investigator assigns, chooses, tests intervention, treatment or exposure.

Observational design- The investigator studies people and exposures in nature

Research designs- These involves methodology and procedures or type of study used in scientific research

CHAPTER TWO
LITERATURE REVIEW

2.1 The concept of clinical research design

Clinical research is medical research involving human subjects, including studies to understand the mechanisms of disease, develop treatment algorithms (including clinical trials), and assess outcomes (Mechanic & Dobson, 1996).

According to Grimes (2002), clinical research falls into two general categories: observational and experimental based on whether the investigator assigns exposure or not. Observational studies describe what is happening with no attempt to intervene or change outcomes (Seers & Critelton, 2001). Observational studies can be either analytical or descriptive. Analytical studies feature a comparison (control) group, whereas descriptive studies do not. Within analytical studies, cohort studies track people forward in time from exposure to outcome. By contrast, case-control studies work in reverse, tracing back from outcome to exposure. Cross-sectional studies measures both exposure and outcome at one time point. Descriptive studies, such as case-series reports, do not have a comparison group. Thus, in this type of study, investigators cannot examine associations, a fact often forgotten or ignored (Grimes, 2002).

Experimental studies attempt to intervene or alter care or treatment in some way and assess its effectiveness (Seers et al, 2001). Experimental trials are also referred to as clinical trials and are subdivided into two: randomized and non-randomized. Clinical trials are research studies that test how well new medical approaches work in people. Each study answers scientific questions and tries to find ways to prevent, screen for, diagnose, or treat disease. Research activity of postgraduate medical trainees is important as it promises better clinical care, critical reasoning, lifelong learning and future research activity. With rising health costs, local literature is important for facilitating evidence based and cost-effective decisions and thereby improving clinical practice (Aslam, Qayuum, Mahmud & Qasim, 2004).

2.2 Availability of Resources and students' choice of research design

Niharika et al (2009) noted that the number of family physicians involved in clinical research at academic medical centers was decreasing due to a shrinking pool of

research resources and increasing clinical demands hence reduction in clinical research output.

According to John (2009), the continued decline of the number of physicians involved in research was associated to financial and administrative barriers, although inadequate community-based infrastructure had also contributed significantly to this troubling phenomenon. Therefore, he suggested that novel physician-friendly research models amenable to conducting efficient clinical research were necessary.

Findings by Eriko, Tishinori and Masayuki (2009) indicated that the contention that "doctors in Japan simply didn't want to take part in clinical trials" was a misunderstanding. Indeed, the results indicated that if an adequate trial infrastructure was present, Japanese physicians were eager to conduct clinical research.

A few trials have been conducted on the African continent over the past two decades. It highlights the gulf between the global burden of disease and research on intervention, the so called 10/90 disequilibrium, and confirms previous findings that trials are under-represented in sub-Saharan research. (Nandi et al, 2005).

In another study it was noted that minority investigators tended be younger, with more limited clinical research infrastructure and support than their white counterparts (Getz & Faden, 2008). This limited their involvement in clinical research.

There are various activities that require financial resources in the implementation of clinical research. Payment of study participants dates back to time immemorial. According to Christine (2005) as far back as the 1820s, William Beaumont, whom many consider to be the father of gastric physiology, gave patient Alexis St. Martin — a French Canadian voyageur suffering from an incompletely healed gunshot wound to the stomach — food, lodging, clothing, and $150 for the opportunity to study his stomach contents for 1 year. Additionally in 1900, renowned American military surgeon Walter Reed paid study participants$100 in US gold to allow themselves to be bitten by infected mosquitoes in the famous yellow fever experiments and an additional $100if they consequently contracted the viral disease (1). According to Susan E. Lederer, author of Subjected to science: human experimentation in America before the Second World War (1), in the US, “paying human subjects for their participation in research became routine in the1920s and 1930s.” Other nonmonetary forms of compensation were also common, such as meals, transportation, and burial costs. From the early 1950s, when the world’s largest clinical research complex, the

NIH Clinical Center, opened, documents show that “normal” healthy volunteers were regularly paid for their participation in biomedical research or money was given to the church or group that organized and recruited these volunteers. This payment could in form of incentive, compensation, reimbursement or reward to the study subjects.

Ciaranello, Walensky, Sax, Chang, Freedberg and Weissman (2009) also talks about offer of payment for study participation (worded as payment, compensation, or reimbursement, including offers to compensate subjects for time, transportation costs, or child care costs), and offer of payment for care for trial-related injury. All these are expected costs to be incurred.

Compared to developed countries, the cost of running a trial is significantly cheaper in developing countries. There are many reasons for this, including lower salary and overhead costs and that less time is required to enroll participants (Mbuagbaw Thabane, Ongolo-zogol & Lang 2011).

In a study by Garcia (2010) health care professionals cited time and money as primary barriers to their participation in research training activities, noting that their involvement was dependent on personal initiative and self-financing.

There are several major sources of AMC-based clinical research financing. Direct sources such as federal and industry-sponsored research grants are supplemented by internal cross-subsidies (such as surplus clinical income, tuition, and endowments). In addition, the clinical research enterprise relies on third-party insurance payments to reimburse the cost of standard care provided to patients in research protocols (Mechanic & Dobson, 1996).

There is a limited pool of central funding available for clinical research while hospitals are faced with economic restraint hence provide little infrastructure for clinical research (Ellis, Butow, Simes, Tattersall & Dunn, 1999).

Nandi et al (2005) concluded that most of the clinical trials are funded by government agencies outside Africa, followed by pharmaceutical companies and international non-government and inter-government organizations. This may reflect a lack of economic ability, political will, or research capacity to conduct intervention research in African countries. Commercial funding is a source of potential bias in trials and may influence results. He adds that although we are not aware of any evidence to link non-commercial agency sponsorship to biased results, research funded by such organizations may be driven by priorities different from those of the country where the trial is done.

Nancy, William and Myron, (2003) stated that amongst the reasons responsible for declining physician investigators included the difficulty securing research grants and debts borne by recent graduate.

On the other hand, Niharika et al (2009) suggested that reduced clinical incomes and fragmented research infrastructures were the major barriers for academic family physicians seeking to participate in research.

Academic physicians now spend much more time seeing patients than in the past, to meet their annual income targets. Thus, the time they have for education and research is sharply reduced (Rettig, 2000).

To address the need for more minorities among the ranks of clinical investigators, the NIH fielded the Undergraduate Scholarship Program. In late 2001, the NIH announced its Clinical Research Loan Repayment Program, which repays educational debts of individuals who spend the majority of their time in clinical research (Nancy, 2003).She further noted that while these initiatives represented an impressive commitment to clinical research on the part of the NIH, salary support was still needed for the majority of trainees in the programs. Corporate foundations also made similar efforts to address the lack of clinical investigators, private foundations and voluntary health agencies doubled their investment in clinical research training and career development. Some foundations formed an alliance to jointly address the early career pipeline of pre-differentiated" investigators by sharing best practices, cosponsoring career development resources, and speaking with one voice to the needs of clinical investigators.

In a program aimed at promoting students participation in research, the pre-doctoral education office encouraged students to submit and present their research findings by providing financial support for students to attend meetings at which their papers had been accepted for presentation (Gonzales, Westfall, Gwyn & Barley 1998). In the same program, offering a financial stipend to students to participate in the Family Medicine Scholars Program and the research assistantship program encouraged many students to participate who might not otherwise have done so. By offering a stipend equal to those provided by other research opportunities available to students, the department involved a substantial number of medical students in primary care research.

In order to promote research activities for students research infrastructure needs extensive improvement, and the meager funding for research must be boosted, so that

there will be a healthier research culture in which students can participate (Aslam, Shakir, & Qayyum 2005)

According to Kjell and Arthur (2000) one of the advantages of observational studies over randomized, controlled trials is the lower cost.

According to Nancy et al (2003) clinical research requires the expertise of many kinds of investigators, including Physicians, dentists, public health workers, nurses, psychologists, laboratory technicians, dietitians, computer Programmers, bioengineers, and others. All these professionals are important resources playing specific roles in the clinical research activities. Each study design requires a certain group of professionals to implement. In a trend that paralleled the growing need for clinical study participants, a shortage of adequately trained clinical investigators developed as early as 2005. By then only 8% of principal investigators conducting industry sponsored clinical trials were younger than 40 years, and there was an insufficient crop of new investigators to replace the older generation. Likewise, less than 4% of competing research grants awarded by the National Institutes of Health (NIH)in 2001 were awarded to investigators aged 35 years or younger (Nancy et al, 2003).

In places where clinical trials are well established, there is a multidimensional structure in the clinical research setting including the clinical director, project manager, physician investigator, study coordinator, clinical trials manager, clinical research associate, study nurse, data manager, monitor.

A clinical trials unit should have a designated number of trained clinical research coordinators working collaboratively with data managers and clinical nurses to organize data collection and trial management. Clinical research coordinators typically organize the initiation of a research study; recruit, screen, and enroll clinical study participants. They also maintain drug accountability logs and constantly interact with study patients to ensure the accuracy of case report forms and regulatory documents. A clinical research nurse can also expand his or her influence and resources during the supervision of clinical trials via collaboration with trained medical assistants and data managers. When appropriately supervised, designated data managers and medical assistants can execute the daily responsibilities associated with study protocols. Furthermore, they can frequently and comprehensively discuss a research protocol with the study participants and their family members, elucidating

the significance of the trial and addressing corresponding questions and concerns (Micha, Graham, Rettenmaier, Brown & Goldstein, 2009).

Sue, Adrian, Carl, William, Ian and Robbin (1999) identified lack of support staff, for example clinical trial nurses, as a barrier to participation in randomized clinical trials. A stable research team is likely to be advantageous in conducting trials successfully. One study identified the protocol itself as a barrier to clinician recruitment, where staff lacked the clinical skills to perform both trial treatments

Studies documented by Nancy et al (2003) indicated that a dearth of nurses, including nursing school faculty, despite an increasing demand for their skills. This shortage was partially attributed to stereotypes about the typical nurse, which did not generally include the nurse as a vital member of a clinical research team. Even with increased enrollments, few nurses were encouraged to participate in clinical research. The lacks of nurse role models with research careers, as well as the heavy workload of nurse-researcher mentors, were significant career deterrents A similar workforce problem existed in dental research, where a small cadre of investigators conducted the bulk of clinical dental research. Developing an adequate clinical research workforce remained a challenge across the spectrum of health care professionals. In particular, economists, social scientists, epidemiologists, social workers, nurses, and occupational therapists were often ideally positioned to translate new evidence into clinical practice.

To successfully address the shortage an interdisciplinary array of clinical investigators within research teams is essential (Nancy et al , 2003). This can be achieved through to expansion of educational loan repayment programs and eligibility for clinical investigators; Increasing opportunities for training in all areas of clinical research, including health services and outcomes research, clinical trials, and research synthesis, and develop a mechanism for collecting longitudinal data on training program outcomes; Develop mentor-training systems for senior investigators, assign mentors to junior investigators, and reward effective mentors in clinical research; Develop appropriate criteria with which to quantify excellence in clinical research and apply these criteria in appointments and promotion within AHCs; Ensure that current and future health care providers are adequately educated in applying clinical evidence to clinical practice and decision making.

Involvement of faculty and students can be facilitated by research staffs, which assist in data entry and analysis, coordinate production of posters and/or slides for presentations, and support completion of articles for submission (Gonzales et al

1998). The staffs also provide the continuity necessary to sustain the program by coordinating projects between faculty and students, recruiting both students and faculty, soliciting funding for student stipends and project expenses, and supporting student submissions of presentations and publications (Gonzales et al 1998).

The amount of time is also essential in the choice of study design. Time is the duration in which all things happen or a precise instant that something happens. In this case it denotes the years, months or weeks spent in acquiring the knowledge, skills and experience of the study design and that it takes to conduct clinical research.

The survey data indicate that most of the respondents worked in predominantly office-based solo practices with limited opportunities to develop research capabilities. Such office-based and solo practices are less likely to have the physician time, resources and infrastructure for effective conduct of clinical research. To develop clinical trials capability in this setting would require the commitment of the physician to set aside adequate time for training and attention to the research, identification and training of a research coordinator, and would require the availability of a well-developed patient information system. This represents substantial investment of time and financial resources often without a clear indication of the value or return on the investment for physicians and their patients.

Aslam et al (2005) states that lack of time, neglect of routine studies and deterioration of clinical skills due to more time being spent on research activities are common problems that may cause discontentment in research.

Clinical trials are further categorized into treatment, prevention, diagnostic and screening trials. Treatment trials test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

Prevention trials look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals, or lifestyle changes. Diagnostic trials are conducted to find better tests or procedures for diagnosing a particular disease or condition. Screening trials test the best way to detect certain diseases or health conditions. Quality of life trials (Supportive Care trials) explore ways to improve comfort and the quality of life for individuals with a chronic illness.

According to Koskei, Siyoi, Kokwaro, Jaoko, Aman, Wasunna - - - Akhwale (2011), clinical trials are conducted in phases. The trials at each phase have a different

purpose and help scientists answer different questions: In phase 1 trials, researchers test an experimental drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects. In phase 11 trials, the experimental study drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety. In phase 111 trials, the experimental study drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely. In phase 1V trials, post marketing studies delineate additional information including the drug's risks, benefits, and optimal use. Each of these phases varies in duration.

Nancy et al (2003) states that one of the reasons responsible for declining physician investigators includes the length of clinical training, and uncertainties about promotion in academic health

Centers (AHCs), where basic science studies are often valued more than clinical research. Prospective clinical researchers face 3 to 5 more years of training than their peers—time that could be spent more remuneratively in clinical practice. The advancement structure of AHCs, aligned to reward individual achievement in terms of independent grant support or high-impact publications, works against those who participate in the multidisciplinary research required for successful clinical research in the future (James, Yolanda, Cheryl & Michael, 2008). This makes many young physicians prefer clinical practice rather than engaging in clinical research.

According to Eriko et al (2009) lack of time was reported as a major hurdle in the involvement of physicians in clinical research. Most physicians in university hospitals in Japan were involved in both patient care and research on molecular and cellular biology including experiments with animals. There are few highly skilled clinical researchers in Japan and opportunities to learn the principles and methodology of clinical research are limited for young Japanese physicians.

For Sue et al (1999) in experimental research involving randomized trials, lack of times a major barrier. The time pressures from usual clinical practice and management duties can preclude clinician commitment to randomized controlled trials and the time demands of recruitment, the consent process, and follow-up in trials may be a barrier.

One of the advantages of observational studies over randomized controlled trials is the greater timeliness (Kjell & Arthur 2000).

2.3 The students' Level of Knowledge and students' choice of research design

Aslam et al (2005) suggested that there is only a limited research infrastructure in many developing countries; this means that opportunities for medical student research are limited. Research is not considered apart of the medical curriculum in many of these countries. Thus, students in these countries rarely get exposed to research at this crucial stage in their academic development when such exposure could encourage further research after qualification.

Lack of awareness of clinical trial opportunities remain among the most frequently cited barrier to participation in clinical research especially clinical trials. This finding supports the need for an easily accessible mechanism for learning about the available clinical trial opportunities early during the process of clinical site selection (James et al, 2008).Students and residents in diverse specialties welcome greater curricular attention to topics such as scientific integrity and research ethics. (Laura, Teddy, Laura, Janet, Katherine & Brian, 2007).

Capacity-building in clinical trials is still needed in most developing countries. The creation of clinical trial sites in low resource settings based on national research needs and the availability of competent or potentially trainable staff can improve the research culture and promote centers of excellence from which other local researchers can copy good practices (Mbuagbaw et al, 2011).

One long-term strategy for promoting health research is to target medical students early in their careers. Most of the research to date on the effectiveness of such a strategy has been done in Western settings. This research has shown that research experience as a medical student is strongly associated with postgraduate research involvement (Aslam et al, 2005).

Studies support the claim that if physicians are exposed to laboratory or clinical research experiences during their student days, they are more likely to carry out research activities in their postgraduate careers. (Jay & James, 2001).

Knowledge can only be satisfactory after it has been put into practice hence the need for experience in the conduct of clinical research. Scot, Tom, Peter, Paulla, Robert

&Robert (1990) states that both specialty training and experience are important in determining whether one gets involved in research activities during the postgraduate period. The study however did not support the notion that medical school experience is the key to generating more physician investigators. On the other hand James et al (2008) states that some level of experience is often considered important in the preparation of individuals to serve effectively as principal investigators. In his study most of the participants were not ready to serve in such roles without further training because of lack prior experience.

Aslam et al (2004) states that the major reasons cited for poor research activity in Pakistan were poor research training and poor research awareness. These are different from the western settings where lack of time and lack of interest were more important obstacles to research as compared to poor training. This lack of research exposure and training underscores the need to review both undergraduate and postgraduate curricula so that some specific educational intervention is incorporated (Aslam et al, 2004).

In a study to determine the barriers to participation in randomized clinical trials findings implied that clinicians participating in clinical trials may be ill prepared for a research role because of inadequate research experience and training (Sue et al, 1999). This will determine whether they will take up clinical research as their career path or do it besides clinical practice.

Hebert, Levine, Smith, & Wright (2003) outlined factors necessary for successful research training including exposure to and guidance from mentors, training in basic research methods, protected time, and an environment supportive of research.

In a study done by Eriko et al (2009), it was found out that in trying to improve their involvement in clinical research, most physicians wanted to attend lectures or seminars on one or more topics related to clinical research. The most frequently cited desired lecture topics being statistical analysis, how to write a protocol, paperwork and procedures (production and management of study documents regarding submission to institutional review board and completion of case report form), and cost management in clinical research. Respondents who had submitted research papers for publication were asked to indicate the criticisms of reviewers. Statistical analysis was the most frequent reviewer criticism, followed by selection of patients, aim or meaning of research, and definition of technical terms. In conclusion Eriko et al (2009) stated that physicians in university hospitals needed more administrative assistance and greater knowledge of the principles and techniques of clinical research,

especially the concepts of biostatistics. Additionally the study results highlighted the need for training in clinical research and biostatistics and the necessity for administrative assistance in the production of study documents requested by the institutional Independent Ethics Committee.

James et al (2008) concludes that the future should also include more attention to the inclusion of clinical trial experiences in formal medical education of physicians and greater access to clinical trials information for both physicians and patients. Although it is unclear to what extent Project IMPACT (Increase Minority Participation and Awareness of Clinical Trials) had increased minority participation in clinical trials, the project participants were highly satisfied with their project-related experiences and training. This suggests the idea of including clinical research in the undergraduate curriculum to enhance development of interest by the students. He further proposed that low rates of participation in clinical trials during formal medical education suggested that more attention should be given to enhancing research experiences of medical students, residents and fellows if minority physician involvement in clinical trials is to be increased.

In order to promote participation in clinical research, the project IMPACT came up with a training program. In order to meet project objectives, three education and training units were developed to educate physicians about clinical trials and encourage their participation. These included: A presentation that provided an overview of clinical trials and the clinical trials process; A CME-approved program focused on training physician investigators to participate in clinical research; and CME-approved program emphasizing Good Clinical Practices, cultural competence and skills building for research participation (James et al, 2008).

Follow-up after training is essential to ensure that those with the interest are given adequate support to engage in research activities of their choice. In an effort to facilitate participation in some level of the research process, a physician investigator database was established; follow-up was done to assess the outcome of the project in facilitating participation in clinical research. This was done by examining the post-training experiences of physicians who participated in the Project, identifying barriers to clinical trial participation, and identify factors which could positively influence physician participation in clinical trials (James et al, 2008). A database of trainees names, contact information, their experience and their expressed area of interest will be useful in the follow-up so that to continually promote participation.

2.4. Students' Attitudes and their choice of research design

Halabi and Hamdan-Mansour (2010) defines attitudes towards research as significant indictors that connect practice to research and enhance evidence-based practice. From 1985 to 2003, the percentage of physicians actively involved in research declined from approximately 5 to 2 percent. Many community physicians consider research to be time consuming, tedious, and financially draining. Consequently, even the physicians who enjoy clinical research are often dissuaded from this endeavor (Micha et al 2009).

Developing a culture of primary care research must occur within the medical school environment, rather than waiting for it to take root during a residency program. Students must be introduced to the values, priorities, and ways of thinking of primary care research early in their educational process (Gonzales et al, 1998).

Attitude toward research influences students' involvement in nursing research (Owens & Kelly, 1998). According to (Halabi & Hamdan –Mansour, 2010) a number of factors may contribute to positive attitudes among students, which include involvement in research activities, participating in data collecting and introducing research concepts in education in earlier levels.

In a study by Laura et al (2007) on ethically relevant attitudes related to clinical research, medical students very strongly agreed that ethics skills are important in clinical research and clinical researchers should possess integrity and also strongly agreed that research ethics should be formally taught. Mandatory participation in research activity has been shown to improve students' knowledge and attitudes towards research.

In a study conducted in Japan whose objective was to assess the willingness of physicians to participate in clinical research and to identify effective methods to promote and enhance clinical research by Eriko et al (2009), found out that a substantial opportunity existed for improving African-American representation in clinical trials via the education, training and development of African-American physicians as clinical researchers. It was further proposed that greater involvement of African-American physicians as investigators in clinical research may facilitate greater African-American patient participation.

Training in research helps to positively modify peoples' attitudes towards a certain research design. For instance according to Eriko et al (2009) after attending the

Project IMPACT training program,19.5% of respondents reported that they had become involved with a clinical trial. Participation in Project IMPACT's clinical trials training programs did not result in a sizeable increase in participation in clinical trials but the attitudes of the majority of the respondents (68%) about clinical trials did become more positive after participating.

Kjell et al (2000) noted that according to many experts observational studies should not be used for defining evidence based medical care. The fundamental criticism of observational studies is that unrecognized confounding factors may distort the results. According to the conventional wisdom, this distortion is sufficiently common and unpredictable that observational studies are not reliable and should not be funded. Other results suggest that observational studies usually do provide valid information. They could be used to exploit the many recently developed, clinically rich data bases. Only with a greater willingness to analyze these data bases is it possible to achieve a realistic understanding of how observational studies can best be used (Kjell et al, 2000).

Randomized clinical trials are the cornerstone of evidence-based decision making and are considered the 'Gold Standard' for clinical research (Mbuagbaw et al 2011). Randomized, controlled trials will (and should) remain a prominent tool in clinical research, but the results of a single randomized, controlled trial, or only one observational study, should be interpreted cautiously. If a randomized, controlled trial is later determined to be "wrong" in its conclusions, evidence from both other trials and well-designed cohort or case-control studies can and should be used to establish the "right" answers (Concato, 2004). According to (Mbuagbaw et al 2011), investigator-initiated pragmatic trials are arguably the way forward for clinical research in developing countries. Local participants can play an important role in planning trials to ensure that protocols are culturally sensitive and beneficial.

2.5. Students' Mentorship and choice of research design

A mentoring relationship is developed between someone who is new to the profession and a more experienced person in the field. However, mentoring relationships can involve someone who has been in the field for a while, but is changing career paths and is looking for guidance and support. It can also be someone who is just looking for support and direction (Jeruchim & Shapiro, 1992)

Kaslow and Mascaro (2007) defines mentoring as a unique and distinctive personal relationship in which more experienced faculty members, clinical supervisors, or professionals who are trusted advisors and wise people engage in a variety of interactions with the interns and postdoctoral fellows whom they mentor. Mentors takes responsibility for developing less experienced people to achieve success by being able to: Act as role models, teachers, and sponsors and guide the personal and professional development of their prote´ge´s; Provide professional expertise, wisdom, knowledge, advise, challenge, counsel, support, and political know-how to help prote´ge´s reach their goals and pursue professional success and advancement; Discern their prote´ge´s personal and vocational dreams, endorse them as realistic, and offer an environment conducive to facilitating these dreams; Care about their prote´ge´s; and Empathize about the difficult choices their prote´ge´s face.

Mentoring is a voluntary and ongoing process that is to the benefit of the intern or postdoctoral resident, mentor, and institution. The interaction can occur anywhere and anytime and it involves formal and informal, professional and social activities

Kaslow and Mascaro (2007) also noted that the "scarcity of experienced mentors and role models" is a disincentive for entering a career in clinical research. The accumulated financial and time pressures as well as the uncertain prospects for promotion have severely diminished the enthusiasm of midcareer clinical investigators who could potentially serve as role models and mentors for the next generation of clinical researchers.

Role models in medical education not only are important in enhancing learning but also have been shown to affect choice of residency and career (Wright, Wong & Newill, 1997). Aslam et al (2005) concludes that good mentorship is a vital component of effective student research, and inadequate mentoring can lead to discontentment with research.

In a study on undergraduate study Melvyn, Surinder and Richard (2008), found out that undertaking research as an undergraduate has broad benefits for undergraduates by influencing their career choices and increasing medical research capacity. He further adds that those students who have done research projects were: positive about the learning experience, ability to formulate research questions, analyze data and review the literature critically and that these students were also more likely to do further research. On the other hand, a retrospective examination of data indicated that individuals with doctoral degrees who had received pre-doctoral research support

were more likely to hold tenure-track faculty appointments, serve in research career positions, receive federal peer-reviewed grant support, and have greater numbers of publications and citations than comparable individuals with doctorates who received no pre-doctoral research support (Maureen, Dilip, Geraldine, Julie & Barry, 2005).

Garcia, Cotrina, Gotuzzo, Gonzalez and Buffardi (2010) found out that lack of experience in implementing policies based on research findings, lack of research mentoring, and lack of opportunities for multidisciplinary research collaboration deterred research training. In a study on examining the impact of health research facilitated by small peer-reviewed research operating grants. Caddell, Hatchette and McGrath (2010) found out that nearly all of the participants reported a positive experience and felt that this research improved their research skills and developed their program of research. A positive impact at the level of the research is a fundamental component of ensuring that novice and junior researchers continue to pursue research opportunities. Perhaps most notable of the personal impacts was the opportunity to mentor and be mentored. Mentorship is essential to building the research careers of novice investigators by providing support and expertise (Caddell et al 2010).

There is a clear need for improvement in the management of students' research projects to enable enthusiastic medical students to publish the results of their work and retain their interest in science (Ivana, Ozren, Hrvoje, Elena, Vinka& Goran 2005).

2.6 Summary of Literature Review

The literature review highlights the fact that availability of resources is important in conducting clinical research hence the choice of research design. That the lack of resources is a barrier to clinical research as evidenced in sub-Saharan Africa. Financial resources may be provided by government, pharmaceutical companies and other interested organizations. This is used at various stages of clinical research whereby experimental designs are considered to be more costly than observational designs. It also highlights the need for various expertize in clinical research which remains a challenge. Time spent in training and in the conduct of research is an important resource in the choice of research design. There is emphasis on the need to include research curriculum and experience in undergraduate and postgraduate because poor research training is a barrier to clinical research. In terms of attitudes there is a need to a develop values and ways of thinking early in academics to enable

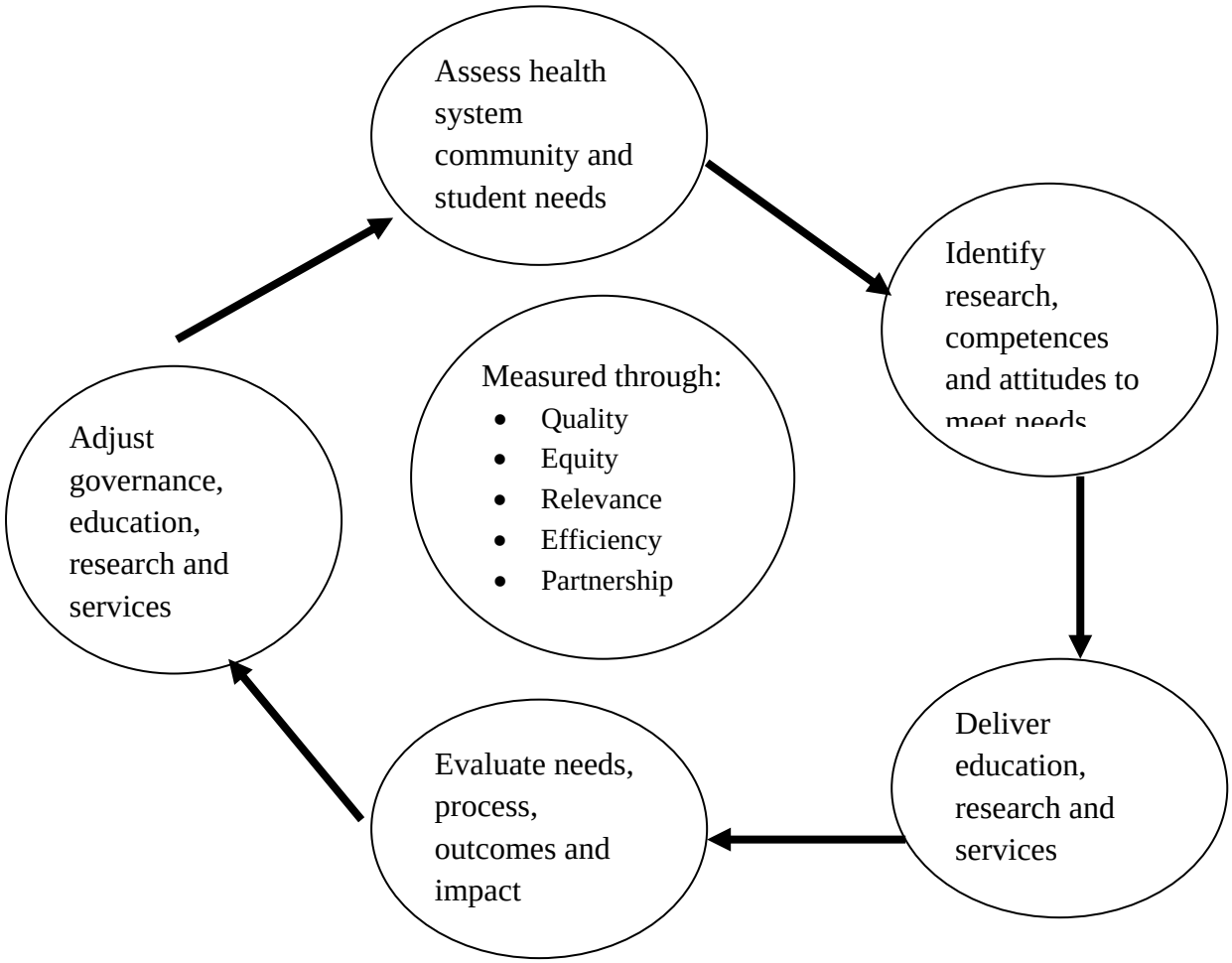
students have the ability to conduct research using any research design. This is because training modifies people's attitudes positively. Finally the review brings out the importance of mentors because scarcity of mentors is a disincentive in clinical research.

Barriers to involvement in research include lack of knowledge of research, negative attitudes towards research, inadequate means of disseminating research findings, lack of institutional support, lack of confidence in research ability and difficulty in transferring research to practice (Halabi&Hamdan –Mansour, 2010).

The literature review reveals that no study has examined the factors influencing choice of research designs by post graduate students conducting clinical research. This study therefore evaluates the factors that influence the choice of either observational or experimental research designs in clinical research through a descriptive study.

2.7. Theoretical framework

Figure 2.1: Social accountability production model (Larkins Sarah et al 2011)



This is a model that was used to train socially accountable health proffessionals. This was to ensure that the health proffessionals form effectice partnerships with the health sector, policy makers and communities to help solve priority needs,contribute to health systems development and become agents of innovation and reform.

The aims of the program:

To generate new evidence and advocate for effective institutional strategies that help health proffessions schools meet needs of underserved communities.

To increase the number of health professions schools using social accountabilityprinciples to meet needs of underserved populations

To support health professional schools engaged in reform through evidence – based policy guideline, practice tools and capacity development

To increase the focus on health equity and social accountability in health professions education and health systems reform

Their guiding principles include:

Health and social needs of targeted communities guide education, research and service programs

Social accountability is demonstrated in action through a 'whole school' approach

Students recruited from the communities with the greatest health demands

Programs are located within or in close proximity to the communities they serve

Health proffessions education is embedded in the health system and take place in the community and clinics instead of predominantly in university and hospital settings

Curriculum intergrates basic and clinical sciences with population health and social sciences; and early clinical contact increases the relevance and value of theoretical learning information technology

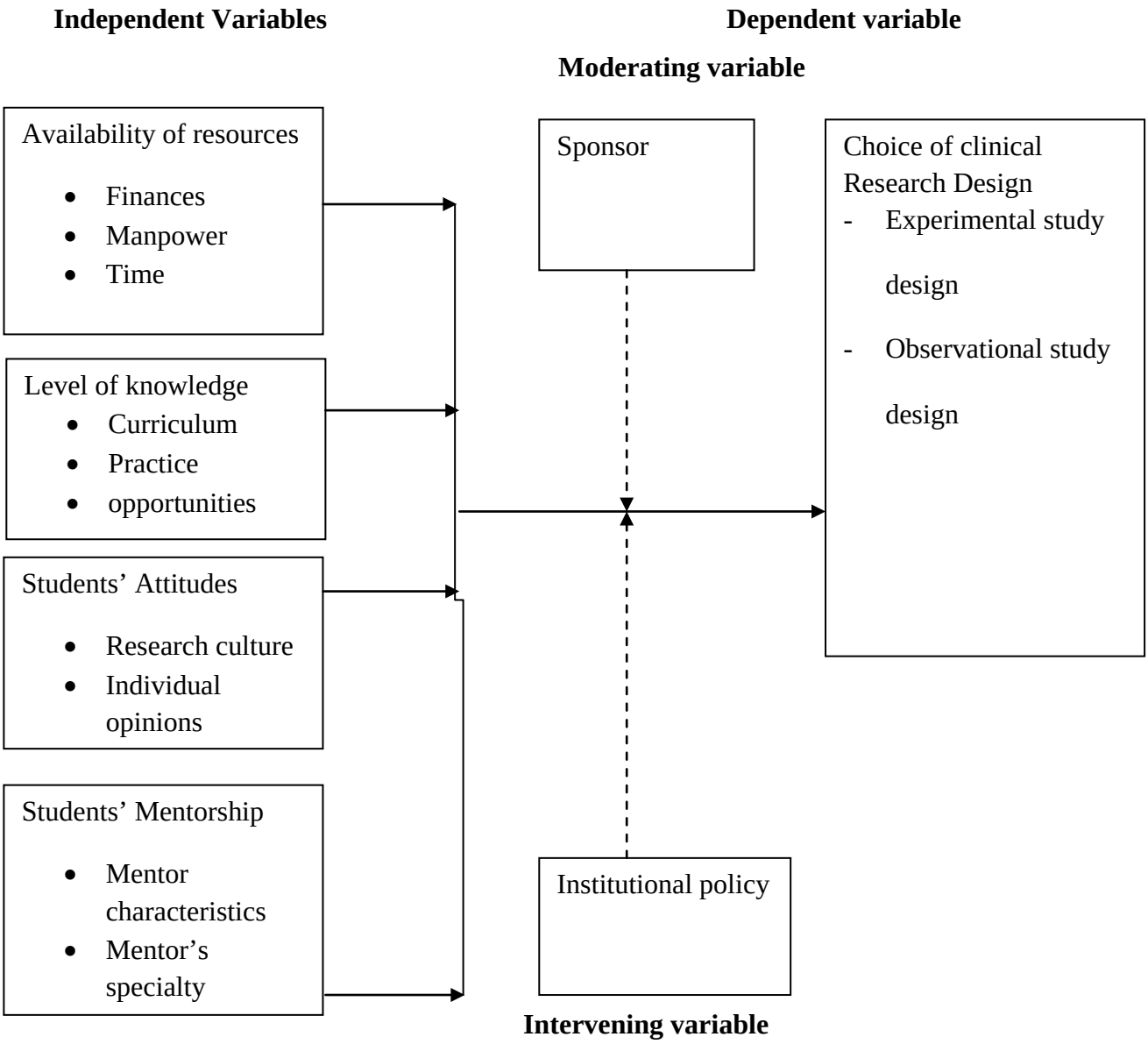
Pedagogic methods are student-centered , problem and service-based and supported by information technology

Community-based practitioners are recruited and trained as teachers and mentors

Health system actors are partners to produce locally relevant competecies

Faculty and programs emphasize and model commitment to public service

Figure 2.2: Conceptual Framework (Onchiri 2014)



According to the above conceptual framework, the specific clinical research designs include randomized clinical trials, non-randomized clinical trials, Cross-sectional surveys, Case studies, Case controls, Cohort studies and Case series. The choice of research design by students pursuing post-graduate degrees is influenced by availability of relevant resources, their level of knowledge, their attitudes and their mentorship. Each research design requires input in terms of finances, manpower and time in order to implement them. The level of knowledge is determined by the curriculum that the students cover, their prior experience in clinical research and

research opportunities that they encounter early in their career. All these influence their choice of research design. Students' own prior attitudes (conceptions and opinions) about each research design may also determine their choice of research design. Additionally, the lecturers or professionals who act as mentors to these students may impact biasness in preference leading to their choice of certain research design. This is mainly in relation to the mentor characteristics and career path.

The social accountability operational model emphasizes on training of health professionals that meet the needs of the populations it serves, designed through needs assessment and understanding the environment it operates in. similarly the conceptual framework explains that the practice of research should be made fit to serve its people by providing the necessary resources, knowledge and mentorship.

CHAPTER THREE
RESEARCH METHODOLOGY

3.1. Introduction

This chapter describes the type of study intended to be carried out and the type of research design to be used in the study. The study is quantitative, concerned with gathering of numerical data that will be analysed to come up with an assessment of the factors influencing the choice of research study designs among the university of Nairobi students doing post graduate studies. The design was a descriptive cross-sectional survey. Data collection was done using a structured questionnaire.

3.2. Research design

The design was a descriptive cross-sectional survey. Descriptive studies are meant to generate a precise and accurate description of the characteristics of the phenomena or a particular social group or individuals and determine the frequency with which some events or characteristics occur in a population or sample under study and the associations that exist among them (Majumder, 2005). The cross-sectional survey is appropriate because there is representative sample hence produced representative information and the data was collected at a single point in time to establish association. It is also less expensive, requires less time, can be used to study several variables like in this study, useful in generating hypothesis and data can be generalized to the larger population.

Survey designs attempt to collect data from members of a population in order to determine the current status of that population with respect to one or more variables (Gay, 1983)**.**This information was collected from the post graduate students registered in the college of health science and are on their last year of study.

3.3. Target population.

The study targeted post graduate students of the College of Health Science in the University of Nairobi in their last year of study. The target population was 214. It targeted students in the schools of medicine, nursing and pharmacy. The post graduate program for master of medicine takes a minimum period of three (3) years after which they sub-specialize, that of MSc Nursing takes a minimum period of 2 years while masters in pharmacy takes 2 years. The total number of postgraduate students in the

College of Health Science as at 2013 was 214. The choice of this target group was due to the fact that the University has a long history of training the highest number of highly qualified health professionals practicing in all parts of the world. It is basically the premier in the training of healthcare professionals. At the post-graduate level, the students have had sufficient exposure to knowledge on clinical research and have chosen their study projects for the master's degree hence they have made a decision on the research design.

The students were from different socioeconomic and family backgrounds. They are a fair representation of the university's population in terms of the social, cultural, gender and economic status. It is also a group of interest due to the fact that they are the ones who will be actively involved in the delivery of health care in addition to taking up the leadership and hence policy formulation in the near future. Most of them are already involved in delivery of health care.

3.3.1 Sample size

The size of the samples was calculated using Fisher's formula (Haynes. et. Al. 2006)

N= (Z*Z) (1-P)/(d*d)

N= Sample size

P=Estimated proportion of students registered for post-graduate degrees, approximately 50%

Z= 1.96, the table value for the standard normal distribution at significance level of 5%

d= Degree of precision value used, plus or minus 5%

n= (1.96*1.96)0.5 (1-0.5)/(0.05*0.05)= 372

for population less than 10,000

nf=n/(n/N), (Haynes et al 2006)

nf= Desired sample size-population less than 10,000

n=Desired sample size-population more than 10,000

N= Estimate of population =214

nf=n/(1+n/N)=

=372/(1+372/214)

=135.85

Approx 136 students

Table 3.1: Proportionate Samples

Specialty	Total No of stds	Percentages (%)	Sample size (n)
Mmed	149	69.9	95
MscN	41	19.1	26
M pharm	24	11	15
Totals	214	100	136

3.3.2 Sampling procedure

The University of Nairobi, college of health science was purposely selected since it possesses the essential characteristics for clinical research and provision of quality health care. This is because of its strategic working relationship with Kenyatta National Teaching and Referral Hospital in medical education, research and policy development.

Sampling units are non-overlapping or independent collections of elements from the population that cover the entire population (Dankit 2000). They include each of the students registered in the post graduate program.

The sample was selected from the students who are registered in the postgraduate programs in the schools of medicine, nursing and pharmacy. The students who participated in the study were selected through random sampling. They were selected during class attendance i.e in the lecture theatre. The questionnaires were administered by the investigator during the visit to the lecture theatres. Informed consent obtained from the students before the questionnaire was administered.

3.4. Research instruments

3.4.1. Pilot

A pilot study was done one week before the actual study in order to test whether the variables were universally understood among the students. This also helped ascertain the reliability of the study instrument. The questionaire was administered to ten (10) participants choosen randomly from among the students. The questionnaires were studied for any errors, omissions and clarity of questions and neccessary corrections made.

3.4.2. Reliability of research instruments

Reliability is the degree to which measures are free from error and therefore yield consistent results (Zikmund 2003). Data from a pilot study which the researcher intends to carry out tested reliability. This was done by assessing whether the sample in the pilot understood the question well and made necessary corrections detected in the pilot study. Pretesting of the questionnaires was done using ten students chosen by simple random sampling. After pre-testing, necessary corrections were made and the study proceeded to the next phase. An assessment was done on whether the variables and indicators used in the questionnaire were universally understood as expected. The level of preference (attitude) was tested by Cronhbach (=0.5716).

The use of similar questions for the different set of respondents was also used to test for reliability. Use of standard questions ensured uniformity.

3.4.3. Validity of research instruments

Validity is the accuracy or meaningfulness and technical soundness of the research. It is the degree to which a test purports to measure what it ought to measure (Mugenda & Mugenda, 1999). A strict random sampling was used to identify the participants for the studies in order to avoid bias hence ensure validity. Additionally, the sample size chosen is fairly representative hence gave results which are conclusive, statistically significant and not influenced by outliers.

3.5. Data collection method

Data collection was done using a structured questionnaire. Dankit (2000) describes a questionnaire as a set of questions designed to extract information relating to a survey.

The questionnaire was administered to the sample of students chosen from the sampling frame.

It is meant to obtain information on factors influencing the choice of study designs among the students. The questionnaire is divided into sub-sections including an introduction, socio-demographic data in addition to sections covering resources, knowledge, attitudes, and mentorship. The questionnaires were administered by the principal researcher after explaining to them the purpose of the study, the rights of the respondents, addressing their group and individual concerns and obtaining informed consent from the participants. The variables and indicators used in the questionnaire were explained to the participants in the context of the study.

3.6. Data management and analysis techniques

3.6.1 Data management

Quantitative data from the selected sample was collected using a structured questionnaire. Data cleaning and validation was performed in order to achieve a clean dataset that was then exported into a Statistical Package for social sciences (SPSS) format. A clean dataset was stored in a computer hard drive for analysis. Back up files were stored in CDs and/or flask discs, this was done regularly to avoid any loss or tampering. All the questionnaires were stored in a lockable drawer for confidentiality.

3.6.2 Data analysis techniques

Data analysis was conducted using SPSS statistical software. Exploratory data techniques were used at the initial stage of analysis to uncover the structure of data and identify outliers or unusual entered values.

Descriptive statistics such as proportions was used to summarize categorical variables while measures of central tendency for continuous variables.

Pearson's Chi-square test was used to test for the strength of association between categorical variables. Three hypotheses were also tested using chi-square. The level of significance was set at 5% (p value- 0.05) in order to judge if an observed difference can be considered due to chance or real. If P value < 0.05, we reject the null hypothesis and conclude that the result is statistically significant. If P value >0.05, we do not reject the null hypothesis i.e. not statistically significant.

All exposure variables (Independent factors) were associated with the dependent variable (choice of study design) to determine which ones have significant association. Cross-tabulation was done to assess the strength of association. All independent variables identified to significantly associate with ‘research design’ were considered together in a Multivariate analysis. This was performed using Binary logistic regression wherebackward conditional method was specified in order to eliminate confounders and effect modifiers.Adjusted odds Ratios (AOR) together with their respective 95% Confidence Interval (CI) was used to estimate the strength of association between the retained independent predictors and ‘research design’.

3.7. Ethical consideration

The permission to conduct was sought from the University of Nairobi management through the school of continuous education, extramural department after presenting a research project.

The data collected in this study is of no harm or risk to the participant because there was no invasive procedure or interference with one’s emotional being. Data collection also took care of respect for autonomy, right of self -determination, privacy, respect and freedom of choice for the participants.

Informed consent was appropriately administered before data collection. The respondents were made aware of purpose of the research, expected duration of the subject's participation, procedures to be followed, how confidentiality was to be maintained, the specific office, name, and telephone number to contact for further information regarding the study and a statement that participation was voluntary and that refusal to participate involves no penalty or loss of benefits to which the person is otherwise entitled, and that the he/she can discontinue at any time.

3.8. Operationalization of variables

Table 3.2: Operationalization Table

Objective	Variable	Indicators	Measure	Data collection	Level of scale	Type of analysis	Level of analysis
How level of knowledge influences choice clinical research among students	Knowledge	Curriculum Practice Opportunities	Research training	Questionnaire Assess syllabus	Nominal	Quantitative	Descriptive Chi-square testing
How availability of resources influences choice of clinical research	Resources	Finance Manpower Time	Average cost, size of manpower and time of the research design	Questionnaire	Interval	Quantitative	Descriptive Chi-square testing
How attitude influences choice of clinical research	Attitudes	Research culture Individual opinion	Opinions on research designs	Questionnaire	Nominal	Quantitative	Descriptive Chi-square testing
How mentorshi-p influences choice of clinical research	Mentorship	Mentor characteristi-cs Mentor's specialty	Impact of a mentoron choice	Questionnaire Interview guide	Interval	Quantitative	Descriptive Chi-square testing

CHAPTER FOUR: DATA ANALYSIS, PRESENTATION AND INTERPRETATION OF RESULTS

4.1 Introduction

This chapter presents the results of the survey, focusing on selected socio-demographic characteristics, field of study, choice of research design and the results on factors influencing the choice of research designs. The results of the relationship between the independent variables and research design are also presented in this chapter.

4.2 Demographic characteristics

Questionnaires were administered to a total of 136 post-graduate students. Table 4.1 presents selected demographic characteristics of the study participants.

Table 4.1: Respondents age and gender

Table 4.1 represents the ages and gender of respondents

Age groups	Gender		Total
	Male	Female	
20-30	20 (26.7%)	19 (31.1%)	39 (28.7%)
31-40	37 (49.3%)	30 (49.2%)	67 (49.3%)
41-50	16 (21.3%)	10 (16.4%)	26 (19.1%)
Above 50	2 (2.7%)	2 (3.3%)	4 (2.9%)
Total	75 (100%)	61 (100%)	136 (100%)

The Table shows that 49.3% (37) of the respondents were males aged between 31 and 40 years while 49.2% (30) of the females were of the same age range. The mean age was 35.4 years with SD of 7.34.

4.3: Respondents' field of study

This table represents the frequencies of the fields of study for the respondents as was sampled before the study.

Table 4.2 Respondents field of study

Field of study	No of respondents	Percentage(%)
Mmed	95	69.9
MScN	26	19.1
Mpharm	15	11
Total	136	100

Majority of the respondents (69.9%) were specializing in Mmed, 19.1% MScN and 11% Mpharm as shown in Table 4.2.

4.4 Respondents' clinical research study design

Table 4.3 represents frequencies and percentages of the clinical research designs chosen by the respondents.

Table 4.3: Respondents' clinical research study design

Study design	No of respondents	Percentage(%)
Experimental study design	16	11.8
Cross-sectional survey	90	66.2
Cohort study	16	11.8
Case control	6	4.4
Case study	4	2.9
Case series	4	2.9
Total	136	100

According to Table 4.3, majority 66.2% (90) of the respondents had chosen cross-sectional study design for their projects.

4.5 Respondent's average cost of the study

Table 4.4 shows the average cost of study for the respondents

Table 4.4: Respondent's average cost of the study

Average cost (ksh)	No of respondents	Percentage
200000	70	51.5
300000	7	5.1
400000	40	29.4
500000	4	2.9
600000	8	5.9
700000	7	5.1
Total	136	100

Table 4.4 shows that slightly over half (51.5%) of the respondents had their studies costing 200,000 while the studies of 48.5% cost more than 200,000.

4.6 Respondents' consideration of cost in choice of clinical research study design

This table shows whether the respondents considered cost in their choice of the study design.

Table 4.5: Whether respondent considered costs of the study design

Response	No of respondents	Percentage
Yes	113	83.1
No	23	16.9
Total	136	100

Table 4.5 shows that majority of the respondents 83.1% (113) considered cost implications before embarking on their chosen clinical research study design while 16.9%(23) did not.

4.7 Whether the respondent can afford a research project in each clinical research study design

This is table shows whether the respondents can afford a research project in each clinical research study design.

Table 4.6: Affordability of study design (n=136)

Study design	Yes	No
Experimental study	39 (28.7%)	97 (71.3%)
Cross sectional study	111 (81.6%)	25 (18.4%)
Cohort study	49 (36.0%)	87 (64.0%)
Case control	61 (44.9%)	75 (55.1%)
Case study	71 (52.2%)	65 (47.8%)
Case series	67 (49.3%)	69 (50.7%)

Table 4.6 shows that 81.6% (111) of the respondents thought they could afford cross sectional study designs while 18.4% (25) could not. 52.2% (71) could afford case study design. 71.3% (97) could not afford experimental study design.

4.8 Study design that the respondents think is most expensive

This table shows frequencies on which Study design respondents think is most expensive

Table 4.7: Which of studies respondent thinks is most expensive

Study design	No of respondents	Percentage
Experimental study design	84	61.8
Cross-sectional survey	19	14
Cohort study	23	16.9
Case control	4	2.9
Case series	6	4.4
Total	136	100

As shown in Table 4.7, 61.8% (84) of the respondents indicated experimental study design was the most expensive design while 16.9% (23) thought cohort study designs were most expensive. 4.4% (6) thought it was case control study designs.

Specific professionals required to carry out their studies

This table gives specific professionals required to carry out their study projects

Table 4. 8: Specific professionals required to carry out the study

Professionals	No of respondents	Percentage
Physicians	8	5.9
Nurses	13	9.6
Laboratory technicians	9	6.6
Statisticians	69	50.7
Research assistants	37	27.2
Total	136	100

Table 4.8 shows that 50.7% (69) of the respondents required statisticians to carry out their studies, 27.2% (37) research assistants and 5.9% (8) physicians.

4.9 Length of the respondents' study from protocol writing to project report presentation

This table represents the statistics on the likely length of the study from project protocol writing to project report presentation

Table 4.9: Likely length of the study from project protocol writing to project report presentation

Months	No of respondents	Percentage
5-10	48	35.3
11-20	80	58.9
More than 20	8	5.9
Total	136	100

As shown in Table 4.9, majority (58.9%) of the respondents expected their studies to take 11-20 months between project protocol writing to completion of project report presentation, 35.3% 5-10 months and 5.9% more than 20 months.

4.10: Whether respondents have had prior training in clinical research

Table 4.10 shows whether respondents had prior training in clinical research

Table 4.10: Prior training in clinical research

Response	No of respondents	Percentage
Yes	103	75.7
No	33	24.3
Total	136	100

Majority (75.7%) of the respondents had prior training in clinical research before the time of conducting their research projects while 24.3% had not as shown in Table 10.

4.11: The length of training in clinical research

This table gives an analysis on the length of training for respondents who had prior training in clinical research

Table 4.11: Length of the training in clinical research (n=103)

Months	No of respondents	Percentage
2-5	42	40.8
6-10	25	24.3
More than 10	36	35.0
Total	103	100

Of the respondents who had undergone prior training in clinical research, 75.7% (103), 40.8% (42) took 2-5 months, 35.0% (36) more than 10 months and 24.3% (25)

6-10 months. The mean period of training was 8 months with a SD of 3.98. This is shown in Table 11.

4.12 Whether respondents covered the whole process of conducting clinical research using various study designs

Table 4.12 shows whether respondents covered the whole process of conducting clinical research using various study designs

Table 4.12: Coverage of the whole process of conducting clinical research during the training (n=103)

Study design	Yes	No
Experimental study	54 (52.4%)	49 (47.6%)
Cross sectional study	72 (69.9%)	31 (30.1%)
Cohort study	71 (68.9%)	32 (31.1%)
Case control	52 (50.5%)	51 (48.5%)
Case study	58 (56.9%)	44 (43.1%)
Case series	44 (42.7%)	59 (57.3%)

Table 4.12 shows that 69.9% (72) of the respondents who had undergone prior training in clinical research covered the whole process of conducting clinical research using cross sectional study design.

4.13 Whether respondents have participated in clinical research before

Table 4.13 is a representation of whether respondents had participated in clinical research previously

Table 4.13: Past participation in clinical research (n=136)

Reason	No of respondents	Percentage
Yes	58	42.6
No	78	57.4
Total	136	100

Table 4.13 shows that majority (57.4%) of the respondents had participated in clinical research before while 42.6% had no experience.

4.14 Respondents' preference on research design

Table 4.14 gives the levels of preference of various study designs ranging from very low to very high.

Table 4.14: Level of preference for the various study designs

Study design	Very low	Low	Moderate	High	Very high	No response	Mean response
Experimental study	15(11.0%)	36(26.5%)	35(25.7%)	24(17.6%)	26(19.1%)	0(0.0%)	3.1
Cross sectional study	14(10.3%)	28(20.6%)	37(27.2%)	33(24.3%)	24(17.6%)	0(0.0%)	3.2
Cohort study	16(11.8%)	37(27.2%)	43(31.6%)	22(16.2%)	18(13.2%)	0(0.0%)	2.9
Case control	13(9.6%)	36(26.5%)	56(41.2%)	20(14.7%)	10(7.4%)	1(0.7%)	2.9
Case study	17(12.5%)	46(33.8%)	48(35.3%)	14(10.3%)	11(8.1%)	0(0.0%)	2.8
Case series	19(14.0%)	53(39.0%)	41(30.1%)	15(11.0%)	8(5.9%)	0(0.0%)	2.6

Table 4.14 shows that cross-sectional study design was moderately preferred by 55.5% of the respondents with a mean response of 3.2. Experimental study design had a mean of 3.1(Moderate). Cohort study had a mean of 2.9, Case control 2.9, case study 2.8 and Case series 2.6. Reliability test with Cronbach's alpha returned 0.5716 showing the data on attitude was moderately reliable.

4.15 Respondents mentorship on research design

Table 4.15a states whether the respondents had mentors in clinical research

Table 4.15a: Whether the respondent has a mentor in clinical research

Response	No of respondents	Percentage
Yes	92	67.6
No	44	32.4
Total	136	100

Table 4.15a shows that majority (67.6%) of the respondents had a mentor in clinical research while 32.4% did not have.

4.16 Period of mentorship

This the table that gives the period of mentorship the respondents had before carrying out their research projects

Table 4.15b: For how long respondent has had the mentor (n=92)

Period	No of respondents	Percentage
1 year	43	46.7
2 years	27	29.3
3 years	20	21.7
Above 3 years	2	2.2
Total	92	100

Table 4.15b shows that of the respondents who had a mentor in clinical research 46.7% (43) had their mentor for 1 year, 29.3% (27) 2 years, 21.7% 3 years and 2.2% for more than 3 years.

Table 4.15c: Whether the mentor influenced choice of study design (n=92)

Response	No of respondents	Percentage
Yes	61	66.3
No	31	33.7
Total	92	100

As shown in Table 4.15c, the choice of study design was influenced by the mentor in 66.3% (61) of the respondents while 33.7% (31) were not influenced.

4.17 What the University should do to increase student's knowledge and reduce barriers to participation in clinical research especially clinical trial

Table 4.16 shows what respondents think should be done to increase students' knowledge and reduce barriers in the choice of the various research designs

Table 4.16: What can be done to increase knowledge and reduce barriers in clinical trials

Opinion	No of respondents	Percentage
Add more content	21	15.4
Increase visibility	32	23.5
Improve on mentoring	51	37.5
Offer a grant writing program	21	15.4
Involve students	11	8.1
Total	136	100

According to Table 4.16, 37.5% (51) recommended improving on mentoring as a means to increase knowledge and reduce barriers in clinical trials, 23.5% (32) Increase visibility, 15.4% (21) Offer a grant writing program same as Adding more content and 8.1% (11) involvement of students.

4.18 The relationship between consideration of cost of the study design on the choice of research study design

Table 4.17 shows the relationship between consideration of cost of study design on the choice of research study design

Table 4.17: Relationship between consideration of cost of the study design on the choice of research study design

Study design	Whether respondent considered costs of the design		Total	X^2
	Yes	No		
Experimental study	12(8.8%)	4 (2.9%)	16(11.8%)	$X^2 = 17.469$ df = 2 p = 0.000
Cross-sectional study	83(61.0%)	7(5.1%)	90(66.2%)	
Other designs	18(13.2%)	12(8.8%)	30(22.1%)	
Total	113(83.1%)	23(16.9%)	136(100%)	

Table 4.17 shows a statistically significant association between choice of study design and consideration of cost, $X^2(2, 136) = 17.469$, $p < 0.05$. This means the cost of the study design influences choice.

Ho (Null Hypothesis): Cost of research study doesn't influence the choice of research study design

Result: x^2 (2, 136) =17.469, p=0.000, Strong association between cost and choice of study design

Conclusion: Reject the null hypothesis; hence cost of the study influences the choice of research study design

4.19: The relationship between choice of clinical research study design and length of training on clinical research

Table 4.18 gives the relationship between choice of clinical research study design and length of training on clinical research

Table 4.18: Relationship between choice of clinical research study design and length of training on clinical research

Study design	Length of training			Total	x^2
	Upto 5 months	6-10 months	More than 10 months		
Experimental study	5 (3.7%)	5 (3.7%)	6 (4.4%)	16 (11.8%)	x^2 = 20.053 df = 4 p = 0.000
Cross-sectional study	46 (33.8%)	22 (16.2%)	22 (16.2%)	90 (66.2%)	
Other designs	3 (2.2%)	8 (5.9%)	19 (14.0%)	30 (22.1%)	
Total	54 (39.7%)	35 (25.7%)	47 (34.6%)	136 (100%)	

Table 4.18 shows a statistically significant association between choice of study design and length of training, x^2 (4, 136) =20.053, p< 0.05, meaning length of training influences choice of study design.

4.20: The relationship between choice of study design and influence of mentor

Table 4.19 gives the relationship between choice of study design and influence of mentor

Table 4.19: Relationship between choice of study design and influence of mentor

Study design	whether the mentor influenced choice of study design		Total	x^2
	Yes	No		
Experimental study	4 (2.9%)	12 (8.8%)	16 (11.8%)	x^2 = 5.861 df = 2 p = 0.053
Cross-sectional study	52 (38.2%)	38 (27.9%)	90 (66.2%)	
Other designs	16 (11.8%)	14 (10.3%)	30 (22.1%)	
Total	72 (52.9%)	64 (47.1%)	136 (100%)	

Table 4.19 shows no statistically significant association between choice of study design and mentor's influence, x^2 (2, 136) =5.861, p> 0.05, meaning mentorship does not influence choice of study design.

Ho (Null hypothesis): Mentorship does not influence the choice of clinical research design

Result: x^2 (2, 136) =5.861, p> 0.053, No association between mentorship and choice of clinical research study design

Conclusion: Do no reject null hypothesis; hence mentorship does not influence choice of clinical research design

4.21: Relationship between choice of study design and prior training in research

Table 4.20 shows the relationship between choice of study design and prior training in clinical research

Table 4.20: Relationship between choice of study design and prior training in research

Study design	whether respondents had prior training in research		Total	x^2
	Yes	No		
Experimental study	10 (7.4%)	6 (4.4%)	16 (11.8%)	x^2 = 6.097 df = 2 p= 0.047
Cross-sectional study	74 (54.4%)	16 (11.8%)	90 (66.2%)	
Other designs	19 (14.0%)	11 (8.1%)	30 (22.1%)	
Total	103 (75.7%)	33 (24.3%)	136 (100%)	

Table 4.20 shows a statistically significant association between choice of study design and prior training in research, x^2 (2, 136) =6.097, p = 0.047, meaning prior training in research slightly influences choice of study design.

Ho (Null hypothesis): prior training in clinical research does not influence the choice of clinical research study design

Result: x^2 (2, 136) =6.097, p = 0.047, Shows an association between prior training in clinical research and choice of clinical research study design

Conclusion: Reject the null hypothesis, hence prior training in clinical research influences the choice of clinical research study design.

4.22 The Relationship between prior training in clinical research and mentorship and choice of research study design

Table 4.21 shows how prior training in clinical research and mentorship relate with the choice of research study design

Table 4.21: Relationship between prior training in clinical research and mentorship and choice of research study design

whether respondents has had training in research	whether the mentor influenced choice of study design		Total	F	P
	Yes	No			
Yes	54(39.7%)	49(36.0%)	103(75.7%)	4.058	0.046
No	18(13.2%)	15(11.0%)	33(24.3%)		
Total	72(52.9%)	64(47.1%)	136(100%)		

Table 4.21 shows a statistically significant relationship between prior training in research and mentor's influence, F (1) n=136) = 4.058, p = 0.046, showing mentor's influence and prior training in research slightly influences choice of study design.

4.23 Factors associated with choosing cross-sectional study as a preferred choice of clinical research design among the students of the University of Nairobi

Multivariate analysis was performed to identify independent predictor(s) of choice of cross-sectional research design as the preferred choice of research design among the

students of the University of Nairobi. Seven main factors associated with choice of cross-sectional design at p<0.05 during bivariate analysis were considered for multivariate analysis. They include (1) Respondent's gender and age, (2) Length of the research study (3) Cost of the study (4) Whether the respondent think they can afford the study (5) Prior training in the research designs (6) preference for the research design (7) Influence of mentorship on choice of research design. Upon fitting the factors using Binary logistic regression and specifying *'backward conditional'* method with removal at P<0.05, four factors were retained in the final model as shown in Table 4.16.

Table 4.22: Factors associated with choosing cross-sectional study as a preferred choice of clinical research design

		95%CI		
Variables	**OR**	**Lower**	**Upper**	**p value**
The respondent think would afford cross sectional design				
Yes	122.10	12.40	1202.59	<**0.001**
No	1.00			
The respondent think would afford case control				
Yes	1.00			
No	4.95	1.27	19.26	**0.021**
The respondent think would afford case series				
Yes	1.00			
No	4.38	1.12	17016.00	**0.034**
The training covered all steps in conducting cross sectional research design				
Yes	3.66	1.14	11.76	**0.029**
No	1.00			

There was a significant association between respondents' feeling that they would afford cross-sectional design and choice of cross-sectional research design (OR=122.10; 95% CI: 12.40 – 1202.59; p=0.001).

Having had a training that covers all steps of conducting cross-sectional research design had significant influence on the choice of cross-sectional design (OR=3.66; 95% CI: 1.14 – 11.76; p=0.029).

CHAPTER FIVE: SUMMARY OF FINDINGS, DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This section gives a summary of the findings from the research study conducted. It also covers discussions that result from the findings of the study of the factors influencing the choice of the research study. This chapter also comes up with the conclusion in relation to the findings in addition to the relevant recommendations.

5.2 Summary of findings

The self-administered questionnaires were administered to a total of 136 post-graduate students. 49.3% of the respondents were males aged between 31 and 40 years while 49.2% of the females were of the same age range. The mean age was 35.4 years with SD of 7.34.Majority of the respondents (69.9%) were specializing in Mmed, 19.1% MScN and 11% Mpharm.

From the study majority (66.2%) of the respondents had chosen cross-sectional study design for their projects. 11.8% of the respondents chose experimental and cohort studies each, 4.4% case control, 2.9% chose case study and case series each.

The first objective of this study was to assess on how the level of knowledge influences the choice of clinical research design among the students of the University of Nairobi. Majority (75.7%) of the respondents had prior training in clinical research before the time of conducting their research projects while 24.3% had not. Of the respondents who had undergone prior training in clinical research, 40.8% took 2-5 months, 35.0% more than 10 months and 24.3% 6-10 months. The mean period of training was 8 months with a SD of 3.98. Additionally, 69.9% of the respondents who had undergone prior training in clinical research covered the whole process of conducting clinical research using cross sectional study design.

Experience is a major aspect of one's knowledge base, in this study majority (57.4%) of the respondents had participated in clinical research before conducting their own research projects while 42.6% had no experience.

In order to improve on knowledge in clinical research among the students, 37.5% of the respondents recommended improving on mentoring as a means to increase knowledge and reduce barriers in clinical trials, 23.5% recommended increasing visibility of available clinical trial programs to students, 15.4% suggested that students be put on grant writing program same as adding more content about clinical trials on the syllabus and 8.1% suggested involvement of students in clinical trials with international collaborating universities and institutions.

There is a statistically significant association between choice of study design and length of training, x^2 (4, 136) =20.053, p< 0.05, meaning length of training influences choice of study design. Additionally, there is a statistically significant association between choice of study design and prior training in research, x^2 (2, 136) =6.097, p = 0.047, meaning prior training in research slightly influences choice of study design.

Null Hypothesis: prior training in clinical research does not influence the choice of clinical research study design.

Result: x^2 (2, 136) =6.097, p = 0.047, Shows an association between prior training in clinical research and choice of clinical research study design

Conclusion: Reject the null hypothesis, hence prior training in clinical research influences the choice of clinical research study design.

When analyzed together prior training and the mentor's influence showed a statistically significant relationship with choice of research study design, F (1) n=136) = 4.058, p = 0.046, showing mentor's influence and prior training in research slightly influences choice of study design.

The study was meant to establish whether availability of resources influences the choice of clinical research design among students of the University of Nairobi. The resources included finances, manpower and time. From the study the slightly over half (51.5%) of the respondents had their studies costing 200,000 while the studies of 48.5% cost more than 200,000. It also showed that majority of the respondents (83.1%) considered cost implications before embarking on their chosen clinical research study design while 16.9% did not.

81.6% of the respondents thought they could afford cross sectional study designs while 18.4% could not. 52.2% could afford case study design. 71.3% could not afford experimental study designs. 61.8% of the respondents indicated experimental study design was the most expensive design while 16.9% thought cohort study designs were most expensive. 4.4% thought it was case control study designs. There is a statistically significant association between choice of study design and consideration of cost, x^2 (2, 136) =17.469, p< 0.05. This means the cost of the study design influences choice.

Ho (Null Hypothesis): Cost of research study doesn't influence the choice of research study design

Result: x^2 (2, 136) =17.469, p=0.000, Strong association between cost and choice of study design

Conclusion: Reject the null hypothesis; hence cost of the study influences the choice of research study design

Manpower is an important resource during implementation of a study project. From among the suggested professionals, 50.7% of the respondents required statisticians to carry out their studies, 27.2% research assistants and 5.9% physicians.

Time is a critical resource in any project. When coming up with a research project the investigator makes a time plan on its implementation. Majority (58.9%) of the respondents expected their studies to take 11-20 months between project protocol writing to completion of project report presentation, 35.3% 5-10 months and 5.9% more than 20 months.

The other objective was to assess how students' attitude influences the choice of clinical research design among students of the University of Nairobi. From the study cross-sectional study design was moderately preferred by 55.5% of the respondents with a mean response of 3.2. Experimental study design had a mean of 3.1(Moderate). Cohort study had a mean of 2.9, Case control 2.9, case study 2.8 and Case series 2.6.

The study was also set to assess how students' mentorship influences the choice of clinical research design among students of the University of Nairobi. Majority (67.6%) of the respondents had a mentor in clinical research while 32.4% did not have. From the respondents who had a mentor in clinical research 46.7% had their mentor for 1 year, 29.3% 2 years, 21.7% 3 years and 2.2% for more than 3 years. The choice of study design was influenced by the mentor in 66.3% of the respondents while 33.7% were not influenced.

On further analysis there is no statistically significant association between choice of study design and mentor's influence, x^2 (2, 136) =5.861, p> 0.05, meaning mentorship does not influence choice of study design.

Ho (Null hypothesis): Mentorship does not influence the choice of clinical research design

Result: x^2 (2, 136) =5.861, p> 0.053, No association between mentorship and choice of clinical research study design

Conclusion: Do no reject null hypothesis; hence mentorship does not influence choice of clinical research design.

On the other hand, a statistically significant relationship between prior training in research and mentor's influence and the choice of the clinical research study design F(1) n=136) = 4.058, p = 0.046, showing mentor's influence and prior training in research slightly influences choice of study design.

There was a significant association between respondents' feeling that they would afford cross-sectional design and choice of cross-sectional research design (OR=122.10; 95% CI: 12.40 – 1202.59; p=0.001). A student who thought they could afford cross-sectional research design was 122.1 times more likely to choose cross-sectional design than the one who thought they could not afford.

Having had a training that covers all steps of conducting cross-sectional research design had significant influence on the choice of cross-sectional design (OR=3.66; 95% CI: 1.14 – 11.76; p=0.029). A student whose training covered all steps in conducting cross-sectional research design was 3.36 times more likely to choose cross-sectional research design compared to those whose training didn't cover all steps of conducting cross-sectional research design.

5.2 Discussions

Relevant skills and knowledge in the practice of research is essential in the successful implementation of clinical research project for a student. From the results of the study majority of the respondents had prior training in clinical research before the time of conducting their research projects while some had not. The length of training however varied, 40.8% took 2-5 months, 35.0% more than 10 months and 24.3% 6-10 months. The mean period of training was 8 months with a SD of 3.98. Additionally, majority of the respondents who had undergone prior training in clinical research covered the whole process of conducting clinical research using cross sectional study design with

the highest score. Henceforth prior training and coverage of the whole process of conducting a research design is essential for a student's choice of the research design.

In his study Aslam et al, (2005) found out that research experience as a medical student was strongly associated with postgraduate research involvement. In this study majority of the respondents had participated in clinical research before and suggested involvement of students in clinical trials with international collaborating universities and institutions in order to improve participation in clinical research. Scot et al (1990) states that both specialty training and experience are important in determining whether one gets involved in research activities during the postgraduate period. On the other hand James et al (2008) states that some level of experience is often considered important in the preparation of individuals to serve effectively as principal investigators. In his study most of the participants were not ready to serve in such roles without further training because of lack prior experience. Further studies supported the claim that if physicians were exposed to laboratory or clinical research experiences during their student days, they were more likely to carry out research activities in their postgraduate careers. (Jay & James, 2001).

On average the students covered all the research designs but when asked on suggested interventions to eliminate barriers to research, they suggested adding more content about clinical trials on the syllabus. The students therefore felt they needed more training in research. Aslam et al (2004) states that the major reasons cited for poor research activity in Pakistan were poor research training and poor research awareness. These are different from the western settings where lack of time and lack of interest were more important obstacles to research as compared to poor training. The lack of research exposure and training underscores the need to review both undergraduate and

postgraduate curricula so that some specific educational intervention is incorporated (Aslam et al, 2004).

Resources relevant to implementation of research influence research activities. The current study was looking at financial resources, time required to conduct research, and manpower needed. The study therefore established that slightly over half of the respondents had their studies costing 200,000 while the studies of the other half cost more than 200,000 and that majority of the respondents considered cost implications before embarking on their chosen clinical research study design. To add to the finding that cost influences choice of the research study design, majority of the students chose Cross-sectional study design which is the same design that a greater majority of the respondents thought they could afford. On the other hand very few students chose experimental study designs which majority of the respondents could not afford and most of the respondents indicated as the most expensive design. According to Niharika et al (2009) the number of family physicians involved in clinical research at academic medical centers was decreasing due to a shrinking pool of research resources and increasing clinical demands hence reduction in clinical research output. Aslam et al (2005) suggested that in order to promote research activities for students research infrastructure needed extensive improvement, and the meager funding for research must be boosted, so that there will be a healthier research culture in which students can participate. And according to Kjell et al (2000) one of the advantages of observational studies over randomized, controlled trials was the lower cost. All this studies emphasize the importance of cost in implementation of research studies.

According to Nancy et al (2003) clinical research requires the expertise of many kinds of investigators, including Physicians, dentists, public health workers, nurses, psychologists, laboratory technicians, dietitians, computer Programmers,

bioengineers, and others. All these professionals are important resources playing specific roles in the clinical research activities. From among the suggested professionals, 50.7% of the respondents required statisticians to carry out their studies, 27.2% research assistants and 5.9% physicians. The students suggested this depending on who they thought was necessary in completion of their projects. Sue et al (1999) identified lack of support staff, for example clinical trial nurses, as a barrier to participation in randomized clinical trials. Gonzales et al 1998 suggested that involvement of faculty and students in research could be facilitated by research staffs, which assist in data entry and analysis, coordinate production of posters and/or slides for presentations, and support completion of articles for submission. The staffs could also provide the continuity necessary to sustain the program by coordinating projects between faculty and students, recruiting both students and faculty, soliciting funding for student stipends and project expenses, and supporting student submissions of presentations and publications (Gonzales et al, 1998). This is possible in institutions where there is an established research unit or department.

Time is a critical resource in any project. When coming up with a research project the investigator makes a time plan on its implementation. Majority of the respondents expected their studies to take 11-20 months between project protocol writing to completion of project report presentation, 35.3% 5-10 months and 5.9% more than 20 months. The time spent in training is important in clinical research. The study established a statistically significant association between choice of study design and length of training, $X^2(4, 136) = 20.053$, $p < 0.05$, meaning length of training influences choice of clinical research study design. According to Eriko (2009) lack of time was reported as a major hurdle in the involvement of physicians in clinical research. Most physicians in university hospitals in Japan were involved in both patient care and

research on molecular and cellular biology including experiments with animals. There were few highly skilled clinical researchers in Japan and opportunities to learn the principles and methodology of clinical research are limited for young Japanese physicians.

For Sue (1999) in experimental research involving randomized trials, lack of times was a major barrier. Similarly Kjell, (2000) states that one of the advantages of observational studies over randomized controlled trials is the greater timeliness. This suggests that given the strict time schedule that students work under in order to complete their academic programs they are more likely to choose research study designs that will allow them complete the research projects in time.

Eriko et al (2009) findings indicated that the contention that "doctors in Japan simply didn't want to take part in clinical trials" was a misunderstanding. Indeed, the results indicated that if an adequate trial infrastructure was present, Japanese physicians were eager to conduct clinical research.

Attitudes can be implied as the values, priorities, and ways of thinking of students early in their educational process in research (Gonzales et al, 1998). Owens & Kelly, (1998) found out that attitude toward research influenced students' involvement in nursing research. In another study Halabi & Hamdan –Mansour, (2010)stated that a number of factors may contribute to positive attitudes among students, which include involvement in research activities, participating in data collecting and introducing research concepts in education in earlier levels. In this study on how students' attitudes influence choice of clinical research design, cross-sectional study design was moderately preferred by more than half of the respondents with a mean response of 3.2. Experimental study design had a mean of 3.1(Moderate), while cohort study had a mean of 2.9, Case control 2.9, case study 2.8 and Case series 2.6. These levels of

preference have an influence on the choice of research study design although this depends on the other factors. For instance according to Eriko et al (2009),participation in Project IMPACT's clinical trials training programs did not result in a sizeable increase in participation in clinical trials but the attitudes of the majority of the respondents about clinical trials did become more positive after participating.

Kaslow & Mascaro (2007) defined mentoring as a unique and distinctive personal relationship in which more experienced faculty members, clinical supervisors, or professionals who are trusted advisors and wise people engage in a variety of interactions with the interns and postdoctoral fellows whom they mentor. The study results shows that majority of the respondents had a mentor in clinical research while 32.4% did not have. The period of mentorship varied, 46.7% had their mentor for 1 year, 29.3% 2 years, 21.7% 3 years and 2.2% for more than 3 years. The choice of clinical study design was influenced by the presence of a mentor in majority of the respondents while a few were not influenced. Kaslow & Mascaro (2007) also noted that the "scarcity of experienced mentors and role models" was a disincentive for entering a career in clinical research. In another previous study by Wright, (1997) it was concluded that role models in medical education not only are important in enhancing learning but also have been shown to affect choice of residency and career.

On cross-tabulation it came out that there was no statistically significant association between choice of study design and mentor's influence, $X^2(2, 136) = 5.861$, $p > 0.05$, which meant that mentorship does not influence choice of study design. Questions arise as to whether mentorship fails to influence choice of study design due to the nature of mentorship.

Garcia et al (2010) found out that lack of experience in implementing policies based on research findings, lack of research mentoring, and lack of opportunities for multidisciplinary research collaboration deterred research training.

Mentorship is essential to building the research careers of novice investigators by providing support and expertise (Caddell et al, 2010). When asked to suggest on ways of improving participation and reducing barriers to clinical research, 37.5% of the respondents recommended improving on mentoring as a means to increase knowledge and reduce barriers in clinical trials.

There was a significant association between respondents' feeling that they would afford cross-sectional design and choice of cross-sectional research design (OR=122.10; 95% CI: 12.40 – 1202.59; p=0.001). A student who thought they could afford cross-sectional research design was 122.1 times more likely to choose cross-sectional design than the one who thought they could not afford.

Having had a training that covers all steps of conducting cross-sectional research design had significant influence on the choice of cross-sectional design (OR=3.66; 95% CI: 1.14 – 11.76; p=0.029). A student whose training covered all steps in conducting cross-sectional research design was 3.36 times more likely to choose cross-sectional research design compared to those whose training didn't cover all steps of conducting cross-sectional research design.

5.3 Conclusions

The study assessed the factors that influenced the choice of clinical research design among post-graduate students in the University of Nairobi.

The factors outlined above influenced the choice of clinical research designs. Cross-sectional survey was the most prevalent clinical research designs conducted in the University of Nairobi.

Post-graduate students require prior training in clinical research with adequate content on the syllabus on all study designs because this influences the choice of a clinical research study design. This training should last for an agreed period of time depending on the syllabus and include experience in active participation in a clinical research activity. This can be better achieved by bench-marking the curriculum with universities that already have the capacity to conduct all designs of research.

The availability of finances, manpower and time provides students with the freedom to choose their preferred clinical study design. Hence availability of resources influences the choice of research study design. The skewed nature in which students chose the cross-sectional study design could be attributed to the limited finances, need for minimal manpower and limitation in time given in order to complete the research projects hence the finding that most study projects designed as cross-sectional. Relevant institutions including universities, research institutions and the government ought to strive to work together to avail these resources in order to improve on the research culture in terms of an environment that allows a student choose any research study with equal chance. An establishment of clinical research unit fully equipped with relevant staff, equipment and modalities for research funding is a worthy idea.

Positive attitude influences the willingness of students in choosing clinical study designs. This is complemented by the other factors. Hence there is need for relevant bodies to look for ways of improving the attitude of students on the various research study designs such role-modelling.

Having a mentor guiding a student might lead to a certain choice in clinical research design but mentorship alone is not likely to influence the choice of clinical research design. This means that the nature of mentorship needs further assessment and improvement.

A majority of respondents considered cost in choosing the research design, thought they could afford cross-sectional survey, and conducted cross-sectional research design. Most of the respondents had prior training in clinical research and had covered all steps of conducting all clinical research designs and they choose cross-sectional research design.

The respondents' feeling that they would afford cross-sectional design and having had a training that covers all steps of conducting cross-sectional research design had a very strong influence on the choice of cross-sectional research design

5.4 Recommendations

The following recommendations are made:

The need to benchmark on the syllabus on clinical research both in skills and practice is critical in ensuring students get enough exposure on clinical research.

There is need for all stakeholders concerned including universities, research institutions, pharmaceutical companies, collaborating institutions to come up with strategies to promote the choice of all clinical research designs for students and healthcare providers

In order to promote research activities for students, research infrastructure needs extensive improvement, and the meager funding for research must be boosted, so that there will be a healthier research culture in which students can participate

Mentorship in training of healthcare providers should include practitioners in related institutions such as research institutions but not be limited to the lecturers and clinical instructors.

Healthcare providers should be keen to identify and utilise available local and international research opportunities

5.5 Suggestions for further research

How adequate is the syllabus for clinical research in Kenyan university education

Establish the nature of mentorship in Kenyan medical education in relation to future career choice in clinical research

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APPENDIX I: QUESTIONNAIRE

Researcher _____

Serial No _____

Date of interview _____

A. DEMOGRAPHIC INFORMATION (Tick the appropriate answer)

1. Sex

   Male [ ] Female [ ]

2. Age. 20-30 [ ] 30-40 [ ] 40-50 [ ] above 50

3. What is your field of specialization (Tick one)

   Mmed [ ] MscN [ ] Mpharm [ ]

4. What is the study design of your project?

   Experimental study design [ ] Case study [ ]

   Cross-sectional survey [ ] Case series [ ]

   Cohort study [ ]

   Case control [ ]

B. RESOURCES (Tick appropriate answer)

5. What is the average cost of your study project?

6. Did you have cost consideration when choosing the study design?

   Yes [ ] No [ ]

7. Given your field of specialization do you think you could afford a project on the following study designs?

   A. Experimental study Yes [ ] No [ ]

   B. Cross-sectional study Yes [ ] No [ ]

   C. Cohort study Yes [ ] No [ ]

   D. Case control Yes [ ] No [ ]

   E. Case study Yes [ ] No [ ]

   F. Case series Yes [ ] No [ ]

8. Of the study designs which one do you think is most expensive (Tick one option)

Experimental study design	[ ]	Case control	[ ]
Cross-sectional survey	[ ]	Case study	[ ]
Cohort study	[ ]	Case series	[ ]

9. Which specific professionals do you require in order to carry out your study? (Tick one)

Physicians	[ ]	Statisticians	[ ]
Nurses	[ ]	Research assistants	[ ]
Laboratory technicians	[ ]	Others …….	

10. How long (in months) is your study likely to take from project or protocol writing to report writing?

C. KNOWLEDGE AND ATTITUDE

11. (a). Have you had prior training in clinical research? Yes [ ] No [ ]

b. If yes to (a) above, how long was the training (in months)

c. If yes to (a) above, did the training course cover the whole process of conducting each of the following study designs?

Experimental study design	[ ]	Case control	[ ]
Cross-sectional survey	[ ]	Case study	[ ]
Cohort study	[ ]	Case series	[ ]

12. a). Have you ever participated in clinical research in the past? Yes [ ] No [ ]

13. From the table below indicate your level of preference for the following study designs (requirements for all designs provided)

	Very low	low	Moderate	High	Very high
Experimental study					
Cross-sectional study					
Cohort study					
Case control					
Case study					
Case series					

D. MENTORSHIP

14. Do you have a mentor in clinical research? Yes [ ] No [ ]

15. If yes to (14) above, for how long have you had the mentor?

    a. 1 year [ ] b. 2 years [ ] c. 3 years [ ] d. above 3 years [ ]

16. If yes to (14) above, did the mentor influence the choice of your study design? Yes [ ] No [ ]

17. Apart from finances, time, manpower, knowledge and mentorship, what other factor do you think influenced the choice of your study design?

18. What more can the University of Nairobi administration and stakeholders do to increase your knowledge of and reduce barriers to your participation in clinical research especially clinical trial? (Prefer one .)

    a. Add more content about clinical trials on the syllabus
    b. Increase visibility of available clinical trial programs to students
    c. Improve on the mentoring program
    d. Offer a grant-writing program
    e. Involve students in clinical trials with international collaborating universities and institutions
    f. Other activity or service (Please describe.)

APPENDIX II: LETTER OF TRANSMITTAL

APPENDIX III: CONSENT FORM

My name is Geoffrey Onchiri, a student at the University of Nairobi pursuing a degree leading to an award of a Masters in Project Planning and Management. I am carrying a study **"An Assessment of the Factors that Influence the Choice of Type of Clinical Research Design. The Case of University of Nairobi Students**".

You have been selected to participate in this study by filling a questionnaire. You are requested to answer the questions truthfully, this questionnaire requires about 5-10 minutes.

You will not get any direct material gain, the results of these study will help the University and other stakeholders implement decisions in order to provide sufficient opportunities for students in research. The information provided will remain confidential. Your participation in this study is voluntary, refusal from the study has no penalty or loss of benefits to which you are entitled, and you may discontinue from the study at any time.

Incase of any inquiry about this study you can contact the principal researcher, Geoffrey Onchiri Mobile. 0724956095 or email. geomvoi2005@yahoo.com

Participant signature:.....