ASSESSMENT OF THE QUALITY OF LIFE AMONG POST RADIOTHERAPY CERVICAL CANCER SURVIVORS COMPARED TO HEALTHY WOMEN AT THE KENYATTA NATIONAL HOSPITAL: A COMPARATIVE CROSS SECTIONAL STUDY

MPOE EPHRAIM TARAIYA

H58/87324/2016

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

FACULTY OF HEALTH SCIENCES

UNIVERSITY OF NAIROBI

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE IN MASTER OF MEDICINE IN OBSTETRICS AND GYNECOLOGY OF THE UNIVERSITY OF NAIROBI

2021

DECLARATION

I hereby declare that this dissertation is my original work and to the best of my knowledge has not been presented elsewhere for the award of a degree.

Sign _____ Date 19/08/2021

Dr. Mpoe Ephraim Taraiya MBChB

H58/87324/2016

Supervisors' Approval:

This proposal is being submitted with our approval as the University supervisors:

Sign _____ Date 19/8/2021

1. Dr. Anne Kihara MBChB, MMED (Obsgyn) FCOG

Consultant Obstetrician and Gynecologist and Senior Lecturer,

Department of Obstetrics and Gynecology,

University of Nairobi.

Sign _____ Date 19/08/2021

2. Dr. Rose Kosgei MBChB, MMED (Obsgyn), MSC, FCOG.

Consultant Obstetrician and Gynecologist and Senior Lecturer,

Department of Obstetrics and Gynecology,

University of Nairobi.

CERTIFICATE OF AUTHENTICITY

This is to certify that this dissertation is the original work of **Dr. Mpoe Ephraim Taraiya** a Master of Medicine student in Obstetrics and Gynaecology, registration number, **H58/87324/2016,** University of Nairobi. The research was carried out in the Department of Obstetrics and Gynaecology, School of Medicine, College of Health Sciences under the guidance and supervision of Dr Anne Kihara and Dr Rose Kosgei. It has not been presented in any other university for the award of a degree.

DEPARTMENT OF OBSTETRIC AND GYNAECOLOGY
P.O. Box 19676, NAIROBI
Date.....
COLLEGE OF HEALTH SCIENCES
UNIVERSITY OF NAIROBI

Signature: ..... **Date:** 13/09/2021

Professor Eunice K. Cheserem,MBChB, M.MED (OBS/GYN), PGDRM

Associate Professor, Department of Obstetrics and Gynaecology,

Consultant Obstetrician and Gyanecologist,

Chairperson, Department of Obstetrics and Gynaecology,

Faculty of Health Sciences, University of Nairobi.

ACKNOWLEDGEMENT

First of all I thank the Almighty God for granting me the strength, determination, courage, wisdom and good health to enable me successfully complete this dissertation.

To my supervisors, Dr Anne Kihara and Dr Rose Kosgei, thank you for your invaluable input, guidance, mentorship and constructive criticism. This dissertation owes its successful completion to you.

I am grateful to the County government of Nakuru and the Ministry of Health for granting me an opportunity to advance my knowledge at the Department of Obstetrics and Gynaecology University of Nairobi.

My appreciation to the Kenyatta National Hospital and in particular the Departments of Obstetrics and Gynaecology and the Cancer Treatment Centre for granting me access to their departments for data collection.

To my research assistants Sally Wangeci and Martha Maina and Andrew Aballa, my Statistician I am forever indebted to you for your great work collecting and analysing my data.

Special recognition to the University of Nairobi's Department of Obstetrics and Gynaecology faculty members and my fellow postgraduate students for sacrificing their time to offer guidance, feedback and criticism. Above all, thank you for your encouragement.

May the Almighty God bless you abundantly.

DEDICATION

To my wife, Dr. Emma Wangari and my son, Dylan for the companionship, moral support and encouragement during my studies.

To my parents Philip and Leah Mpoe, for all the sacrifices you made to see my siblings and I through school.

To my grandmother Opportuna Nkoyo for raising me up and inculcating in me the importance of honesty, hard work and the fear of the Lord.

Thank you all.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

DEFINITION OF TERMS

Health: The WHO defines health as "a state of complete physical, mental and social well-being not merely the absence of disease or infirmity". The state of 'well-being' can be assessed by the perceived or actual improvement in the quality of life of the individual.

Quality of life: is the state of well-being that is a composite of two components: the ability to perform everyday activities that reflect physical, psychological, and social well-being; and patient satisfaction with levels of functioning and control of the disease.

HRQOL: the subjective perception of the positive and negative aspects of a cancer patient's life and symptoms including adverse effects of treatment and therefore evaluates a subjective health status.

LIST OF ABBREVIATIONS

ANCOVA- Analysis of Covariance

CCSs: Cervical Cancer Survivors.

EORTC- European Organization for Research and Treatment of Cancer

EORTC QLQ C-30- European Organization for research and treatment of cancer quality of life questionnaire

EORTC QLQ CX-24: European organization for research and treatment of cancer quality of life questionnaire cervical cancer module.

FACIT-sp: Functional assessment of chronic illness therapy-spiritual

FACT-G: Functional assessment of cancer therapy general.

HIV- Human Immunodeficiency virus.

HRQOL- Health related quality of life

KNH- Kenyatta National

Hospital LMIC- Low and

Middle Income Countries.

MFI: Multidimensional Fatigue Inventory.

MOH: Ministry of Health.

PI: Principal Investigator.

PROs: Patient Reported Outcomes.

PS: Performance scores.

QOL- Quality of life

RA: Research assistant.

STAI: Spielberger State Anxiety Inventory.

UoN -University of Nairobi

WHO -World Health Organization.

WHOQOL BREF: world health organization quality of life questionnaire

ABSTRACT

Background: Cervical cancer is the fourth commonest malignancy of women globally. Most patients present with advanced disease whose mainstay of management is chemo-radiotherapy. Chemo-radiotherapy has both short and long-term effects that affect the quality of life (QOL) of survivors. No local studies have evaluated QOL of CCSs given these complications.

Objective: To compare the QOL of post-radiotherapy cervical cancer survivors and healthy women attending the reproductive health services clinic at the Kenyatta National Hospital.

Methodology: A comparative prospective cross-sectional study of 103 post-radiotherapy cervical cancer patients and 107 cancer-free women attending the reproductive health services clinic at KNH was done between May and July 2019. Systematic sampling was used to recruit study participants and data collected using the EORTC QLQC30 questionnaire. The demographic characteristics of patients were captured, and five functional scales of QOL (physical, role, cognitive, emotional, and social), three symptom scales (nausea, pain, and fatigue), and five single items (dyspnea, insomnia, appetite loss, diarrhea constipation) were evaluated. Data analysis was done using v21 of the statistical package for social scientists (SPSS). Summary statistics for demographic data were computed. The Mann-Whitney U test and Kruskal Wallis test were used to calculate within and between-group comparative analyses of QOL scores and the Analysis of Covariance (ANCOVA) use to control confounding. Analyses were at 95%CI. A $P<0.05$ was significant.

Results: Two hundred and ten patients aged 22-80 years [range 22-80 among cancer survivors and 22-59 among healthy women] were recruited. A majority of cervical cancer survivors were aged 51-60 (36.3%), married (68.0%), unemployed 80.3%), and had a primary level of education (62.1%). A majority had stage 2B of cancer (35.9%), were treated with chemo-radiotherapy (75.4%), and had a post treatment duration of <2 years after (72.0%). Fewer cervical cancer survivors than healthy women had a tertiary level of education [OR (95%CI) = 0.0(0.0-0.02), p=0.01] or were married [OR (95%CI)

=0.7(0.4-1.6), p=0.48]. The odds of unemployment and grand multiparity were 8.6 times and 51 times higher among cervical cancer survivors ($p<0.05$). The QOL scores for cervical cancer survivors for GHS (64.7 and 78.3), Physical (87.6 and 92.2), Role (85.6 and 95.6), Emotional (82.0 and 88.6), Cognitive (81.1 and 90.5), and social functioning (65.1 and 93.2) were significantly lower among cervical cancer survivors compared to healthy women ($p<0.05$). The scores for symptoms such as fatigue (20.5 and 11.1), pain (25.2 and 11.8), and appetite loss (14.5and 6.5) were significantly higher among cancer survivors than healthy women ($p<0.05$).

Conclusion: The QOL of cervical cancer survivors is significantly lower than healthy women.

Keywords: Quality of Life, cervical cancer, EORTC QLQC30, radiotherapy

CHAPTER ONE

1.0 INTRODUCTION

1.1 Epidemiology of Cervical cancer

Cervical cancer is the fourth commonest malignancy amongst women worldwide and the seventh commonest among all malignancies with 528,000 women diagnosed annually with approximately 85% in LMIC (1). It is responsible for causing 266,000 deaths globally with the vast majority (87%) in developing countries (1). The incidence of cervical cancer is steadily increasing in sub-Saharan Africa with 75,000 new cases and more than 50,000 deaths annually. The eastern Africa region has the highest age standardized incidence and mortality rates of cervical cancer.

In Kenya and the greater Eastern Africa region cervical cancer is the 2nd commonest malignancy in women with 4,802 new cases and 2,451 deaths annually(2). Majority of these cases are diagnosed late with 80.5% presenting with stage >/=IIB(3)(4) disease where the mainstay of treatment is chemoradiation. This mode of treatment is associated with both acute and late side effects that negatively impact on the CCSs QOL by affecting their general health status and ability to carry out activities of daily living. Advanced stage disease is also often chronic and incurable with a high risk of recurrence significantly affecting QOL(5).

In a study conducted by Maranga et al titled Analysis of factors contributing to the low survival in cervical cancer patients undergoing radiotherapy in Kenya, the mean age of diagnosis of cervical cancer is 49 years with 28.2% of patients aged between 40-49 and a peak incidence at 47 years (37 in HIV positive patients)(3). The same study found that the histologic varieties were 90% squamous cell carcinoma and 5.6% adenocarcinoma with well, moderately and poorly differentiated accounting for 21%, 39.2% and 32% respectively.

The overall cervical cancer survival in the developed world where the rate of early screening and management is high is approximately 68% with 5 year stage specific survival rates of 80-90%, 50-65%, 25-35% and 15% for stages I, II, III and IV respectively with a median survival of 43 months(6)(7). This is however not the case in Kenya(8) with a median survival of 15.1 months and stage specific median survival durations of 21, 18,15 and 11 months for stages I, II, III and IV respectively. This discrepancy could be explained by late detection of disease,

inaccurate clinical staging, high prevalence of anemia necessitating transfusion and the high burden of HIV.

HRQOL covers the subjective perception of the positive and negative aspects of a cancer patient's life and symptoms including adverse effects of treatment and therefore evaluates a subjective health status. In this regard HRQOL is as important as the overall survival in the formulation of treatment decisions.

A good QOL is said to be present when the hopes and expectations of an individual are matched and fulfilled by their experiences. Thus to improve on the patient's QOL there is need to narrow the difference between hopes, dreams and actual real life happenings for each patient. Others have described QOL as representing the functional effect of an illness and its consequent therapy upon the patient as perceived by the patient (9). QOL can also be expressed as patient perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns (10). These varied definitions show that QOL is very subjective and varies from patient to patient and is highly influenced by factors such as culture, religion, societal norms etc.

A new concept in management of gynecologic malignancies currently aims not only at saving life, achieving tumor control, overall survival and disease free survival but also on the effect of treatment on the survivor's QOL(11). However few local studies have compared QOL with that of healthy women which would provide greater insight into the change in QOL and aid in the formulation of QOL target levels(12). QOL consideration plays an important role in exploring pertinent precautions and in evaluating the quality of medical health service. It also meets the novel medical goal proposed by WHO of preventing and treating disease, prolonging survival, increasing QOL, reducing death rate, and promotion of mental and physical health.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Assessment of QOL among cancer patients

A systematic literature review established that HRQOL is multidimensional and its assessment should therefore be undertaken with multidimensional instruments as uni-dimensional instruments are insufficient and do not collect all relevant information. These tools can be broadly classified into 4 categories(13): generic, cancer specific, cancer site specific and survivor specific instruments. This study will employ the EORTC questionnaires which have been validated in cervical cancer patients, there are plenty of studies for comparison and are easy to administer.

Generic instruments include the short form of medical outcome study questionnaire (SF-36), quality of life index (QLI), European QOL scale- 5 dimensions (EQ5D) and the abbreviated version of World Health Organization QOL questionnaire (WHOQOL BREF). These tools assess the general aspects of QOL. They assess the general health status of respondents and are useful for comparisons with the general population.

Cancer specific tools assess the QOL of cancer patients as a whole. They include the Cancer rehabilitation evaluation system short form (CARES-SF), The European organization for research and treatment of cancer QOL questionnaire (EORTC QLQ-30) and the Functional assessment of cancer therapy general (FACT-G) questionnaires. The FACT-G and EORTC QLQ-30 have both demonstrated high reliability with Cronbach's coefficients >0.7 and have been shown to be more appropriate and incorporate adaptive and coping mechanisms(14).

Cancer site specific tools are specifically designed to assess cancers afflicting specific organs. As regards cervical cancer they include the EORTC cervical cancer module (EORTC CX-24), The FACT cervical cancer module (FACT-Cx) and the QOL instrument for cancer patients-cervical cancer (QLICP-CE). They are specifically designed to assess the QOL in cervical cancer patients and the effects of its treatment. They are however used in conjunction with their corresponding cancer specific tools. The FACT-Cx is a 42 item tool with 27 of the questions from the FACT-G and 15 additional questions.

The routine use of these tools in clinical care improves communication and interaction between the physician and the patient and could potentially improve care. This is as a result of the incorporation of the patients' perspective in the formulation of their care plan. It also gives the patient a greater understanding of effects of treatment on their QOL which ultimately ensures informed decision making(15). A randomized controlled trial also demonstrated that patient reported outcomes (PROs) can be taken into account during stratification as they're better predictors of survival as compared to performance scores (PS)(16). Such information is particularly important in those patients with limited survival and for whom the goals of treatment are to lengthen survival while at the same time improving or maintaining the QOL. Studies have also demonstrated that the HRQOL especially the physical, functional and mental domains significantly affect overall survival(17,18). This calls for the incorporation of QOL measures in the planning and follow up of therapy in cancer patients in addition to other clinical variables.

This study will employ the EORTC questionnaires which have been validated in cervical cancer patients, there are plenty of studies for comparison and they are easy to administer.

2.2 Global situation: Assessment of Quality of Life among Cancer Survivors

A study in Thailand comparing the QOL of life of gynecologic cancer survivors at least 6 months post treatment with that of healthy controls found that the subscale scores measuring physical, family/social, emotional and functional well-being were higher in the patient group compared to the healthy group. This translates to a positive effect of recovery from treatment on the QOL. This could be explained by patients adapting to their life circumstances through modification of their values, internal standards, and own conceptualization of QOL over time, a phenomenon called "response shift". Higher education levels and having the husband as the caregiver correlated with higher QOL scores while financial difficulties had a negative effect on the QOL(19). These findings were replicated in a second Thai study comparing the QOL of CCSs to that of healthy controls. The patient group demonstrated higher scores in emotional/social functioning, global health scores and lower physical/role functioning, appetite loss and financial difficulties (20).

A study on the QOL and sexual function of 860 cervical cancer survivors (CCSs) compared to 494 healthy controls by Park et al in Korea found similar scores in majority of the domains in both groups. However survivors reported more constipation, diarrhea, financial difficulties and poorer social functioning. Radiotherapy recipients had worse emotional functioning, peripheral neuropathy and dyspareunia. In addition to this CCSs reported greater symptoms, reduced vaginal and sexual functioning, poorer body image, greater sexual worry, menopausal features, lymphedema and sexual performance related anxiety compared to controls(12).

Bergmark et al compared vaginal changes and sexual function of 247 CCSs to that of 330 controls with no history of cancer in Sweden and found greater dyspareunia, inadequate lubrication, shortened vagina and reduced vaginal elasticity in the survivor group resulting in greater distress. There was however no difference in the rate of orgasms(21).

A comparative Danish study investigated the psychological and social effects in advanced cervical cancer after radiotherapy with that of healthy controls. This data was collected at the completion of treatment and at 1, 3, 6, 12, 18 and 24 months post treatment. Depression and worry were found high initially but leveled off to match that of controls at 6 months with 50-60% of the respondents reported to be irritable at any time. The ability to remember was similar to that of controls suggesting that there were no disease or treatment related effects on memory. Role functioning was generally lower than that of controls at all times but was found lowest initially on completion of therapy and at 1 month post treatment. The QOL scores were lower for the cervical cancer group but progressively improved reaching their maximum at 18 months post therapy. The concern for disease was however high throughout the follow up duration(22).

Le Borgne et al conducted a study in France to assess the long term QOL in CCSs (173) at 5, 10 and 15 years post therapy and compared the scores with healthy controls (594). 5 QOL questionnaires were administered to the respondents: SF-36, EORTC QLQ C30, QLQ CX 24, MFI and STAI for anxiety. Majority of the survivors had received combination therapy. At 15 years post therapy majority of the CCSs had greater mental fatigue, lymphedema and symptom experience; with reduced global health status, lower emotional functioning while sexual functioning improved over time. Patients who had undergone both surgery and

adjuvant therapy had worse QOL while low income and the presence of at least 2 comorbidities had a negative effect on the QOL. Overall both the cases and controls had a good similar QOL, however the CCSs had a poor psycho-emotional domain with radiotherapy recipients suffering from greater physical complications(23).

2.3 African situation: Assessment of Quality of Life among Cancer Survivors

A study in Khartoum set out to assess the subjective QOL of stable women cancer outpatients and their caregivers and the factors associated with QOL using the WHOQOL-BREF questionnaire(24). It also compared their QOL to that of psychiatric and diabetic patients. The study sample included patients with cancer of the breast, ovary and cervix. The results showed the QOL of the patients was lower than that of caregivers but higher than that found in diabetic and psychiatric patients. The variables associated with a higher QOL amongst the cancer patients were higher educational level (at least high school), married status, better employment, care by a spouse and a longer duration of illness. The patients who had received radiation therapy had higher physical health, psychological, spiritual and social relations scores.

In addition to this, patients who were currently ill and those who'd been ill for a longer duration had lower scores.

A Moroccan study compared the QOL of cervical cancer survivors 5-10 years after diagnosis to that of healthy controls and the socio-demographic predictors of the quality of life(25). The EORTC QLQ30 and CX24 together with the Functional assessment of cancer therapy-spiritual (FACT-Sp) questionnaires were administered to the study participants. The emotional functioning of the survivors was deranged in comparison to that of the controls while the role, social and physical functioning were comparable. The commonest reported symptom was pain with financial difficulties also prominent. The rate of constipation was also higher in the patient group. There was also a finding of greater lymphedema, lower body image contentment with higher vaginal dryness and hot flushes rates in the patient group. Advanced tumor stage, brachytherapy, change of marital status after diagnosis and brachytherapy had a negative effect on the QOL. Spiritual well-being on the other hand had a positive effect on the QOL. This study was limited by the nonresponse to some of the sexuality questions.

A South African study at the University of Stellenbosch evaluated demographic characteristics and QOL of HIV positive women with cervical cancer(26). They found no improvement in insomnia, nausea, vomiting, sexual function or social role among the HIV positive patients with HIV negative patients having better improvement in physical, emotional, social and cognitive function as compared to the positive patients. The global health score was also greater in the HIV negative category. Peripheral neuropathy in HIV positive patients improved post therapy but returned to pretreatment levels at 3 months. The seropositive patients were generally younger (by 7 years), had higher education and had a higher rate of unemployment.

2.4 Kenyan situation: Assessment of Quality of Life among Cancer Survivors

No local comparative studies have been conducted. However several studies evaluating the QOL of cervical cancer patients have been done. A study at KNH evaluated the determinants of QOL among gynecological oncology survivors attending palliative care with 56% of the respondents being cervical cancer patients(27). The QOL was measured using the Missoula vitas QOL index (MVQOLI). Patients who were formally employed, >65 years, earning >Ksh 10,000 and attained at least high school education had better QOL scores. However, married patients had lower total QOL and psychological scores. Recipients of radiotherapy had the lowest scores with surgical patients having the best.

A second study done at KNH set out to determine the burden of psychosexual dysfunction in patients post radiotherapy for cervical cancer by measuring the vaginal length post radiotherapy, sexuality , sociodemographic factors associated with the same and the measures taken by patients to reduce the adverse effects of radiotherapy(4). Only 38% of the respondents engaged in sexual activity post radiotherapy with marital status (married), education level (high) and sexual activity pre radiotherapy being the most significant determinants of activity post radiotherapy. 48% had worse sexual function overall with 66.3% reporting a subjective reduction in the vaginal length, dyspareunia in 60.5% and a reduced sexual desire in 62.8%. on measurement all women had a stenotic vaginal canal with younger women more likely to have a longer vaginal canal. Married respondents and those engaged in sexual activity also had a longer canal. Majority (74.2%) didn't have any counseling on sexuality with only 6.6% reporting using any measures to reduce radiotherapy side effects.

A similar study assessing the QOL of patients undergoing radiotherapy for inoperable cervical cancer at KNH using the EORTC QLQ C30 showed that all aspects of functions were affected with poor overall health and QOL. Majority of the patients also reported overwhelming financial difficulties; a third had a low self-esteem while only 13 % were still interested in sexual activity. However majority of the patients had a good social support network either from children, spouse, family, friends or other groups such as churches. Only 14% had an excellent overall QOL(28).

2.5 Appropriateness of comparison model, relevance and Utility

By comparing the QOL of CCSs to that of healthy women a baseline level can be established upon which target QOL levels can be set for our local setting(12). Additionally the information derived from this study will help in the formulation of measures that will help mitigate against the negative effects of radiotherapy on the survivor's QOL. Lastly information gathered from this study will help guide patient decision making while enrolling for therapy.

Comparison with healthy women also enables the assessment of the degree of disruption and deterioration in the quality of life that is directly attributable to cervical cancer and its management by radiotherapy and not merely due to the pre-existing, social, economic, cultural and religious circumstances. This will in turn be useful during pretreatment counseling of patients enabling them prepare adequately to deal with the effects of treatment and set realistic goals of therapy.

2.6 Study Justification

Cervical cancer is the commonest gynecological malignancy in Kenya and also affects women in the reproductive age groups. With majority of our patients (80.5%) presenting with advanced stage disease the mainstay of management is chemo-radiotherapy. A diagnosis of cancer is associated with psychological challenges such as anger, fear, sadness, anxiety, depression and guilt in addition to social stigma. Reproductive performance, sexuality and body image are also affected by the disease.

While the recommended management for advanced cervical cancer is combination of chemotherapy and radiotherapy, these are associated with both early and late toxicities involving the bladder, rectum and loss of fertility which cause significant patient distress. These factors combined, negatively affect the quality of life of CCSs. However despite this there is still scant knowledge regarding this subject especially in our local setting. None of the local studies has compared CCS QOL to that of healthy controls.

In addition to this previous studies have not used any cervical cancer specific questionnaire which enables the evaluation of the adverse effects of therapy.

Healthcare practitioners focus on physical complaints and rarely inquire about the patients' QOL. This is as a result of lack of time to fully explore QOL issues, inadequate training on matters related to QOL, personal discomfort due to cultural/religious issues and lack of knowledge on the availability of effective treatment strategies to manage such issues.Patients on the other hand rarely raise such issues with their physicians due to fears/concerns that the physician will be uncomfortable, fear of being dismissed and perception that there is no treatment for their problems.

The goal of this study therefore is to assess the QOL of these patients and help in formulation of activities to help improve care, modify therapy if possible and offer appropriate supportive care. Comparison with healthy women will also aid in the setting of targets for cancer patients during planning of treatment. By comparing with healthy women we will be able to establish the effect of cervical cancer and its therapy on the survivors QOL.

2.7 Conceptual Framework

2.7.1 Narrative

A diagnosis of cervical cancer causes psychological challenges such as anxiety, guilt, anger, depression and sadness coupled with worries regarding loss of fertility, sexual dysfunction and body image with feelings of unattractiveness and being 'unwhole'.

The standard management for advanced cancer of the cervix and high risk early stage disease is concurrent chemo-radiotherapy with both external beam and intra-cavitary radiotherapy. However in our set up majority of the patients don't receive this (3). Radiotherapy is

associated with short term and long term adverse effects such as bladder and bowel dysfunction, sexual dysfunction, menopausal symptoms, lymphedema which all negatively affect QOL. Additionally definitive management is not commenced immediately patients are referred to the radiotherapy unit as a result of the high volume of patients seen at the facility coupled with the few radiotherapy machines and staff available. This creates a backlog. Financial challenges also contribute to this delay.

Furthermore treatment interruptions are not uncommon due to machine breakdown and development of adverse effects that necessitate halting of the treatment. These adverse effects include anaemia, neutropenia and severe gastrointestinal and urinary complaints. Such interruptions have been shown to have a negative effect on the prognosis and QOL.

Social and demographic factors such as age, marital status, possession of health insurance, educational level and family income also have an impact on the expected QOL. The FIGO stage not only affects prognosis and overall survival but also the QOL. Other important clinical variables are coexistent morbidities such as HIV. Lastly the waiting time from diagnosis to mapping, initiation of therapy to completion also impacts on the survivors QOL.

2.7.2 Diagrammatic

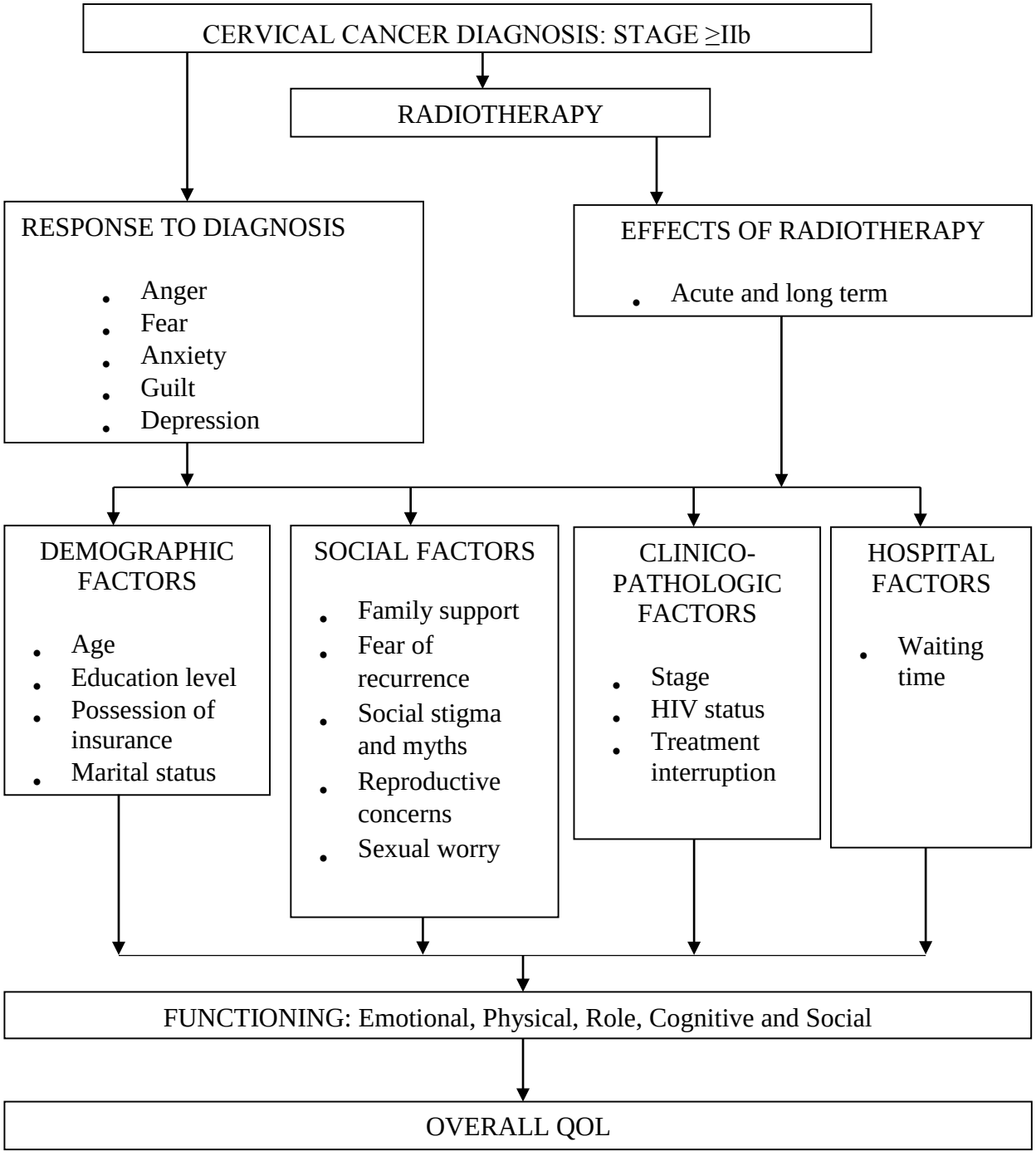

Figure 1: Conceptual framework

2.8 Research Question

What is the quality of life of post radiotherapy cervical cancer survivors at the KNH radiotherapy unit compared to that of healthy women attending the KNH reproductive health services clinic?

2.9 Objectives

2.9.1 Broad objective

Using the EORTC tool, to assess the Quality of Life of post radiotherapy cervical cancer survivors at the KNH radiotherapy unit compared to that of healthy women attending the KNH reproductive health services clinic

2.9.2 Specific objectives

Using the EORTC tool:

1. To assess the Quality of Life among cervical cancer survivors attending the radiotherapy clinic at the Kenyatta National Hospital
2. To assess the Quality of Life among healthy women attending the reproductive health services clinic at the Kenyatta National Hospital
3. To compare the Quality of Life among post radiotherapy cervical cancer survivors attending the radiotherapy clinic with healthy women attending reproductive health services clinic at the Kenyatta National Hospital

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

This was a hospital-based comparative cross sectional study in which the QOL of post radiotherapy cervical cancer survivors at the KNH radiotherapy unit was assessed and compared to that of healthy women attending the reproductive health services clinic.

3.2 Study setting

The study was carried out at the Radiotherapy and the reproductive health services (clinic 66) units of Kenyatta National Hospital Nairobi. The KNH offers both preventative and curative services for a variety of illnesses, to patients from all over Kenya. It has a bed capacity of 1800. It is also the largest referral hospital in the country and the main public hospital that offers radiotherapy services in the entire country supplemented by other public and private facilities. The unit offers both external beam radiotherapy and brachytherapy to cervical cancer patients in addition to providing radiotherapy services to other disciplines. It is manned by radio-oncologists, postgraduate students, nuclear physicists, technicians and nurses. There's also an outpatient clinic where newly diagnosed patients are seen and prepared for therapy and patients who have completed radiotherapy are followed up. Approximately 15 to 20 new cervical cancer patients are enrolled for radiotherapy every Monday with an average of 120 patients receiving radiotherapy daily in two shifts. Each patient undergoes a total of 25 radiotherapy sessions over a 5 week period concurrently with weekly chemotherapy. The reproductive health services clinic (clinic 66) offers a variety of sexual and reproductive health services including family planning and cervical cancer screening. It is manned by gynecologists, reproductive health residents and nurses.

3.3 Study population:

Post radiotherapy cervical cancer survivors on follow up at the KNH radiotherapy unit and healthy women seeking reproductive health services at Clinic 66. The CCSs enrolled were those who met the inclusion criteria.

Healthy women were clients who had presented to the unit for reproductive health services such as contraception, screening etc. To be enrolled as part of the healthy group the women must have had no health complaints on presentation, had normal physical examination findings, had no chronic medical condition and had no history of management for any malignancy.

3.4 Sampling and sample size

Sample size calculation was done using the following Fleiss formula:

$$\text{Sample size} = \frac{r+1}{r}\frac{(p^*)(1-p^*)(Z_{\beta}+Z_{\alpha/2})^2}{(p_1-p_2)^2}$$

r = the ratio of controls to cases (1)

P* = measure of variability = proportion cases + proportion controls/2 = 0.085 Khalil et al (25)

Z_{β}=Value corresponding to the power of the study, in this case 80% = 0.84

$Z\alpha$ = Value corresponding to the normal standard deviate at 95% C.I in this case = 1.96, with 0.05 level of significance

P1 = proportion of participants with outcome of interest among cases

P2 = proportion of participants with outcome of interest among controls

P1-P2 = effect size (difference in proportion of cases (0.14) and controls (0.03)

In the Moroccan study by Khalil et al 14% of the cervical cancer survivors reported a positive symptom experience compared to 3% in the healthy comparison group.
Therefore:

Sample size = (2/1) (0.085) (1-0.085)

$(0.84+1.96)^2/(0.14-0.03)^2 = 100$

Unmatched Cohort and Cross-Sectional Studies (Exposed and Nonexposed)

Two-sided confidence level: 95%

Power: 80 %

Ratio (Unexposed : Exposed): 1

% outcome in unexposed group: 3 %

Risk ratio: 4.66667

Odds ratio: 5.26357

% outcome in exposed group: 14 %

	Kelsey	Fleiss	Fleiss w/ CC
Exposed	101	100	118
Unexposed	101	100	118
Total	202	200	236

In total, 200 subjects, 100 cervical cancer survivors and 100 healthy women, were needed for our study. This was adjusted by a factor of 10% to cater for non-responders. Thus, 220 subjects, 110 survivors and 110 healthy women, were recruited. To recruit participants of our study consecutive non-probabilistic sampling was used. Survivors who met our inclusion criteria were recruited sequentially until we got the desired number. The same process was used to select comparator group.

3.4.1 Sampling procedure

For the 220 participants, simple random sampling was used to select the study participants. For either of the study groups, health talks were held by the Principal Investigator (PI) or Research Assistant (RA) at the respective clinics to sensitize the patients and healthcare workers about the study. Patients who satisfied the inclusion criteria were identified during the clinic visits and enrolled into the study. On average, 10 participants were enrolled on each of the clinic days.

3.5 Recruitment and consenting

A cross-sectional evaluation of quality of life post radiotherapy treatment for cervical cancer compared to healthy women attending the well woman clinic was done. A summary of the inclusion and exclusion criteria is as shown in the table below:

Table 1: Study enrollment criteria for the study group (cancer survivors)

Inclusion Criteria	Exclusion Criteria
• Cervical cancer post radiotherapy at least 3 months • No other history of cancer	• Patient with recurrent disease • Patient with other cancers other than cervical cancer

Table 2: Study enrollment criteria for the comparison group (Healthy volunteers)

Inclusion Criteria	Exclusion Criteria
• Healthy cancer free women with no morbidity attending the reproductive • Healthy women with normal physical examination findings	• Patients with history of psychiatric illness • Patients with a chronic medical condition health services clinic for contraceptive and cervical cancer screening services.

As shown in the diagram below, upon verbally accepting to participate in the study following the health talk, all potential study participants were escorted to a private room within the clinic. The study procedure was explained to them individually including the benefits, harm and procedure including the final results dissemination. From here, the written consent, both in English and Swahili, was obtained by either the PI or RA. Those who declined further participation were excluded from the study. Patients with cervical cancer: All the women who consented and met the inclusion criteria were recruited until the sample size was achieved. The files of each participant interviewed were marked with a code to avoid re-interviewing.

3.6 Variables and Confounders

The demographic and clinical characteristics of the study participants were analyzed with the main study variables being qualitative;

Table 3: Study variables

Objective	Exposure variable	Outcome variable	Sources of data
Socio-demographic and reproductive characteristics	-Age -Marital status -Education level -Employment status -Parity		-Questionnaire. -patients files.
Clinical characteristics	-FIGO Stage -Histology -Emergency radiotherapy -Treatment interruption		Questionnaire Patient files
	-Comorbidities		
QOL of cervical cancer survivors versus healthy women		Physical, cognitive, role, emotional and social functioning; Global QOL.	EORTC QOL Questionnaires.

3.6.1 QOL of cervical cancer survivors post radiotherapy:

This was assessed using the EORTC QLQ C-30 and then converted to a final score of 0-100 using the EORTC scoring manual.

3.7 Data collection and management

Data was collected using 2 sets of questionnaires. The socio-demographic and clinical parameters were collected from the patients' files using a questionnaire designed by the investigator. Any missing information was corroborated from the patients. The QOL data on the other hand was collected using the EORTC-general cancer QOL questionnaire (QLQ-C30) using both its English and Swahili versions.

These questionnaires have been extensively tested in multicultural and multidisciplinary settings and have been confirmed to be reliable and valid. The EORTC QLQ C-30 comprises

thirty questions which include five functional scales (role, cognitive, social, emotional, physical and role); three symptom scale for pain, fatigue, nausea and vomiting; six single items for dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial impact, and a global health status score which assesses the overall QOL. Each of the multiitem scales includes a different set of items – no item occurs in more than one scale. The EORTC QLQ C30 questionnaire uses a four-point Likert response scale (not at all, a little, quite a bit, and very much) to assess each functional or symptom item, while a seven-point response scale is used to assess global health status (from very poor to excellent). The categorical raw scores were linearly transformed into a score of 0–100 for processing according to the EORTC scoring manual. A high scale score represents a higher response level. The higher scale score for the functional scale or the global health status/QOL represents a higher level of functioning or higher QOL, whereas the higher level of symptoms/problems for the symptom/item scales represents a higher level of dysfunction.

3.8 Materials

Stationery, questionnaires, data storage files, password protected computers, hard drives and flash drives.

3.9 Quality assurance

The following measures were taken for quality assurance throughout all the stages of the study.

a) Data obtained from the records and files was confirmed from the participants and relevant health care providers
b) Data was stored in password protected computers, hard drives and flash drives to ensure confidentiality and accessible to only the principal investigator, supervisors and statistician
c) Quiet comfortable rooms were used for the interviews at the participant's convenience.
d) The participant were interviewed using Kiswahili, English or both versions which facilitated understanding and accurate responses

3.10 Analysis

Data was entered and cleaned up using SPSS database with cross checking with the recorded interviews to ensure accurate information. The incomplete data was excluded from the analysis. These were stored in password protected hard drives and limited access computers.

Data was analyzed using the Statistical Package for Social Sciences (IBM SPSS version 21) and presented as frequencies, percentages, Odds ratios, bar graphs and charts. The socio-demographic characteristics of the two groups were compared and presented as proportions, percentages in tables. To assess the QOL among cervical cancer survivors and the healthy women in the comparison group, the scores of the EORTC tools are presented as means with outcomes categorized as either low or good quality of life.

The Cochran-Mantel-Haenszel method was used to estimate the association between cervical cancer post radiotherapy and quality of life and healthy controls and quality of life after adjusting for confounding factors such as age, socio economic status and level of education. Multi variate analyses of the various factors such as age, with psychosocial status and quality of life. Chi Square test of association used to establish the association between cervical cancer and quality of life of women. A statistical significance will be set at $P < 0.05$.

3.11 Ethical considerations

The study was submitted to the Kenyatta National Hospital/ University of Nairobi ethics review committee (KNH/UON ERC) for ethical approval before commencing the recruitment. Permission was also sought from the University of Nairobi department of Obstetrics & Gynecology and the KNH administration before the study commencement.

The following ethical issues were considered.

- Informed consent was obtained from the participants after informing them about the study objectives and benefits.
- Confidentiality and anonymity was maintained by making sure no identifier information such as name, patient number will be collected. Clients will be assigned codes. In addition all the information collected was stored in cabinets under lock and

key while the transcribed data was stored in password protected computers and flash drives only accessible to the principal investigator and research assistants.

- Failure to provide informed consent to participate in the study did not compromise the quality of care received and the respondents reserved the right not to answer uncomfortable questions.
- Benefits: the study has generated data which will be useful in the formulation of follow up and supportive protocols for cervical cancer patients post radiotherapy. There were no potential risks to the study participants as no invasive procedures will be undertaken.
- Participants seeking to withdraw from the study were allowed to do so.
- Patients found to have a low QOL were linked to a social worker while those with physical symptoms were referred for appropriate management.

3.12 Study limitations

Long term/longitudinal follow-up to assess the evolution and change of the QOL over time was not possible due to time constraints. It wasn't possible to evaluate the pre-treatment QOL as this was a crosssectional study. Some records were missing from the patients files.

CHAPTER FOUR

4.0 RESULTS

A total of 210 women were included in the final analysis, 103 cervical cancer survivors and 107 healthy cancer free women.

4.1 Study Flow chart

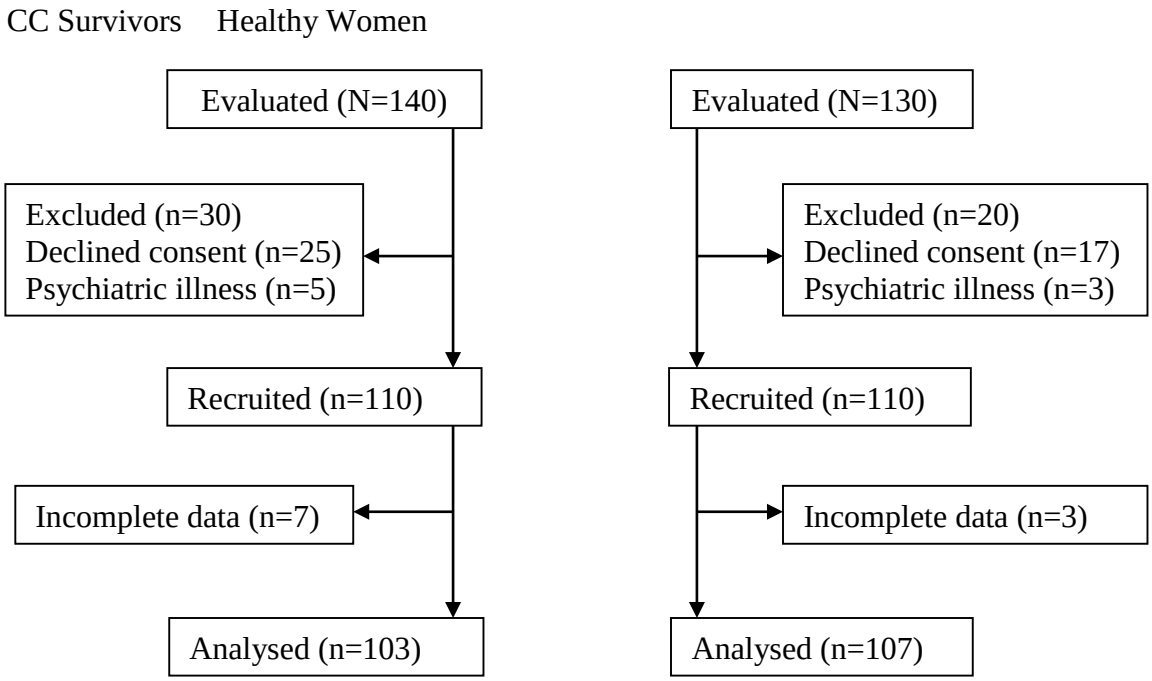

Figure 2: Study flow chart

4.2 Demographic Characteristics

The mean age of cervical cancer survivors was 53.6 years: range 28-80 years, and median 53 years. Thirty-seven (36.3%) were age group 51-60 years, while majority, seventy (68.0%) were married. Sixtyfour (62.1%) of the CCSs attained had primary level education with Ninety-one (88.3%) lacking any form of employment and 11.7% (12/103) employed. The mean parity for cervical cancer survivors was 4.93 (SD=2.2) with 64 (62.7%) being multiparous Sixty-four.

The mean age of healthy cancer free women was 37.6 years, with majority, Thirty-eight (39.2%) aged between 41-50 years and more than half, Fifty-eight (54.7%) having attained tertiary level education. Their level of unemployment was Fifty (46.7%). Obstetrically the Mean parity was 2.39 (SD=1.34) with Eighty-six (92.5%) being nulliparous.

Cancer survivors were 8.7 (1.9-40) and 81 (15-456) times likely to be age group 41-50 and 51-60 years with reference to the <30 age group than cancer-free women. The marital status was comparable, while more cancer free women were likely to have a secondary p<0.01 and tertiary P<0.01 education and any form of employment p<0.01 (Table 4).

Table 4: Comparison of demographics

	CC Survivors n (%)	Healthy women n (%)	OR	95% CI	P
Age Group	102	97			
<30	2 (2.0)	22 (22.7)			Reference
31-40	8 (7.8)	32 (33.0)	2.8	0.53-14	0.21
41-50	30 (29.4)	38 (39.2)	8.7	1.9-40	<0.01
51-60	37 (36.3)	5 (5.2)	81	15-456	<0.01
60+	25 (24.5)	0 (0.0)			Na
Marital Status	103	107			
Single	22 (21.4)	20 (18.7)			Reference
Married	70 (68.0)	81 (75.7)	0.79	0.40-1.6	0.48
Divorced	4 (3.9)	3 (2.8)	1.2	0.24-6.1	0.81
Separated	7 (6.8)	3 (2.8)	2.1	0.48-9.3	0.31
Education Level	103	106			
Primary	64 (62.1)	7 (6.6)			Reference
Secondary	25 (24.3)	41 (38.7)	0.07	0.02-0.17	<0.01
Tertiary	3 (2.9)	58 (54.7)	0.00	0.0-0.02	<0.01
None	11 (10.7)	0 (0.0)			Na
Employment Status	103	107			
Employed	12 (11.7)	57 (53.3)	0.12	0.05-0.24	<0.01
Not Employed	91 (88.3)	50 (46.7)	8.6	4.2-18	<0.01
Parity	102	93			
Nulliparous	0 (0.0)	6 (6.5)			Na
Multiparous	64 (62.7)	86 (92.5)	0.02	0.00-0.15	<0.01
Grandmultiparous	38 (37.3)	1 (1.1)	51	6.8-382	<0.01

The commonest disease stage at diagnosis was stage IIB reported by Thirty-seven (35.9%) patients with majority having undergone combined therapy with external beam radiation and chemotherapy (75.4%). Most of the clients had a post treatment duration of <2years at 72.0%

(72/100) of cases with Sixty (58.3%) requiring emergency therapy and 20.4% (21/103) having had their treatment sessions interrupted (Table 5).

Table 5: Treatment Characteristics of cervical cancer survivors

	N	%
Stage of cancer	103	
1A	2	1.9
1B	19	18.4
2A	12	11.7
2B	37	35.9
3A	14	13.6
3B	14	13.6
4A	5	4.9
Treatment	65	
Chemoradiotherapy	49	75.4
EBT + Brachytherapy	9	13.8
EBT only	6	9.2
EBT + Brachytherapy + Chemotherapy	1	1.5
Emergency Radiotherapy	103	
Yes	60	58.3
No	43	41.7
Treatment sessions Interrupted	103	
Yes	21	20.4
No	82	79.6
Time since completion of treatment	100	
< 2 years	72	72.0
2-4 years	13	13.0
>4 years	15	15.0

4.3 Chronic conditions

Thirty-eight cervical cancer survivors (36.9%) reported at least one of four chronic conditions. Of the 38, HTN was reported by 55.3% (21/38); while 28.9% (11/38), 18.4% (7/38), and 2.6% (1/38) reported having HIV, Diabetes Mellitus (DM), and CKD respectively (Table 6).

Table 6: Chronic Conditions of cervical cancer survivors

	N	%
	103	
Chronic Conditions	38	36.9
HTN	21	55.3
HIV	11	28.9
Diabetes Mellitus	7	18.4
CKD	1	2.6

4.4 Support system

Ninety-five (92.2%) respondents reported having received some counseling prior to initiation of treatment, while 86.4% (89/103) reported having good family support (Table 7).

Table 7: Support systems of cervical cancer survivors

	N	%
	103	
Counselling	95	92.2
Family Support	89	86.4

4.5 Quality of life

4.5.1 Cervical cancer survivors

The QOL score for cervical cancer survivors on global health status/QOL was 64.7±22.9: range 0-100, and median 66.7. The QOL score for the physical functioning was 87.6±18.6: range 0-100 and median 93.3. The QOL score for the role functioning was 85.6±25.0: range 1-117 and median 100. The QOL score for the emotional functioning was 82.0±20.2: range

25-108 and median 91.7. The QOL for cognitive functioning was 81.1±19.8: range 17-100 and median 83.3. The QOL for social functioning was
65.1±32.0: range 0-100 and median 66.7 (Table 8).

Table 8: Quality of Life of cervical cancer survivors

	N	Mean	SD	Median	Min	Max
Global Health Status/QOL	103	64.7	22.9	66.7	0	100
Physical Functioning	103	87.6	18.6	93.3	0	100
Role Functioning	103	85.6	25.0	100	0	117
Emotional Functioning	103	82.0	20.2	91.7	25	108
Cognitive Functioning	103	81.1	19.8	83.3	17	100
Social Functioning	103	65.1	32.0	66.7	0	100

4.5.2 Factors Influencing Global Health Status/QOL

The Global Health Status scores differed by the education level, $p<0.01$, employment status, $p<0.01$, and family support, $p=0.02$ of participants. The GHS scores for women with a tertiary education 80.8±19.3 were higher than of women with no formal education 53.3±23.3 $p<0.01$ and primary education 67.1±21.0 $p<0.01$, but were comparable to the scores of women with a secondary education 70±26.7, $p=0.07$. Moreover, the GHS scores of women with a form of employment 77.2±24.5 and had family support
67.8±20.1 were statistically significantly higher than unemployed women 68.8±22.7 $p<0.01$ and women who lacked family support 44.6±29.3 $p=0.02$. Parity $p=0.09$, age $p=0.09$, marital status $p=0.78$, stage of disease $p=0.44$, time since completion of treatment $p=0.12$, access to counseling services $p=0.12$, and presence of chronic complications $p=0.86$ did not significantly influence QOL/GHS of cervical cancer survivors. (Table 9).

Table 9: Demographics and global health status/QOL of cervical cancer survivors

	N	Mean	SD	Mean Rank	P
Education					0.11
Primary	64	68.6	21,0	56.76	
Secondary	25	59.0	25.1	46.10	
Tertiary	3	72.2	25.4	57.17	
None	11	56.5	233	36.32	
Employment					0.70
Employed	12	63.1	32.8	55.04	
Not Employed	91	64.9	21.4	51.60	
Family support					0.02*
Yes	89	67.8	20.1	55.60	
No	14	44.6	29.3	29.11	
Age					0.42
<30	2	54.1	23.1	31.50	
31-40	8	44.7	31.6	38.50	
41-50	30	65.2	21.7	49.85	
51-60	37	67.5	21.1	56.57	
60+	25	65.6	19.7	51.74	
Marital Status					0.80
Single	22	66.7	20.2	54.36	
Married	70	64.2	24.2	51.35	
Divorced	4	52.0	35.4	41.00	
Separated	17	70.2	19.4	57.36	
Parity					0.74
Multiparous	64	63.9	24.3	50.77	
Grandmultiparous	38	66.0	20.8	52.72	
Stage					0.44
1A	2	87.5	17.6	84.25	
1B	19	67.1	21.4	54.89	
2A	12	65.9	16.8	52.71	
2B	37	59.6	23.2	44.81	
3A	14	70.2	20.5	58.54	
3B	14	64.8	26.9	53.46	
4A	5	65.0	34.5	57.20	
Chronic conditions					0.86
Yes	38	64.2	23.1	51.37	
No	65	65.0	22.7	52.37	
Time since completion of treatment					0.12
< 2 years	72	67.8	17.3	53.72	
2-4 years	13	58.9	30.1	47.35	
>4 years	15	50.0	31.9	37.77	
Counselling support					0.12
Yes	95	65.2	22.2	52.53	
No	8	58.3	30.8	45.75	

4.6 Quality of Life of Healthy women

The QOL score for cervical cancer survivors on global health status was 78.3±22.5: range 0-100, and median 83.3. The QOL score for the physical factor was 92.2±11.1: range 60-133, and median 93.3. The QOL score for the role factor was 95.6±12.6: range 33-133 and median 100. The QOL score for the emotional factor was 88.6±18.0: range 25-133 and median 100. The QOL for cognitive factor was 90.5±19.0: range 0-133 and median 100. The QOL for social factor was 93.2±20.6: range 0-133 and median 100 (Table 9).

Table 10: QOL scores for Healthy women

N		Mean	SD	Median	Min	Max
Global Health Status/QOL	107	78.3	22.5	83.3	0	100
Physical Functioning	107	92.2	11.1	93.3	60	133
Role Functioning	107	95.6	12.6	100	33	133
Emotional Functioning	107	88.6	18.0	100	25	133
Cognitive Functioning	107	90.5	19.0	100	0	133
Social Functioning	107	93.2	20.6	100	0	133

4.7 Comparison of Quality of life (adjusted for confounding)

The mean score for GHS of cervical cancer survivors (64.7) was statistically significantly lower than that of cancer free women (78.3): $F=10.96$, $p<0.01$. The scores for all the domain functions were significantly lower than those of healthy women. (Table 10).

Table 11: Comparison of adjusted QOL scores for CC survivors and cancer-free women

	CC Survivors	Cancer Free		
	Mean score	Mean score	F	P
Global Health Status/QOL	64.7	78.3	10.96	<0.01
Physical Functioning	87.6	92.2	7.12	<0.01
Role Functioning	85.6	95.6	11.05	<0.01
Emotional Functioning	82.0	88.6	5.97	0.01
Cognitive Functioning	81.1	90.5	4.87	0.02
Social Functioning	65.1	93.2	37.58	<0.01

CHAPTER FIVE

DISCUSSION, CONCLUSIONS, AND RECOMMENDATIONS

5.1 Discussion

In this study majority of the survivors were aged between 41-60 years at 65.7% with a mean age of 53.6 years and a range of 24-80 years. This is comparable to other local studies conducted at KNH and in Kenya. In a study by Njuguna et al 60.5% of the cancer survivors were aged between 40-59 years while another study by Kamau et al found a mean age of 49 with a range of 21-94 years(28). Mionki found majority of patients with locally advanced disease at greater than 45 years to account for 55.2%. Jain et al in India found 80% of the CCSs >45 years, 76.2% had attained primary level education and below with 75% of them being married(29).

Majority of the respondents were married 68%, unemployed 88.3%, and had low education level 72.8% probably accounting for the late presentation for diagnosis and management. Multi-parity is a known risk factor for cervical cancer and this was evidenced by all of the cervical cancer survivors being multiparous (100%).

68% of the CCSs had disease stage IIB and above with majority, 35.9% having stage IIB. This is comparable to the findings of Maranga et al where 80.5% of the respondents had >/= stage IIB with the majority also having stage IIB at 30%(8). 86.5% of the patients also had >/= stage 2B in a study conducted in India. The presentation of many of the patients with advanced stage disease is probably attributable to the lack of awareness and information regarding cervical cancer symptoms and the poor accessibility of cervical cancer screening facilities in Kenya.

In our study, 92.2% and 86.4% of the survivors reported having received pretreatment counseling and had family support respectively during their treatment. This was significantly more than the findings of Kamau et al who found that survivors received social support of between 56.6-71% from spouses, children, family and friends(28).

CCSs had a poor global health status/QOL as compared to their healthy counterparts and in comparison to the EORTC reference ranges. These findings are similar to those of Klee et al

in a prospective comparative study where at all points in time CCSs had poorer overall GHS and domain scores in comparison to healthy women(22). Wenjuan in China using the FACT-G QOL tool also found lower physical, psychological, functional wellbeing and overall QOL scores in the CCSs group(30). In a critical review Vistad et al also reported poorer QOL and domain scores in CCSs(31). Similar outcomes have also been reported by other researchers(23)

However other studies have found no significant differences in the QOL. Sarah Bradley found no significant difference which could be explained by the fact that majority of the patents had stage I disease, had at least a high school education and were more likely to be employed factors which have a positive effect on a survivors QOL(32). A Sudanese study also found survivors reporting better QL and domain scores probably due to the fact that only survivor's with good social support and the fact that all patients received reimbursements for their medical expenses(33). Lee also found comparable scores due to inclusion of only patients who had been sexually active in the prior 3 months. This was coupled by the long interval between completion of treatment and the QOL as QOL has been shown to progressively improve with time(34).

Among the functional domains the most impaired function was social functioning which is similar to the findings of Park et al in South Korea(12) and those of Ayana et al in Ethiopia(5).

In this study the QOL was affected by the survivor's education level, employment status and presence of family support during their illness. This is consistent with the findings of Awadalla et al in Sudan who found better QOL scores in survivors with higher education and better employment(33). There was also a positive correlation between educational level and FACT-G scores in a study by Wilailak et al(19) while

Ogoncho et al(27) found an association between the patient's age, education level, income, occupation and duration of illness and their QOL. In addition to this Osann et al found poorer QOL in survivors who had a poor social support, those with comorbidities, low education level and with sleep problems(35).

In this current study the age, marital status, stage of disease, presence of comorbidities and the time elapsed since completion of treatment did not significantly affect the QOL in keeping

with the findings of Bradley et al where marital status, age, education level, ethnicity, religion, income including stage of disease, treatment modality, length of time since diagnosis, and nature of side effects were not significantly associated with QOL(32). Klee et al found improvement in patient's scores over time(22) while Le Borgne found the presence of at least 2 comorbidities negatively affected QOL(23). In South Africa HIV positive patients were found to have worse QOL scores as compared to their sero-negative counterparts(26). Pasek et al on the other hand found a correlation of QOL scores with the age and cancer stage of the respondents(36). These findings are possibly due to the low number of patients with comorbidities in our current study and the preponderance of locally advanced disease in our set up as opposed to early stage disease in other more developed parts of the world.

In the symptom scales the most reported complaint was financial difficulties while the CCSs also reported significantly worse fatigue, nausea/vomiting, pain, appetite loss and constipation in comparison to their healthy counterparts while the scores for insomnia, dyspnoea and diarrhea were comparable. The high financial difficulty scores are similar to findings of Ayana et al in Ethiopia(5) and were despite all the survivor's having their treatment costs covered by the NHIF. This is probably due to the costs of travelling as most are not residents of Nairobi and the need to pay for investigations and drugs after exhaustion of their insurance cover limits.

5.2 Conclusion

- Cervical cancer survivors reported poor scores in the GHS/QOL and all functional domains.
- The QOL of cervical cancer patients was affected by the education level, employment status and support from family members while there was no relationship with the marital status, age, stage of disease, comorbidities and duration of time since completion of treatment.

5.3 Recommendations

- Routine assessment of QOL of patients should be incorporated as part of their standard follow up with provision of counseling services and encouragement of family support to all cervical cancer survivors. Additionally the NHIF cover should be expanded to help cushion the survivors from financial difficulties.

- A prospective QOL study to establish the evolution of cervical cancer survivors quality of life from diagnosis through treatment and follow up and to determine other modifiable factors that potentially affect the CCSs QOL.
- Effective symptom management during follow up of the survivors to reduce the high symptom scores reported by the survivors which negatively affect their QOL.

REFERENCES

1. Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S. and others. 2013. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11. International Agency for Research on Cancer, Lyon F. Fact Sheets by Cancer [Internet]. 2013 [cited 2018 Jun 28]. Available from: http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx

2. HPV Information Center. Human Papillomavirus and Related Diseases Report KENYA. 2017;(July). Available from: http://www.hpvcentre.net/statistics/reports/KEN.pdf

3. Maranga IO, Hampson L, Oliver AW, Gamal A, Gichangi P, Opiyo A, et al. Analysis of Factors Contributing to the Low Survival of Cervical Cancer Patients Undergoing Radiotherapy in Kenya. Hawkins SM, editor. PLoS One [Internet]. 2013 Oct 30 [cited 2018 Jun 28];8(10):e78411. Available from: http://dx.plos.org/10.1371/journal.pone.0078411

4. Kagema F. Case records and commentaries in Obstetrics and Gynaecology. 2003 [cited 2018 Aug 8]; Available from: http://erepository.uonbi.ac.ke/handle/11295/30172

5. Ayana BA, Negash S, Yusuf L, Tigeneh W, Haile D. Health related quality of life of gynaecologic cancer patients attending at Tikur Anbesa Specialized Hospital (TASH), Addis Ababa, Ethiopia.
   BMC Womens Health [Internet]. 2018 [cited 2019 Mar 29];18(1):7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29304790

6. Survival Rates for Cervical Cancer, by Stage [Internet]. [cited 2018 Sep 21]. Available from: https://www.cancer.org/cancer/cervical-cancer/detection-diagnosis-staging/survival.html

7. Brookfield KF, Cheung MC, Lucci J, Fleming LE, Koniaris LG. Disparities in survival among women with invasive cervical cancer. Cancer [Internet]. 2009 Jan 1 [cited 2018 Sep 21];115(1):166–78. Available from: http://www.ncbi.nlm.nih.gov/pubmed/19097209

8. Maranga IO, Hampson L, Oliver AW, Gamal A, Gichangi P, Opiyo A, et al. Analysis of Factors
   Contributing to the Low Survival of Cervical Cancer Patients Undergoing Radiotherapy in Kenya.
   Hawkins SM, editor. PLoS One [Internet]. 2013 Oct 30 [cited 2018 Aug 7];8(10):e78411. Available from: http://dx.plos.org/10.1371/journal.pone.0078411

9. Schipper H, Clinch J, McMurray A, Levitt M. Measuring the quality of life of cancer patients: the

Functional Living Index-Cancer: development and validation. J Clin Oncol [Internet]. 1984 May
[cited 2018 Aug 14];2(5):472–83. Available from: http://www.ncbi.nlm.nih.gov/pubmed/6374052

10. Study protocol for the World Health Organization project to develop a Quality of Life assessment instrument (WHOQOL). Qual Life Res [Internet]. 1993 Apr [cited 2018 Aug 14];2(2):153–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/8518769

11. Yucel B, Atasever Akkaş E, Okur Y, Ay Eren A, Fuat Eren M, Karapınar H, et al. The impact of radiotherapy on quality of life for cancer patients: a longitudinal study. [cited 2019 Mar 29]; Available from: https://www.mascc.org/assets/Pain_Center/2014_September/september2014-6.pdf

12. Sang YP, Bae DS, Joo HN, Chong TP, Cho CH, Jong ML, et al. Quality of life and sexual problems in disease-free survivors of cervical cancer compared with the general population. Cancer. 2007;110(12):2716–25.

13. Zeng YC, Ching SSY, Loke AY. Quality of life measurement in women with cervical cancer:
implications for Chinese cervical cancer survivors. Health Qual Life Outcomes [Internet]. 2010 Mar 19 [cited 2018 Sep 19];8:30. Available from: http://www.ncbi.nlm.nih.gov/pubmed/20302624

14. Teckle P, Peacock S, McTaggart-Cowan H, van der Hoek K, Chia S, Melosky B, et al. The ability of cancer-specific and generic preference-based instruments to discriminate across clinical and self-reported measures of cancer severities. Health Qual Life Outcomes [Internet]. 2011 Nov 28
[cited 2018 Sep 19];9:106. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22123196

15. King S, Exley J, Parks S, Ball S, Bienkowska-Gibbs T, MacLure C, et al. The use and impact of quality of life assessment tools in clinical care settings for cancer patients, with a particular emphasis on brain cancer: insights from a systematic review and stakeholder consultations. Qual Life Res [Internet]. 2016 [cited 2018 Aug 15];25(9):2245–56. Available from:
http://www.ncbi.nlm.nih.gov/pubmed/27039304

16. Gotay CC, Kawamoto CT, Bottomley A, Efficace F. The Prognostic Significance of PatientReported Outcomes in Cancer Clinical Trials. J Clin Oncol [Internet]. 2008 Mar 10 [cited 2018
Aug 15];26(8):1355–63. Available from:
http://www.ncbi.nlm.nih.gov/pubmed/18227528

17. Ashing-Giwa KT, Lim J won, Tang J. Surviving cervical cancer: Does health-related quality of life influence survival? Gynecol Oncol [Internet]. 2010;118(1):35–42. Available from: http://dx.doi.org/10.1016/j.ygyno.2010.02.027

18. Chase DM, Huang HQ, Wenzel L, Cella D, McQuellon R, Long HJ, et al. Quality of life and survival in advanced cervical cancer: A Gynecologic Oncology Group study. Gynecol Oncol [Internet]. 2012;125(2):315–9. Available from: http://dx.doi.org/10.1016/j.ygyno.2012.01.047

19. Wilailak S, Lertkhachonsuk A-A, Lohacharoenvanich N, Luengsukcharoen SC, Jirajaras M, Likitanasombat P, et al. Quality of life in gynecologic cancer survivors compared to healthy checkup women. J Gynecol Oncol [Internet]. 2011 Jun 30 [cited 2018 Aug 15];22(2):103–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21860736

20. Prasongvej P, Nanthakomon T, Jaisin K, Chanthasenanont A, Lertvutivivat S, Tanprasertkul C, et al. Quality of Life in Cervical Cancer Survivors and Healthy Women: Thai Urban Population Study. Asian Pac J Cancer Prev [Internet]. 2017 [cited 2018 Jun 28];18(2):385–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28345784

21. Bergmark K, Åvall-Lundqvist E, Dickman PW, Henningsohn L, Steineck G. Vaginal Changes and Sexuality in Women with a History of Cervical Cancer. N Engl J Med [Internet]. 1999 May 6 [cited 2018 Oct 17];340(18):1383–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/10228188

22. Klee M, Thranov I, Machin D, Mrcr H. Life after Radiotherapy: The Psychological and Social Effects Experienced by Women Treated for Advanced Stages of Cervical Cancer. 2000 [cited 2018 Aug 15]; Available from: http://www.idealibrary.com

23. Le Borgne G, Mercier M, Woronoff AS, Guizard AV, Abeilard E, Caravati-Jouvenceaux A, et al. Quality of life in long-term cervical cancer survivors: A population-based study. Gynecol Oncol [Internet]. 2013;129(1):222–8. Available from: http://dx.doi.org/10.1016/j.ygyno.2012.12.033

24. Awadalla AW, Ohaeri JU, Gholoum A, Khalid AOA, Hamad HMA, Jacob A. Factors associated with quality of life of outpatients with breast cancer and gynecologic cancers and their family caregivers: a controlled study. BMC Cancer [Internet]. 2007 Jun 19 [cited 2018 Aug 8];7:102. Available from: http://www.ncbi.nlm.nih.gov/pubmed/17578579

25. Khalil J, Bellefqih S, Sahli N, Afif M, Elkacemi H, Elmajjaoui S, et al. Impact of cervical cancer on quality of life: beyond the short term (Results from a single institution): Quality of life in longterm cervical cancer survivors: results from a single institution. Gynecol Oncol Res Pract [Internet]. 2015 [cited 2018 Aug 8];2:7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/27231567

26. du Toit G, Kidd M. A prospective study of demographic features and quality of life in HIVpositive women with cervical cancer treated at Tygerberg Hospital. South Afr J HIV Med [Internet]. 2015;16(1):35–9. Available from: http://www.sajhivmed.org.za/index.php/hivmed/article/view/368

27. Machuki Ogoncho I, Osogo Omuga B, Wakasiaka S, Muiva M. Determinants of Quality of Life Among Gynaecological Cancer Patients on Follow Up at a Referral Hospital in Kenya. Am J Nurs Sci [Internet]. 2015;4(3):127–30. Available from: http://www.sciencepublishinggroup.com/j/ajns

28. Kamau RK, Osoti AO, Njuguna EM. Effect of diagnosis and treatment of inoperable cervical cancer on quality of life among women receiving radiotherapy at Kenyatta National Hospital. East Afr Med J [Internet]. 2007 Jan [cited 2018 Oct 13];84(1):24–30. Available from: http://www.ncbi.nlm.nih.gov/pubmed/17633581

29. Jain A, Ganesh B, Bobdey S, Sathwara J, Saoba S. Sociodemographic and clinical profile of cervical cancer patients visiting in a tertiary care hospital in India. Indian J Med Paediatr Oncol. 2017 Jul 1;38(3):291–5.

30. Zhou W, Yang X, Dai Y, Wu Q, He G, Yin G. Survey of cervical cancer survivors regarding quality of life and sexual function. J Cancer Res Ther [Internet]. 2016;12(2):938. Available from: http://www.cancerjournal.net/text.asp?2016/12/2/938/175427

31. Vistad I, Fosså SD, Dahl AA. A critical review of patient-rated quality of life studies of long-term survivors of cervical cancer. Vol. 102, Gynecologic Oncology. 2006. p. 563–72.

32. Bradley S, Rose S, Lutgendorf S, Costanzo E, Anderson B. Quality of life and mental health in cervical and endometrial cancer survivors. Gynecol Oncol. 2006;100(3):479–86.

33. Awadalla AW, Ohaeri JU, Gholoum A, Khalid AOA, Hamad HMA, Jacob A. Factors associated with quality of life of outpatients with breast cancer and gynecologic cancers and their family caregivers: a controlled study. BMC Cancer [Internet]. 2007 Jun 19 [cited 2018 Aug 16];7:102. Available from: http://www.ncbi.nlm.nih.gov/pubmed/17578579

34. Lee Y, Lim MC, Kim SI, Joo J, Lee DO, Park S-Y. Comparison of Quality of Life and Sexuality between Cervical Cancer Survivors and Healthy Women. Cancer Res Treat [Internet]. 2016 Oct [cited 2019 Mar 30];48(4):1321–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26875196

35. Osann K, Hsieh S, Nelson EL, Monk BJ, Chase D, Cella D, et al. Factors associated with poor quality of life among cervical cancer survivors: implications for clinical care and clinical trials. Gynecol Oncol [Internet]. 2014 Nov [cited 2018 Oct 11];135(2):266–72. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25192629

36. Pasek M, Suchocka L, Urbański K. Quality of life in cervical cancer patients treated with radiation therapy. J Clin Nurs [Internet]. 2012 Oct [cited 2018 Jun 28];n/a-n/a. Available from: http://doi.wiley.com/10.1111/j.1365-2702.2012.04350.x

ANNEXES

Annex 1: Letter to ERC

Dr. Ephraim
Taraiya
(MBChB)
H58/87324/2016
January, 2019.

The Chairperson,
Ethics, Research and Standards Committee,
Kenyatta National Hospital and University of Nairobi,
P.O. Box 20723,
NAIROBI

Dear Sir/Madam,

RE: SUBMISSION OF MASTERS DEGREE RESEARCH PROPOSAL FOR APPROVAL

I wish to submit my research proposal for approval by your committee after presentation to the department. I am currently a 3rd year student pursuing a Master's Degree in Obstetrics and Gynecology at the University of Nairobi, College of Health Sciences.

Yours Sincerely,

Dr. Ephraim Taraiya,
Department of Obstetrics
and Gynecology, College of
Health Sciences University
of Nairobi.

Annex 2: Consent Form/ Fomu ya Idhini

Study title:

QUALITY OF LIFE OF POST RADIOTHERAPY CERVICAL CANCER SURVIVORS VERSUS HEALTHY WOMEN AT KNH, A COMPARATIVE CROSS SECTIONAL STUDY

Principal investigator: Dr. Ephraim Taraiya Mpoe.

Introduction:

I Dr. Ephraim Taraiya, a postgraduate student at the Department of Obstetrics & Gynecology, University of Nairobi, am conducting a study on the quality of life of post radiotherapy cervical cancer patients at the KNH radiotherapy unit compared to healthy women attending reproductive health services clinic. You are hereby requested to participate in the study.

This information will help you make a decision on whether to participate in the study or not. You may ask any questions about the study or anything in this form that is not clear.

Purpose of the study:

A diagnosis of cervical cancer and subsequent radiotherapy result in both short term and long term physical and psychological effects which adversely affect the survivors' quality of life. This effect has not been studied and compared to that of healthy women in our population.

This study will evaluate quality of life of women with cervical cancer post radiotherapy and compare to that of healthy women attending the well woman clinic to establish if there's a significant impact on quality of life in the women with cervical cancer post radiotherapy.

Benefits:

Your participation in the study will help us obtain this information that will be used to tailor pragmatic counseling interventions to prepare women for life after radiotherapy. The knowledge generated from this study is expected to benefit your household, the local community, Kenya and women globally.

Possible risks:

The study will have no invasive procedures and you'll only be required to answer a few questions. There will be no added risks to your standard care as that accorded to other patients.

Voluntarism:

This is a voluntary exercise and you can withdraw at any point during the study with no repercussions. The management you receive at the hospital will be standard and not influenced by your decision.

Compensation:

No compensation will be offered for participation in the study.

Procedure:

As a study participant, the researcher and research assistant will obtain some information from your medical records and conduct a short interview with you and your responses filled in a questionnaire.

Confidentiality:

The information from you and from the medical records will be confidential. No names or any information identifying you will be included in the questionnaires and the final report.

Contact information:

If you have any questions regarding the study, you can contact Dr. Ephraim Taraiya through telephone number 0727 371 289. You may also contact the KNH/UoN/ERC Commitee-0735-274288/0721-665077.

Or

The chairperson,

KNH/UON Ethics and Research Committee P.O. Box 20723-

00202, Nairobi.

Telephone number: (254-020) 2726300-9 Ext 44355 Email:uonknh_erc@uonbi.ac.ke

Your participation in the study will be highly appreciated.

Consent:

I_____ hereby voluntarily consent to participate in the study. I acknowledge that a thorough explanation of the nature of the study has been given to me by Dr./Mr./Mrs._____. I clearly understand that my participation is completely voluntary.

Signature of Participant _____ Date _____

Signature of Researcher/ Assistant _____ Date _____

Fomu ya Ithini:

KICHWA CHA UTAFITI:

UBORA WA MAISHA YA WANAWAKE WENYE SARATANI YA UZAZI BAADA YA KUTIBIWA KWA MIALE UKILINGANISHWA NA WANAWAKE WENYE AFYA NJEMA KATIKA HOSPITALI YA KITAIFA YA KENYATTA.

Mtafiti Mkuu: Dkt. Ephraim Taraiya Mpoe

Utangulizi:

Mimi Dkt. Ephraim Taraiya, mwanafunzi wa shahada katika Idara ya Uja uzito na Magonjwa ya wanawake, Chuo kikuu cha Nairobi, ninafanya utafiti juu ya ubora wa maisha ya wanawake wenye saratani ya njia ya uzazi baada ya kutibiwa kwa miale ukilinganishwa na wanawake wenye afya njema katika hospitali ya Kitaifa ya Kenyatta.

Unaombwa kushiriki katika utafiti huu.

Maelezo haya yatakusaidia kufanya uamuzi juu ya kushiriki katika utafiti huu. Unaweza kuuliza swali lolote kuhusu utafiti au chochote katika fomu hii kukuwezesha kuelewa zaidi.

Kusudi la utafiti:

Ugonjwa wa saratani ya kizazi na matibabu yake kwa kutumia miale husababisha madhara ya muda mfupi na ya muda mrefu ya kimwili na kisaikolojia ambayo yanaathiri ubora wa maisha ya waathiriwa. Athari hizi hazijachunguzwa na kulinganishwa na ile ya wanawake wenye afya njema katika nchi yetu.

Utafiti huu utapima ubora wa maisha ya wanawake walio na saratani ya kizazi na kuilinganisha na ile ya wanawake wenye afya wanaohudhuria kliniki ya wanawake ili kuthibitisha ikiwa kuna athari kubwa juu ya ubora wa maisha katika wanawake walio na saratani ya kizazi baada ya matibabu.

Faida:

Ushiriki wako katika utafiti huu utatusaidia kupata habari hii ambayo itatumika kuunda hatua na sera za kuwatayarisha wagonjwa hawa kwa maisha baada ya matibabu. Utafiti huu unatarajiwa kufaidi familia yako, jamii yako, nchi na wanawake duniani.

Hatari zinazowezekana:

Utafiti huu hautakuwa na athari zozote kwako na utahitajika tu kujibu maswali machache. Hakutakuwa na hatari zaidi ya huduma ya kawaida kama ile iliyopewa wagonjwa wengine.

Hiari:

Hili ni zoezi la hiari na unaweza kujiondoa wakati wowote wakati wa utafiti bila lawama. Usimamizi unaopokea kwenye hospitali utakuwa wa kawaida na hautaathiriwa na uamuzi wako.

Fidia:

Hakuna fidia itatolewa kwa kushiriki katika utafiti huu.

Utaratibu:
Kama mshiriki wa utafiti, mtafiti na msaidizi wa utafiti watapata maelezo kutoka kwenye kumbukumbu zako za matibabu na kufanya mahojiano mafupi nawe.

Usiri:

Taarifa kutoka kwako na kutoka kwa kumbukumbu za matibabu itakuwa siri. Hakuna majina wala maelezo yoyote ya kukutambulisha yatakayonukuliwa kwenye ripoti ya utafiti huu.

Maelezo ya mawasiliano:

Ukiwa na swali lolote kuhusu utafiti huu, unaweza kuwasiliana na Dkt. Ephraim Taraiya kupitia namba ya rununu 0727 371 289. Unaweza pia kuwasiliana na KNH / UoN / ERC Committee kupitia nambari 0735-274288 / 0721-665077.

Ama:

Mwenyekiti,

KNH / UON Kamati ya Maadili na Utafiti S. L. P. 20723-
00202, Nairobi.
Nambari ya simu: (254-020) 2726300-9 : 44355

Barua pepe: uonknh_erc@uonbi.ac.ke

Tutakushukuru sana kwa ushiriki wako katika utafiti huu.

Idhini:
Mimi_____ nimeamua kwa hiari yangu mwenyewe kushiriki katika utafiti huu baada ya maelezo ya kina kutoka kwa Dkt. / Bwana / Bi._____. Ninaelewa wazi kwamba ushiriki wangu ni kwa hiari.

Sahihi ya Mshiriki _____ Tarehe _____

Saini ya Mtafiti / Msaidizi _____ Tarehe _____

Annex 3: Questionnaire

Date: Participant Code:

A: SOCIODEMOGRAPHIC AND CLINICAL CHARACTERISTICS

1. What is your age? (years):
2. What is your marital status?

☐ Single ☐ Married ☐ Divorced ☐ Separated

3. What is your highest educational level?

☐ Primary ☐ Secondary ☐ Tertiary ☐ None

4. Are you employed? ☐ Yes ☐ No

5. Parity: (using the format Para…..+……)…….
6. Do you have health insurance ie NHIF?

☐ Yes ☐ No

7. Do you still get your menses?

☐ Yes ☐ No

Questions 8-14 will only be administered to Cervical cancer survivors.

8. What is the stage of your disease?

☐ I ☐ II ☐ III ☐ IV

9. Do you have any other chronic conditions?

☐ DM ☐ HTN ☐ HIV ☐ Others

10. How many months ago did you complete treatment?

☐ 3 months-2 year ☐ 2-4 ☐ >4

11. Did you receive emergency radiotherapy?

Yes ☐ ☐ No

12. Were your radiotherapy sessions interrupted for whatever reason?

☐ Yes ☐ No

13. Did you receive any counseling before starting treatment?

☐ Yes ☐ No

14. Does your family support you?

☐ Yes ☐ No

ENGLISH

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:

Your birthdate (Day, Month, Year):

Today's date (Day, Month, Year): 31

_____

_____

		Not at All		A Little	Quite a Bit	Very Much
1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4	
2.	Do you have any trouble taking a long walk?	1	2	3	4	
3.	Do you have any trouble taking a short walk outside of the house?	1	2	3	4	
4.	Do you need to stay in bed or a chair during the day?	1	2	3	4	
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4	

During the past week:	**Not at All**	**A Very Little**	**Quite a Bit**	**Much**
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

Please go on to the next page

[redacted]

ENGLISH

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1 2 3 4 5 6 7

Very poor Excellent

30. How would you rate your overall quality of life during the past week?

1 2 3 4 5 6 7

Very poor Excellent

EORTC QLQ-C30 (toleo la 3)

Tunapenda kujua mambo kadhaa kukuhusu wewe na afya yako. Tafadhali jibu maswali yote wewe mwenyewe kwa kuzungushia duara kwenye nambari inayokueleleza zaidi wewe. Hakuna jibu “zuri” au “baya”. Taarifa utakazotoa zitabaki kuwa siri.

Tafadhali jaza herufi za kifupi cha majina yako:

Tarehe ya kuzaliwa (Siku, Mwezi, Mwaka):

Tarehe ya leo (Siku, Mwezi, Mwaka): 31

		Hapana	Kidogo tu	Kiasi	Sana
6.	Unapata shida yoyote unapofanya kazi ngumu, kama vile kubeba mifuko mikubwa ya kununulia vitu au sanduku?	1	2	3	4
2.	Una tatizo lolote unapotembea umbali mrefu?	1	2	3	4
3.	Unapata shida yoyote utembeapo umbali mfupi nje ya nyumba?	1	2	3	4
4.	Unahitaji kupumzika kitandani au kwenye kiti wakati wa mchana?	1	2	3	4
5.	Unahitaji msaada wakati wa kula, kuvaa, kuoga au kwenda msalani?	1	2	3	4

Katika kipindi cha wiki moja iliyopita:	Hapana	Kidogo tu	Kiasi	Sana
8. Umekuwa ukishindwa kufanya kazi zako au shughuli za kila siku ipasavyo?	1	2	3	4
30. Umekuwa ukishindwa kuendelea kufanya mambo yako unayoyapenda au shughuli zako za wakati wa mapumziko?	1	2	3	4
8. Ulishindwa kupumua vizuri?	1	2	3	4

9.	Ulikuwa na maumivu?	1	2	3	4
10.	Ulihitaji mapumziko?	1	2	3	4
11.	Umekuwa na matatizo ya kupata usingizi?	1	2	3	4
12.	Umejisikia dhaifu?	1	2	3	4
13.	Umekosa hamu ya chakula?	1	2	3	4
14.	Umesikia kichefuchefu?	1	2	3	4
15.	Ulitapika?	1	2	3	4
16.	Umekuwa na tatizo la kufunga choo?	1	2	3	4

Tafadhali endelea ukurasa unaofuata

KISWAHILI

Katika kipindi cha wiki moja iliyopita:		Hapana	Kidogo tu	Kiasi	Sana
17.	Umeharisha?	1	2	3	4
18.	Umejisikia mchovu?	1	2	3	4
19.	Maumivu yaliingilia shughuli zako za kila siku?	1	2	3	4
31.	Umekuwa na shida ya kuwa makini na vitu? Kwa mfano kusoma gazeti au kuangalia televisheni kwa umakini?	1	2	3	4
21.	Umekuwa ukijisikia hali ya kukasirika kwa upesi?	1	2	3	4
22.	Umekuwa na wasiwasi?	1	2	3	4
23.	Ulijisikia kukasirika?	1	2	3	4
24.	Umejisikia kuvunjika moyo?	1	2	3	4
25.	Umekuwa ukipoteza kumbukumbu ya mambo yaliyopita, pia kusahau kufanya mambo unayotakiwa kufanya?	1	2	3	4
26.	Hali yako ya kiafya au matibabu vimeingilia maisha yako ya kifamilia?	1	2	3	4
27.	Hali yako ya kiafya au matibabu vimeingilia maisha yako				

ya kijamii?	1	2	3	4
28. Hali yako ya kiafya au matibabu vimekusababishia matatizo ya kifedha?	1	2	3	4

Kwa maswali yafuatayo tafadhali zungushia duara kwenye namba kati ya 1 mpaka 7 ambayo inakueleleza zaidi wewe

29. Unaweza kuitathmini vipi hali yako ya kiafya katika kipindi cha wiki moja iliyopita?

1 2 3 4 5 6 7

Mbaya sana Nzuri sana

30. Kwa ujumla unaweza kutathmini vipi hali yako ya maisha au mwenendo wa maisha yako katika kipindi cha wiki moja iliyopita?

1 2 3 4 5 6 7

Mbaya sana Nzuri sana