QUALITY OF LIFE OF PATIENTS UNDERGOING SURGICAL TREATMENT FOR EARLY-STAGE CERVICAL CANCER AT TWO REFERRAL HOSPITALS IN KENYA

BY

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A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE IN REPRODUCTIVE HEALTH OF MOI UNIVERSITY

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DECLARATION

I hereby declare that this research report is part of my fulfillment of the degree of Master of Medicine in Reproductive Health - MMED RH. It is my original work under the guidance of my supervisors and has not been presented before for a masters' degree in any other University.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

Ca Cervix   Cancer of the Cervix

EQ-5D-5L   5-dimension 5 -level tool

FACT   Functional Assessment of Cancer Therapy

FIGO   International Federation of Gynecology and Obstetrics

HPV   Human Papilloma Virus

HRQOL   Health Related Quality-Of-Life

IREC   Institutional Research and Ethics Committee

KNH   Kenyatta National Hospital

LMICs   Low and Middle-Income countries

MTRH   Moi Teaching and Referral Hospital

QOL   Quality of Life

WHO   World Health Organization

OPERATIONAL DEFINITIONS

Cases: Patients with histologically confirmed cancer of the cervix

Loss to follow-up: Failure to return for a scheduled visit for a period exceeding 3 months from the date of the last visit.

Cervix: The lowermost part of the uterus, which is a cylindrical-shaped structure composed of stroma and epithelium.

Quality of Life: An individual's 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.

Surgically Amendable Stage: Cervical cancer FIGO Stage IA1-1B2.

Total hysterectomy: A surgical operation aimed at removing a woman's entire uterus and cervix.

Radical hysterectomy: When a surgeon removes the whole uterus and its surrounding tissues, the cervix and the top part of the vagina.

ABSTRACT

Background: Cervical cancer is a major cause of death among women globally. In low- and middle-income countries (LMICs) such as Kenya, it is the second most prevalent cancer among women and the third leading cause of mortality. Currently, there is limited published data on the quality of life (QOL) of women suffering from the disease, especially those treated at the two leading national hospital in Kenya. This is despite the fact that majority of these women receive cervical cancer treatment at Moi Teaching and Referral Hospital (MTRH) and Kenyatta National Hospital (KNH) in Kenya. Furthermore, surgical treatment is a major component in the management of cervical cancer in these facilities.

Objective: To determine the quality of life of patient undergoing surgery as treatment for surgically amenable stage of cancer of the cervix at MTRH and KNH.

Methods: A prospective cohort study conducted among 71 patients undergoing surgery for surgically amenable cervical cancer stage. Consecutive sampling of women who met the eligibility criteria was used to identify potential participants who underwent a written informed consenting process. The participants were enrolled pre-operatively and an interviewer administered questionnaire used to comprehensively assess the five dimensions of the quality-of-life assessment tool (EQ-5D-5L) namely: mobility, self-care, ability to perform usual activities, pain or discomfort and depression or anxiety. The overall duration of data collection was seventeen months (October 2019 to February 2021) with each participant followed-up for three months post-operatively. Descriptive statistical techniques were used to describe the study participants while a bivariate analysis technique was used to compare the difference in participant's socio demographic and characteristics with a p-value ≤0.05 considered to be statistically significant.

Results: The mean age of the study participants was 47.94 (±10.25) years with 66 (93%) of them being married, 37 (52.1%) unemployed and 39 (54.9%) having health insurance. Nearly two-thirds (63.5%) of the women enrolled had a parity of four or more, 69 (97.2%) did not have a family history of cervical cancer, none reported a history of cigarette smoking while 57 (80.3) were negative to human immunodeficiency virus (HIV) test. Most women (47.9%) had Stage 1 B2 of cervical cancer followed by those with stage 1 B1 seen in 28 (39.4%) of the women enrolled. There were statistically significant differences in pain/discomfort (p=0.028) and anxiety/ depression (p=0.028). Patients aged 20-35 years had a two-fold increased likelihood (AOR=2.44; 95% CI: 1.30, 3.10; p=0.011) of reporting better quality of life scores compared to older women. The lower the cervical cancer stage (Stage 1 A2), the higher the likelihood for improved quality of life following surgical management of cervical cancer (AOR=5.69; 95% CI: 3.55, 6.89; p=0.001).

Conclusion: This study reports that being aged 20-35 years old and having a lower cervical cancer stage were the socio demographic and clinical factors that increased the likelihood of a good quality of life outcome following surgical management of cervical cancer. The statistically significant differences in the quality of life following radical hysterectomy were on pain and anxiety levels reduction.

Recommendation: More attention and clinical focus should be offered to cervical cancer patients who are elderly and with advanced cervical stages to improve their quality of life quality of life by focusing more on addressing their pain/ discomfort and anxiety/depression.

CHAPTER ONE: INTRODUCTION

1.1 Background Information

The cervix is a cylindrical- shaped structure in the lowermost part of the uterus. It is composed of stroma and epithelium (Bhatla et al., 2018). Its intravaginal part (the ectocervix) projects into the vagina and is lined by squamous epithelium while the endocervical canal extends from the internal os (located at the junction with the uterus) to the external os (that opens into the vagina) which is lined by columnar epithelium (Hertzum-Larsen et al., 2019) . Malignancy of the cervix commonly originates within the transformation zone (the area between the old and new squamocolumnar junction) from the ectocervical or endocervical mucosa (Hammes et al., 2007; Li et al., 2017).

Cervical cancer is the third most common gynecological cancer among women and among top eight most prevalent cancers globally (Bhatla et al., 2018). In Africa and other low and middle income economies/countries, cervical cancer is ranked as the second most common cancer among women after breast cancer with a disease burden of 15.9%. In Kenya (Globocan, 2020), the prevalence of cervical cancer was estimated at 12.4% among all cancers and second to breast cancer among both sexes and women at 19.7%. This has lead to the call to action by the World Health Organization for elimination of cervical cancer through full vaccination of 90% of girls by the age of 15 years and 70% of women being screened by the age of 35 years and treatment of 90% of precancerous lesions (cervical intraepithelial neoplasia-CIN) by the year 2030. Recent developments in medical imaging and increased use of minimally invasive surgery have changed the paradigm for management of these cases with the International Federation for Gynecology and Obstetrics (FIGO)

Gynecologic Oncology Committee revising their staging system based on these advances (Kim et al., 2019; Nkfusai et al., 2019).

In Kenya, Cervical cancer has been reported to be common among premenopausal women aged between 36 and 46 years with most of them diagnosed with an advanced stage of the disease (Owenga & Nyambedha, 2018). In a study conducted in Canada's British Columbia region, approximately 40% of women with invasive cervical cancer were aged between 35 and 49 years (Simkin et al., 2021), while in Korea, the average age of women with cervical cancer undergoing radical hysterectomy was 49 years (Kim et al., 2019). Higher mean age of women with cervical cancer of 58.9 ($\pm$10.4) years was reported in Turkey with 48.7% of the women enrolled being post-menopausal (60 years or more) with more than half married (Goker et al., 2011). In a study assessing the quality of life of women with cervical and other gynaecological cancers attending an outpatient medical facility in Sudan, less than one-third (31.5%) of the participants had a minimum of high school education (Awadalla et al., 2007). This is in contrast to findings reported in Denmark where 80% of the women seeking cervical cancer services had completed secondary education and were formally employed (Hertzum-Larsen et al., 2019). Therefore, it is imperative to study the sociodemographic characteristics of women undergoing radical hysterectomy at two major national referral hospital in Kenya, which is one of the objectives of this study.

Patients presenting with cervical cancer receive various interventions such as radical hysterectomy for surgical amenable stages (Stage 1 to Stage 1B II) and chemoradiation for locally advanced stages (Stage 1B III to Stage 4a), similarly for chemoradiation for advanced stages such as stage 4B. This study focuses on patients with surgically amenable stages of cervical cancer who may need radical hysterectomy. Quality of life assessment among cervical patients is an important

process because it helps in the identification and provision of the physical, psychological, social and spiritual needs of the patients before during and after treatment (Xiao et al., 2016). However, various studies have questioned the quality of life these patients have following radical hysterectomy. Since cancer of cervix treatment involves modern methods of screening and surgery, it is necessary to understand the quality of life of these patients who will need to live with the long-term effects of such invasive procedures (Frumovitz et al., 2005). The main indicators used in quality-of-life assessment include mobility, ability to perform usual activities, pain/discomfort, anxiety/depression and selfcare (Bhatla et al., 2018). A patient's wellbeing, ability to perform daily tasks and being contented with one's everyday life activities are hallmarks for a good quality of life (Xiao et al., 2016). The World Health Organization recommends that patients' quality of life is a combination of their physical, psychosocial and spiritual wellbeing which could be affected by medical interventions such as surgery and chemotherapy (Correia et al., 2018). This study therefore, set out to determine the major indicators of quality of life among patients with surgically amenable cervical cancer who had undergone radical hysterectomy at two major national hospitals in Kenya.

1.2 Statement of the problem

Cervical cancer is established as a major cause of morbidity and mortality among women globally. In Kenya and other countries with developing economies within sub-Saharan Africa, it is the second most prevalent cancer after breast cancer among women. Because of this huge disease burden, majority of the women affected are still in their reproductive age and this raises concerns about their resultant quality of life. The great disease burden is further compounded by the high prevalence of human immunodeficiency virus infections within countries with a high disease burden. Because of the many early detection programmes such as the see and treat strategy introduced in Kenya and other sub-Saharan Africa countries, women with cervical cancer are now identified early and prescribed radical hysterectomy for their surgically amenable cervical cancer. However, this procedure is associated with the complete removal of the uterus, parametrium (round, broad, cardinal and uterosacral ligaments), cervix, the upper one third to one-half the vagina and bilateral pelvic lymph nodes resection. The removal of the ovaries and fallopian tube is an integral part of the rad hyst, the ovaries will be removed in post-menopausal women and trans positioned in pre-menopausal women who may require radio therapy after and this may interfere with their perception of wellbeing especially in the aspect of fertility and child bearing ability and psychosexual health and wellbeing. Because of these complications such as longer operation time, pain, and side effects of LN dissection like lymphedema which reduces QOL the quality of life of women who have undergone radical hysterectomy could be influenced by both the physical (pain, discomfort, low energy and fatigue, sleep disturbance and medication dependency) and psychological (anxiety and depression) domains. Most of the studies conducted in many developing countries have focused on the prevalence and disease burden of

cervical cancer with a few focusing on early screening and interventions for the disease. However, very few published studies have focused on the resultant quality of life among women who undergo radical hysterectomy as an intervention for surgically amenable early-stage cervical cancer. This study therefore aims to determine these women's quality of life by assessing both the physical and psychological domains at two national referral and teaching hospitals in Kenya. Because of this huge disease burden, major concerns on the QOL of these women resulting from both the disease itself and treatment modalities have been raised**.**

Most studies done in other populations on the impact of treatment for cancer of cervix on QOL, evaluated women in all stages of the disease, and included all treatment modalities.

1.3 Justification

Because of the high disease burden associated with cervical cancer, there is need to determine whether the current early interventions that is radical hysterectomy improves the patient's quality of life. Although anecdotal data exist on the perceived quality of life of cervical cancer patients who have undergone radical hysterectomy, much of this data has been generated from populations outside sub-Saharan Africa. This study population is essentials because of the unavailability of palliative care services such as pain medication, counselling, survivorship care among others. This is despite the fact that there are sociodemographic, economic and ethnic differences in perceived quality of life among patients seeking intervention procedures. This warrants a local study in two national and teaching hospitals in Kenya where majority of the radical hysterectomy are offered. Furthermore, selecting Kenyatta National Hospital and Moi Teaching and Referral hospital as the study sites for this research gives a holistic representation of cervical cancer patients of varying socioeconomic, ethnic and demographic characteristics. Knowledge on the quality of life of cervical cancer patients who have undergone radical hysterectomy is important to both gynecologists oncologist and policy makers on the appropriateness of the intervention to the long term patient survival and well-being. This study therefore adopted the universally accepted EQ-5D-5L quality of life assessment tool to assess the patient's perception their well-being following radical hysterectomy. This therefore warrants a study to determine whether surgical treatment has impact on the QOL of patients in set-ups where majority of radical hysterectomies are performed. The data on the impact of surgery on QOL will provide clinicians with useful information about patients expectation and assist in treatment decision making through better understanding of treatment benefits. QOL can improve other health outcomes,

therefore several disciplines should all work in collaboration. Results from this study are also important to psychologists and counselors In mental health units whose anxiety may be brought about by the status of their cancer disease as a cancer diagnosis can lead to a lot of anxiety.

1.4 Study Hypothesis

H_0 The quality of life of patient undergoing surgery for early stage cancer of cervix does not improve after surgery.

H_1 The quality of life of patient undergoing surgery for early stage cancer of cervix improves after surgery.

1.5 Objective

1.5.1 Broad Objective

The main objective of this study was to determine quality of life of patient undergoing surgery for early-stage cancer of cervix at MTRH and KNH

1.5.1 Specific Objectives Specific

1. To describe social demographic and clinical characteristics of patients with early stage cervical cancer MTRH and KNH.

2. To determine the impact of surgical treatment on quality of life of patients with early stage cervical cancer at MTRH and KNH.

3. To determine factors associated with change in quality of life following surgical treatment of patients with early stage cervical cancer at MTRH and KNH.

1.6 Research questions

1. What are the socio demographic and clinical characteristics of patients with cancer of the cervix at MTRH and KNH?

2. What is the impact of surgical treatment on quality of life of patients with early stage cervical cancer at MTRH and KNH.

3. What are the factors associated with change in quality of life following surgical treatment of patients with early stage cervical cancer at MTRH and KNH.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

2.1.1 Epidemiology

Among Women cervical cancer is the the leading causes of death from cancer, and epidemiologically it behaves like a venereal disease of low infectiousness (X.-R. Zhang et al., 2021).

In 2018 there were 570,000 cases of cervical cancer and of 311,000 deaths worldwide, which essentially put cervical cancer as the fourth most common cancer in women worldwide after breast cancer, colorectal cancer and lung cancer (Arbyn et al., 2020). Of all cervical cancer cases worldwide 84% occurred in developing countries or low resource setting countries. Similarly 88% of all death from cervical cancer occurred in the developing world (Arbyn et al., 2020).

In a recent study to review trends of cervical cancer in sub Saharan Africa it was found that, the incidence rates had increased over a 10-25 year period in 10 population based cancer registry of the sub Saharan countries studied namely Kenya, South Africa Uganda, Zimbabwe, Mauritius Seychelles and Gambia. (Jedy-Agba et al., 2020).

However in the developed world, the rates of cervical cancer incidence and mortality were lower than those in developing countries. The differences in rates are more profound when the focus is on subcontinents. There is a high burden of disease in southern Africa and eastern Africa. The highest incidences are found in countries from eastern, southern, or western Africa (Arbyn et al., 2020).

2.1.2 Risk factors, screening and prevention

Risk factors of cervical cancer have both behavioral and infectious dimensions. For the infectious contributors, evidences suggests that persistent infection with various high risk human papillomavirus (HPV) is the cause for development of cervical cancer and its precancerous lesions such as cervical intraepithelial neoplasia. Oncogenic HPV infection is necessary for the development of cervical cancer. More than 70 per cent of the cervical cancers are attributed to types 16/18 which is sexually transmitted. Sexually transmitted disease with chlamydia and genital herpes is associated with increased risk of acquiring HPV infection co-infection with HIV may weaken the immune systems to control HPV infection (Mohanty & Ghosh, 2015).

The invasive cancer development process could extend and prolong up to 20 years from the precursor lesion caused by the HPV. Nonetheless, other numerous risk factors exist such as sexual intercourse at a young age (<16 years old), multiple sexual partners, smoking, high parity and low socio-economic status (S. Zhang, Xu, Zhang, & Qiao, 2020).

Age of sexual intercourse debut increases the risk of developing cervical cancer i.e early age. Similarly the risk approximately doubles with two partners and triples with six or more partners (Vesco et al., 2011).

Parity is a risk factor, where age of less than 18 years at full-term pregnancy and high parity have been associated as risk factors for HPV infection and/or developing cervical cancer. Also, with first sexual encounter at a younger age or proximity to menarche increasing the risk (Johnson, James, Marzan, & Armaos, 2019).

Lengthy use of oral contraceptives for more than 5 years also increases the risk of developing cervical cancer. This risk increases 1.9-fold for every 5 years of oral contraceptive use. (Vesco et al., 2011). Women who have been treated for cervical intraepithelial neoplasia have a 2- to 3-fold increased risk of developing cervical cancer in the future (Johnson et al., 2019).

Almost 90% of incident HPV infections are not detectable within the first 2 years from the acquisition of infection and persist only in a small proportion, of this infection one- tenth of them become persistent, which could develop cervical precancerous lesions, with those with the longer latency of HPV getting either the cervical intra epithelial neoplasia and cervical cancer. Therefore with that in mind new initiatives for prevention and early detection have been formulated. The two main approaches for control of cervical cancer namely, prevention of invasive cancer by robust and timely HPV vaccination and screening for precancerous lesions (Bhatla & Denny, 2018). Screening methods mainly involve the traditional Pap smear, visual inspection with acetic acid & Lugol's iodine (VIA/VILI), liquid-based cytology (LBC) and HPV testing (S. Zhang et al., 2020).

The Director-General World Health Organization in May 2018 initiated a global call to action geared towards the elimination of cervical cancer, and called for all stakeholders to unite behind this common goal. This global strategy to eliminate cervical cancer proposes that cervical cancer is eliminated as a public health problem; a threshold of 4 per 100 000 women-years for elimination as a public health problem; and the following 90-70-90 targets that must be met by 2030 for all countries to be on the path towards cervical cancer elimination (WHO, 2020).

The 90-70-90 proposes that 90% of girls fully vaccinated with HPV vaccine by age 15 years. 70% of women are screened with a high-performance test by 35 years of age and again by 45 years of age and finally 90% of women identified with cervical disease receive treatment (90% of women with pre cancer treated, and 90% of women with invasive cancer managed) (WHO, 2020). In Kenya vaccination for HPV was rolled out by President Uhuru Kenyatta in October 2019.

2.1.3 Pathophysiology

The cervix, is the lowermost part of the uterus. It is a cylindrical- shaped structure composed of epithelium and stroma. The intravaginal part, is called the ectocervix, which projects into the vagina and is lined by squamous epithelium. The endocervical canal extends from the internal os (internal opening) at the junction with the uterus to the external os which opens into the vagina and is lined by columnar epithelium. Most cases of cervical cancer arise in the transformation zone from the ecto- or endocervical mucosa. The transformation zone is the area of the cervix between the old and new squamocolumnar junction (Bhatla & Denny, 2018).

However, clinical and histologic definitions of the cervical transformation zone (TZ) and squamocolumnar junction (SCJ) vary considerably. In a study conducted among the board members of the European Federation of Colposcopy member societies and members of the International Society of Gynecological Pathologists, 22 expert colposcopists and 34 gynecologic pathologists responded. There was consensus that the TZ is the area where squamous metaplasia has occurred. There was consensus that the original SCJ can appear colposcopically indistinct in cases of maturation of the metaplastic squamous epithelium but can be identified histologically by the presence of the so-called last cervical gland. It was agreed that the border between the

metaplastic squamous epithelium and the columnar epithelium on the surface of the cervix is called the new SCJ (Prendiville & Sankaranarayanan, 2021).

Cancer of the cervix is mostly thought to originate from a prolonged and persistent Human Papilloma Virus (HPV) infections. There are over 200 HPV variants of which 12 have been found to be carcinogenic by the International Agency for Research on Cancer, where HPV-16 accounts for 50% and HPV-18 accounts for 10% of all cervical cancer cases, respectively (Johnson et al., 2019).

Of the aforementioned to variants (HPV 16 and 18), infection with one of them accounts for a 435-fold and 248- fold increased risk of developing cervical cancer, respectively, as compared with an uninfected individual (Basu, Banerjee, Singh, Bhattacharya, & Biswas, 2013). In 99.7 % of patients with cervical cancer the genome of high risk HPV can be detected in cases where there have been prolonged infection (Johnson et al., 2019). As is well known HPV is sexually transmitted and by age 45 years 80% of women will be infected at some point in their life time (NJNNPS, 2017). Infection with HPV is often acquired during adolescence and early adulthood stages. Since the infection is asymptomatic 10-15 years to manifest and exhibit in the cervix (Chelimo, Wouldes, Cameron, & Elwood, 2013).

2.1.4 FIGO staging

Until recently, the FIGO staging was based mainly on clinical evaluation and examination with the addition of select procedures, were allowed by FIGO to change the staging. In 2018, this was redrafted by the FIGO Gynecologic Oncology Committee to enable imaging and pathological findings, where available, to assign the stage (Bhatla & Denny, 2018), the revised system of staging is as shown in table below

Table 1:The FIGO staging table (Bhatla et al., 2018)

	Description
I	The carcinoma is strictly confined to the cervix (extension to the uterine corpus should be disregarded)
IA	Invasive carcinoma that can be diagnosed only by microscopy, with maximum depth of invasion <5 mm
IA1	Measured stromal invasion <3 mm in dept
IA2	Measured stromal invasion ≥3 mm and <5 mm in depth
IB	Invasive carcinoma with measured deepest invasion ≥5 mm (greater than Stage IA), lesion limited to the cervix uteri
IB1	Invasive carcinoma ≥5 mm depth of stromal invasion, and <2 cm in greatest dimension
IB2	Invasive carcinoma ≥2 cm and <4 cm in greatest dimension
1B3	Invasive carcinoma ≥4 cm in greatest dimension
II	Cervical carcinoma invades beyond the uterus but not to the pelvic wall or to the lower third of the vagina
IIA	Without parametrial invasion
IIA1	Clinically visible lesion less than4.0 cm in greatest dimension.
IIA2	Clinically visible lesion greater than 4.0 cm in greatest dimension.
IIB	With obvious parametrial invasion but not upto the pelvic wall
III	The tumor extends to the pelvic wall and/or involves lower third of the vagina and/or causes hydronephrosis or nonfunctioning kidney.
IIIA	Tumor involves lower third of the vagina with no extension to the pelvic wall.
IIIB	Extension to the pelvic wall and/or hydronephrosis or nonfunctioning kidney.
IIC	Involvement of pelvic and/or para-aortic lymph nodes, irrespective of tumor size and extent (with r and p notations)
IIIC1	Pelvic lymph node metastasis only
IIIC2	Para-aortic lymph node metastasis
IV	The carcinoma has extended beyond the true pelvis or has involved (biopsy proven) the mucosa of the bladder or rectum. A bullous edema, as such, does not permit a case to be allotted to stage IV.
IVA	Spread of the growth to adjacent organs.
IVB	Spread to distant organs beyond the pelvic area

2.1.5 Diagnosis, management and description of radical hysterectomy in cancer of cervix

Diagnosis of Stage IA1 and IA2 is made on microscopic examination of a LEEP (loop electrosurgical excision procedure) or cone biopsy specimen, which includes the entire lesion. Lesions that are visible clinically, and those with substantial dimensions, are allocated to Stage IB, subdivided in the latest staging as IB1, IB2, and IB3 based on the biggest diameter of the lesion. In the case of visible lesions, a punch biopsy may generally be sufficient, however if not satisfactory a small loop biopsy or cone may be required. Clinical evaluation is the first step towards allocation of staging. (Bhatla & Denny, 2018).

Management and treatment of cervical cancer depends on cervical cancer stage and can be by surgery or radiation therapy, with chemotherapy, a valuable accompaniment.

Historically the first person to perform a radical hysterectomy was Dr John G. Clark of the Johns Hopkins Medical School and publish a description of a radical hysterectomy in which all of the parametria were removed (Webb, 1997). However, the operation of radical hysterectomy for the treatment of cervical cancer is commonly known as 'Wertheim's operation' named after Professor E. Wertheim of Vienna (Webb, 1997). Dr John D Clark performed a more radical procedure after careful pathological study of cervical cancer in the 17th century (Webb, 1997).

The surgical treatment of cervical cancer is represented by the radical abdominal hysterectomy. This operation is two fold: the organ extended surgery in this case the uterus and the conception of the lymphatic removal surgery (Marin, Plesca, Bordea, Moga, & Blidaru, 2014). However the pioneer surgeon of hysterectomy had different

views regarding lymphatic node resection. In a paper written by Clark in 1913 he believed that removal of the nodes was more of a prognostic than a therapeutic procedure, while Wertheim in 1900 stated that it was not essential to do node resection in every case especially if they appear not to be enlarged (Webb, 1997).

The Viennese surgeon Ernst Wertheim and the Romanian surgeon Thoma Ionescu, were the pioneer surgeons in regard to radicality, who defended their views and practice their in 1902, at the International Congress of Surgery and Gynecology in Rome (Marin et al., 2014).

This procedure was associated with high mortality rates at 30% for Wertheim's first 100 patients (Mikuta, 1995), and 19% for the first 500 patients (Wertheim, 1912).

In the surgical approach, Wertheim proposed that the uterus removal be extended by not only excision of the uterus, but also the surrounding tissues parametrium and, of the superior vagina; regarding the lymph node resection, Wertheim suggested the removal of the palpable lymph nodes only (Marin et al., 2014). In contrast Thomas Ionescu was a strong believer of the pelvic lymph node resection regardless of palpability (Marin et al., 2014).

In 1921, H. Okabayashi along with his Professor S. Takayama published their own technique, which had as peculiarity of, the preservation of the nerve plexus.

The Piver–Rutledge–Smith classification which was published in 1974 includes the class I–V category, has gained substantial favor (Sun et al., 2018).

In Piver class I (Te linde modification) is a hysterectomy where all cervical tissue is removed. In Piver class II , is a modified radical hysterectomy where the aim is to remove more para cervical tissues. Piver class III (Meig's) is radical hysterectomy surgery where there is a wide radical excision of the parametrial and paravaginal

tissues in addition to pelvic nodes resection. Piver class IV hysterectomy aims to remove completely all periureteral tissue, and additionally extensive resection of the perivaginal tissues and excision of the internal iliac vessels along this part of the pelvic wall. Although the surgery is no longer used the aim of Piver class V hysterectomy is to resect central recurrent cancer affecting portions of the distal ureter or bladder (Piver, Rutledge, & Smith, 1974; Sun et al., 2018)

Querleu and Morrow published another classification that was different from the Piver–Rutledge–Smith method of radical hysterectomies in Lancet Oncology magazine in 2008 (Marin et al., 2014; Querleu & Morrow, 2008). This is a modification of Piver classification. This method of classification radical hysterectomy, describes four different types of performing radical hysterectomy (types A, B, C, and D), with a few additional sub classification, such as subtype C1, which includes nerve sparing surgery, and subtype C2, which does not include the nerve sparing surgery (Sun et al., 2018).

The Table below briefly describe the types of radical hysterectomy as per the Piver and Querleu (Piver et al., 1974; Querleu & Morrow, 2008) classification. The table is adopted from FIGO 2018 cancer report (Bhatla & Denny, 2018).

Table 2:Types of radical hysterectomy

	Simple extrafascial hysterectomy	Modified radical hysterectomy	Radical hysterectomy
Piver and Rutledge Classification	Type I	Type II	Type III
Querleu And Morrow classification	Type A	Type B	Type C
Indication	Stage IA1	Type IA1 with LVSI. IA2	Stage IB1 and IB2, selected Stage IIA
Uterus and cervix	Removed	Removed	Removed
Ovaries	Optional removal	Optional removal	Optional removal
Vaginal margin	None	1–2 cm	Upper one-quarter to one-third
Ureters	Not mobilized	Tunnel through broad ligament	Tunnel through broad ligament
Cardinal ligaments	Divided at uterine and cervical border	Divided where ureter transits broad ligaments	Divided at pelvic side wall
Uterosacral ligaments	Divided at cervical border	Partially removed	Divided near sacral origin
Urinary bladder	Mobilized to base of bladder	Mobilized to upper vagina	Mobilized to middle vagina
Rectum	Not mobilized	Mobilized below cervix	Mobilized below cervix
Surgical approach	Laparotomy or laparoscopy or robotic surgery	Laparotomy or laparoscopy or robotic surgery	Laparotomy or laparoscopy or robotic surger

A study conducted in La Paz University Hospital in Madrid, Spain it was determined that laparoscopic radical hysterectomy for early stage cervical cancer, is a viable procedure especially in high resource settings, that reveal advantages such as less post-surgical complications, shorter duration of hospital stay, and earlier resumption of usual physical and daily activities. However more studies are needed in order to establish the oncological outcomes of this technique (Arispe, Pomares, De Santiago, & Zapardiel, 2016). Similarly it was found in another study done in Magee-Women's Hospital of the University of Pittsburgh that, laparoscopic radical hysterectomy is a practical alternative to laparotomy for early stage cervical cancer. Similar surgical

outcomes are attained and realised with significantly less morbidity (Taylor, McBee Jr, Richard, & Edwards, 2011). However, in a systematic review and meta-analysis performed in an academic medical setting, it was found that, that among patients undergoing radical hysterectomy for early-stage cervical cancer, laparoscopic radical hysterectomy was linked to an increased risk of recurrence and death compared with laparotomy (Nitecki et al., 2020).

2.1.6 Socio demographic characteristics of patient with cervical cancer

Assessment of socio-demographic profile and clinical characteristics gives a better picture of the determinants of cervical cancer especially in a low-resource setting like Kenya where the current study was conducted

In a study done in Canada British Columbia it was determined that there were significant differences in the number of observed cases of cervical cancer by ethnicity or race compared with the expected cases based on the ethnicity or race distribution of the general population. In detail, it was found that a greater number of observed cases than expected in women who self-identified as a visible minority (Filipino, Korean or Japanese) or Indigenous (Simkin et al., 2021)

In a study done over a 1 year period in Mumbai India, majority of patients diagnosed with cervical cancer were aged between 45-64, most of the study participant professed the Hindu religion given the locality of the study, slightly over half of the patients studied were illiterate, with almost three quarters of them being married. Majority of participant were homemakers as their occupation with 70% living in the rural areas (Jain, Ganesh, Bobdey, Sathwara, & Saoba, 2017).

In a hospital based cross sectional study done in New Delhi, India it was observed that illiteracy, low socioeconomic status, early sexual debut, high fertility, home

delivery, reproductive tract infections, use of insanitary clothes during menstruation and anemia were observed in majority of women with advanced cervical cancer (Dahiya et al., 2017).

In Bamenda Cameroon a review of patient charts treated for cervical cancer in regional hospital found that the most affected age-group with cervical cancer was 50-54year (Nkfusai et al., 2019).

A Chinese cohort profile study found that the mean age of patient with cervical cancer was 49.19 at diagnosis, where most patient were married, while most lived in the rural settings. In same study most patients were at clinical stage 1B2 although the FIGO staging used was (2009) (X.-R. Zhang et al., 2021). An Indian study established that the most prevalent stage at diagnosis was stage 2in their participant with only 2% having AID/HIV positive (Jain et al., 2017).

2.2 Quality of life and measuring tools

The definition of Quality of Life (QoL) is broad and subjective. According to WHO, QoL is defined as individuals' perceptions 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 (Harper & Orley, 1996).

The use of the term subjective has different meaning to different people and can be assumed as not reliable because it is not 'objective'. Subjective can be synonymous with self-perceived meaning that a person primarily gives information about him or herself (Megari, 2013).

World Health Organization quality of life assessment (WHOQOL) identified six domains that form the quality of life namely: physical domain, psychological domain, level of dependence, social relationships, environment and spiritual beliefs (Harper & Orley, 1996).

Other definitions of QOL suggest that it is a global personal assessment of a single dimension which may be causally responsive to a variety of other distinct dimensions: it is a unidimensional concept with multiple causes (Cella & Nowinski, 2002).

In 1993 Patrick and Erickson define health-related quality of life (HRQoL) as the merit assigned to a time in life of life where the merits are modified by the impairments of functional states, perceptions and social opportunities that are influenced and affected by disease, treatment, injury or policy (Megari, 2013).

In the field of health and medicine Quality of life (QOL) is an important concept. It is interpreted and defined differently within and between disciplines, and different fields of health and medicine (Haraldstad et al., 2019).

There is a strong influence on both physical health and quality of life in people with chronic illness such as cancer. Therefore, understanding of the factors that determine HRQOL ensures that there is proper assessment, evaluation and appraisal of these factors for a better recognition and understanding of a patient's state during chronic illness and also during treatment (Sosnowski et al., 2017).

In a systemic review of research on health related quality of life done, it was determined that, quality of life research had a variety of target groups, QOL measure and study designs. The results also showed that of the total research reviewed only 13% of those provided the definition of QOL, and 6% were able to distinguish between health related quality of life and quality of life in general. It was also found

out that most researches stated the domains of the QOL, however most of the researches reviewed did not state the reason for choosing a particular tool to assess the QOL (Haraldstad et al., 2019).

In many situations it is not expected a return to normal and usual activities, especially in the presence of a chronic disease such as cervical cancer, or a progressive and worsening condition. There are also condition where disease cause permanent disability and as such it is a herculean task to return to the normal physical and mental status that would be regarded as a better QOL (Megari, 2013).

There are various questionnaires for the research and analysis of patient-related QOL. QoL studies may use generic and/or condition-specific measures to evaluate the relevance to a patient's life and assess if there is a direct relationship between treatment change in QOL and specific outcomes (Arriba, Fader, Frasure, & Von Gruenigen, 2010).

There is a wide range of instruments and modes of questionnaire administration used by the many studies, this may hinder comparisons between population groups with the same sociodemographic and clinical characteristics, or needs. There is paucity of date or few on QOL and the factors affecting productive capacity, mobility and physical wellbeing especially in the aging population. This was found in a systemic review of QOL research done between 2008 and 2018 (Pequeno, de Araújo Cabral, Marchioni, Lima, & de Oliveira Lyra, 2020).

From the result of different studies it is clear that no sole tool is generally appropriate for the target population being studied and a particular disease that is being investigated for its impact on quality of life (Nasim et al., 2018).

Measures that are commonly used in the research of chronic disease and QOL are the Medical Outcomes Study 36-Item Short- Form Health Survey (SF-36), the Nottingham Health Profile (NHP) and the EuroQol (EQ- 5D). Translation to many languages of these instruments are available, and as such used in many countries. An example of specific instrument that is used to access cancer therapy and QOL is the Functional Assessment of Cancer Therapy- General (FACT-G) (Megari, 2013).

In a review that was conducted to identify the most frequently used health-related quality of life (HRQOL) tools in the world, it was found that the most frequently used HRQOL tools were: EQ5D, SF and WHOQOL. It was evident from the review that disease-specific studies have been conducted various tools, in different studies regardless of the disease or domain of questionnaires (Nasim et al., 2018).

In this study therefore we seek to establish how surgery impact on patient QOL using EQ-5D-5L tool. The 5-level EQ-5D version (EQ-5D-5L) was authored by the EuroQol Group in 2009. The EQ-5D-5L essentially consists of 2 pages: the EQ-5D descriptive system and the EQ visual analogue scale (Herdman et al., 2011). This questionnaire is consistent with our objectives especially given the fact that this was a prospective study. EQ-5D questions were valid across board in both the pre-operative and post-operative period. In the cases of FACT Cx which is a specific QOL measure for cervical cancer, some of the questions were not relevant post operatively after radical hysterectomy, while the EQ-5D had question that could be asked at the follow-up period. We needed to ask similar question both pre and postoperatively to objectively analyse the change in QOL.

In the EQ-D-5L the descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The patient is asked to indicate his/her health state by ticking the box next to the most appropriate statement in each of the five dimensions. This decision results in a 1-digit number that expresses the level selected for that dimension. The digits for the five dimensions can be combined into a 5-digit number that describes the patient's health state. The EQ VAS records the patient's self-rated health on a vertical visual analogue scale. These instrument has been applied in a variety of health sector settings, in patient-reported outcome exercises, in population health studies, and in health technology assessment (Herdman et al., 2011).

In the Chinese Journal for cancer, a study found that patients with precancerous lesions and early cervical cancer show better overall QOL than do those with advanced cervical cancer (Xie et al., 2013). Additionally, patients with early cancer recovered faster than those who had advanced cancer in terms of both physical and mental functions. Therefore, early detection and treatment initiatives may improve the QOL for patients with precancerous lesions and cervical cancer (Xie et al., 2013).

Not all commonly used QOL surveys are sensitive to changes during the perioperative period and may not be suitable for use in surgical quality metrics. However, the study analyzed QOL of all surgical gynecologic patients and did not seek to analyze QoL of other treatment modalities (Doll et al., 2014).

2.3 Quality of life after radical hysterectomy for early stage cervical cancer

In China a study was conducted to assess the possible disparities between total laparoscopy and laparotomy regarding their effect on postoperative quality of life in cervical cancer patients who underwent radical hysterectomy with/out lymphadenectomy alone and were followed up for a period of 52 weeks. It was determined that cervical cancer patients after radical hysterectomy with/out lymphadenectomy were able to cope well, and had better quality of life after surgery regardless of surgical approach used as either laparotomy or laparoscopy. However it was the opinion of the authors that a longitudinal and randomized controlled studies with bigger populations be conducted to better compare the effects of laparoscopy to laparotomy regarding change in QOL post-operatively (Xiao, Gao, Bai, & Zhang, 2016).

A Review of hospital databases was done in a retrospective cohort study to assess the impact of simple hysterectomy versus radical hysterectomy impact on quality of life, the review found that hysterectomy results in detrimental effects on the quality of life especially in women who underwent radical hysterectomy (Selcuk et al., 2016). However several other study seems not to go hand in hand with this findings.

In a 10 year period from January 2004 to June 2014, patients who presented to Campus Bio-Medico of Rome for type C2/type III radical hysterectomy as treatment for cervical cancer, were evaluated for the long-term effect on quality of life after radical hysterectomy it was established that there was negligible impact on QOL after surgery (Plotti et al., 2018). However in a study done in Italy which confers the same socio demographic setting finding were different from the Rome study. In the Verona study to assess quality of life and survival after nerve-sparing radical hysterectomy, done in the Gynecologic Oncology Unit of the Sacred Heart Hospital of Negrar

(Verona) Italy and the Department of Obstetrics and Gynecology of Bologna University Hospital Italy , between January 1997 and November 2009, it was found that Post- operative quality of life after nerve sparing quality of life was better, with the same overall survival as compared to radical hysterectomy (Ceccaroni et al., 2012).

In a study conducted by The University of Texas conducted at the Anderson cancer Centre to compared two treatment groups, those who underwent surgery and those who had radio therapy after a diagnosis of cancer of the cervix. It was found out that those treated with surgery alone can expect their overall quality of life to improve (Frumovitz et al., 2005). However, in another study carried out between January to June 2016, in tertiary Thammasat University Hospital, Thailand, it was concluded that, cervical cancer patients who had undergone radical hysterectomy as treatment, may have a better quality of life. Furthermore they established that early detection of early stage cervical cancer prudent, as treatment at an early stage did not impact on the quality of life (Prasongvej et al., 2017).

While comparing Meigs (type III) or Okabayashi (type IV) radical hysterectomy with pelvic lymph node resection for early- stage cervical cancer, it was established that Quality of life was not significantly different in patients treated regardless of the type of the radical hysterectomy that was performed (Derks et al., 2016).

In a Chinese settings, a multi-center retrospective study was conducted in which patients who were diagnosed with cancer of the cervix and underwent radical hysterectomy, from 2012 to 2018 in 18 different medical centres.it was established that those who underwent open radical hysterectomy and had large amount of operative blood loss were at risk of having poor QoL (Wang et al., 2021).

In North Carolina an institution based cohort study, patients were enrolled from august 2012 to June 2013 and medical records data was retried including comorbid conditions demographics, and operative outcomes. Although this study focused on Pre-operative quality of life, it enrolled all gynecological malignancy. Of those cervical cancer were only 10%, where they evaluated the association between baseline QOL pre-operatively measures, and 4 weeks post-operative morbidity. They found out that lower pre-operative QOL scores are significantly associated with post-operative morbidity and hospital readmission (Doll et al., 2014).

Finally in Uttar Pradesh India, a study evaluated the QOL of patient diagnosed with cancer of the cervix before and after treatment and the effect of treatment on QOL. It was established that there was improvement of QOL after treatment especially in the aspect of physical wellbeing and emotional wellbeing (Rahman, Singh, & Qureshi, 2017)..

Our current study had therefore set out to establish if radical hysterectomy contributed to the improvement of Quality of life using EQ-5D-5L tool, which is a validated tool and found to be the most commonly used tool in assessment of health related quality of life (Haraldstad et al., 2019). With this concept being broad and subjective, several studies pointed earlier have used different tools, but the main domains of measuring QOL are still addressed as per WHO definition (Harper & Orley, 1996). This tool has been used in a variety of health related quality of life assessment studies. In 2017 in kings medical college India Zakia et al used the EQ-5D-5L, which was a prospective study that evaluated the QOL before and after treatment of cervical cancer patients across all stages and included all treatment modalities (Zakia et al 2017)

In china Zhao min assessed the QOL among Chinese ethnic minorities using the afore mentioned tool. In that study they evaluated in a cross-sectional study the QOL of the ethnic minorities suffering from both cervical precancerous lesions and cancer of the cervix itself (Zhao et al 2021).

In justification of using the EQ-5D-5L, it was prudent to use a tool that was not only consistent but also reliable, where by same questions needed to be asked pre operatively and post operatively, questions in the tools had to be relevant at both times. Some of the tools had questions which wee relevant only pre operatively, while the same questions could not be asked post operatively. Specifically, the functional assessment of cancer therapy tool had questions that were relevant only pre operatively, questions to do with symptomatology, while after removal of the uterus same symptoms could not be expected, because the organ that was causing the said symptoms were removed, such as vaginal discharge and/or bleeding.

Similarly, questions needed to be asked across all age groups, regardless of cervical cancer stage. While it would have been relevant to ask a woman of child bearing age if they are concerned about their ability to have children, the same question would not have been relevant to older women who had achieved their family sizes as was the case in the other tools. So to minimize biases and errors, it was necessary to select a tool that had consistency in timing of questions and reliable at any given point and to any participant.

Internationally there are several tools that are being used in trials for patient reported outcomes for cervical cancer. Of those 27 trials three trials are using EQ-5D-5L, further reinforcing the fact that this tool used in this study is not only validated but

widely used and internationally accepted (Rutherford, Campbell, White, & King, 2019).

This tool has also been used in several local studies in Africa, eastern Africa and Kenya. It has been used to assess the psychometric QOL of malaria patients in Nigeria in plateau state (Jimam, Ismail, & Dayom, 2020). In eastern Africa the same tool has been used to assess QOL and health state in Ethiopia (Welie et al., 2020). Similarly it has been used in our local Kenyan settings to assess the QOL of health care workers in Kenya (Muthuri, Senkubuge, & Hongoro, 2021).

2.4 Conceptual framework
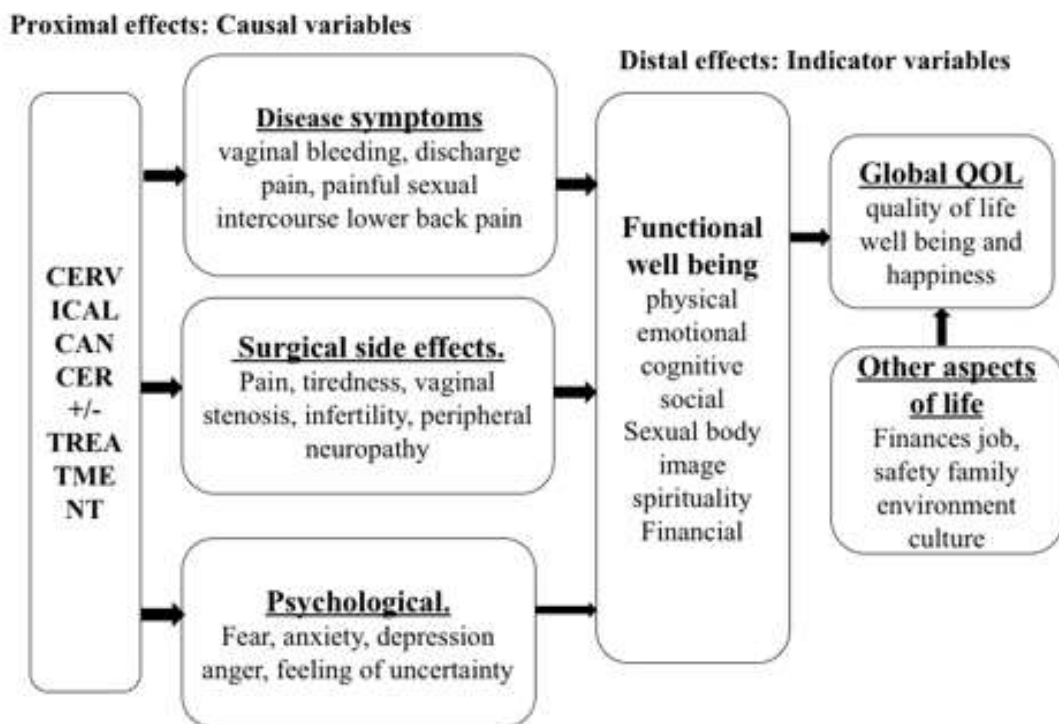
Figure 1: Conceptual framework
Source (Rutherford et al., 2019)

Cervical cancer and its treatments may affect a person's QOL. Proximal effects occur directly as a consequence of the cervical cancer and/or treatment for the disease, such as disease symptoms (e.g. PV bleeding pain, fatigue) and side effects and treatment

(vaginal stenosis and infertility). These may consequently affect a person's ability to function and their overall sense of wellbeing, i.e. cause distal effects. A cervical cancer diagnosis, impact psychological wellbeing or indirectly impact via experience of symptoms, side effects, and loss of functional ability and infertility. Therefore, Quality of life was the dependent variable in this study with the participants social demographic and clinical characteristics considered as independent variables. For predictor (independent) variables that significantly affected the participant's quality of life at the bivariate level, a logistic regression was conducted to determine whether the relationship was affected by any confounders.

DEPENDENT VARIABLE	INDEPENDENT VARIABLES
Quality of Life (QOL)	**Socio Demographic Characteristics** 1. Age 2. Marital Status 3. Education 4. Occupation 5. Health Insurance 6. Residence **Clinical characteristics** 1. Parity 2. History of Cervical cancer 3. History of smoking 4. HIV Status **5.** Cervical cancer stage

CHAPTER THREE: MATERIAL AND METHODS

3.1 Study design

This was a prospective cohort study conducted among women with surgically amenable stage of cervical cancer and scheduled of radical hysterectomy.

3.2 Study area

The study was carried out at two national hospitals in Kenya namely: the Moi Teaching and Referral Hospital (MTRH) in Eldoret and Kenyatta National Hospital (KNH) in Nairobi. Moi Teaching and Referral Hospital is the second largest teaching and referral hospital in Kenya located in Eldoret town of Uasin Gishu County, which is 310 kilometers Northwest of Nairobi, the capital city of Kenya. The hospital serves both inpatient and outpatient clients majority of whom are drawn from Western Kenya with a population of approximately 20 million. The facility has a specialized cancer and chronic diseases treatment and research center (known as the Chandaria cancer and chronic diseases center) and a large surgical unit and four gynecology oncologists able to provide radical hysterectomy surgery for patients with early-stage cervical cancer. After a confirmatory diagnosis of cervical cancer, patients undergo various modalities of treatment such as surgery for early-stage disease. During follow up, patients are monitored clinically and medical images are obtained both post-operatively.

The Kenyatta National Hospital is the oldest and largest national referral hospital located in Nairobi – which is the capital city of - Kenya. It is a public, tertiary, referral hospital that also houses the school of medicine of University of Nairobi. It is located in the area to the immediate west of Upper Hill in Nairobi, which is the capital and largest city in Kenya. Its location is about 3.5 kilometers (2 mi) west of the city's central business district. The hospital complex measures 45.7 acres (18.5 ha) with an

influx of cancer patients from not only East Africa but the greater African continent. It offers surgery chemotherapy, radiotherapy, immunotherapy, targeted therapy, and hormone therapy for cancer patients. Specifically, cervical cancer patients with an early stage of the disease receive radical hysterectomy as a treatment modality.

3.3 Study Period

This study was carried for a period of 17 months from October 2019 to February 2021, with each participant followed for twelve weeks after radical hysterectomy to assess the women's perception of their quality of life.

3.3 Study population

The study population was women newly diagnosed with cervical cancer with a confirmatory histopathological, radiological and clinical finding of surgically amenable stage of IB2 or below; and admitted to either KNH or MTRH.

3.4 Sample size and sampling procedure
3.4.1 Sample size

The main objective of the study was to assess the Quality of Life of patients newly diagnosed and surgically treated cancer of the cervix.

The postulated hypothesis is: H_1: The quality of life of patient undergoing surgery for early-stage cancer of cervix improves after surgery.

Therefore, this study adopted formula from (Hulley et al). In a previous study conducted at India's King George Medical University on the quality of life for women with cervical cancer (Rahman *et al.,* 2017), it was determined that the average change in the participants quality of life pre- and post-radical hysterectomy was 20.1.

In the aforementioned study they found a standard deviation of 20.1 for the mean change in QOL of the function scale which included physical function, role function,

emotional function, cognitive function and social function between baseline to six months after using Wilcoxon test.

The investigator used a minimum difference of 20.2 in mean change quality of life after surgery.

$$n = \frac{2x\sigma^2(Z_{1-\alpha/2} + Z_{1-\beta})^2}{(d)^2}$$

Where:

σ^2 = Standard deviation of mean change in quality of life

d = Effect size $(\mu_1 - \mu_2)$

$Z_{1-\alpha/2}$= Standard normal critical value for two-sided test at with a type I error (**α=0.05**)where$Z_{1-\alpha/2}$=1.96.

$Z_{1-\beta}$= Standard normal critical value for **β** type II error (**β=0.20**);$Z_{1-\beta}$=**0.84.**

$$n = \frac{2x20.2^2(1.96 + 0.84)^2}{(10)^2} = 63.98$$

2× 408.04(7.84)/100=63.98

Adding a likely attrition during follow-up of 10% (n=6.4) gives 70.4

Therefore, a total sample size =71 patients with early-stage cervical cancer.

3.4.2 Sampling Procedure

Consecutive sampling was used to select participants for the study.   Every eligible Gynaecological cancer patient receiving care at the palliative care unit, Kenyatta National Hospital and at Chandaria cancer center MTRH and consented to participate in the study was interviewed. This process was repeated until the required sample size was obtained.

3.5 Eligibility criteria

3.5.1 Inclusion criterion

Newly diagnosed patients of cancer cervix at surgically amenable stage (FIGO stage 1B2 and below)

3.5.2 Exclusion criteria

1. Women with comorbidities that are contraindications of surgery

2. Women with diagnosed psychiatric disorders

3. Patient who are diagnosed with advanced stages of cervical cancer (Stage IB3 and above).

3.6 Study Procedure

Women who presented with a histologically confirmed diagnosis of cervical cancer at the gynecology oncology units of both KNH and MTRH were considered as potential participants for the study and provided with general information about the study. They were identified by both the principal investigator and research assistants at the gynecology oncology clinics of the study site and had their medical history taken and physical examination conducted as per the standard of care. Appropriate laboratory and radiological investigations such as a complete blood count, abdominopelvic CT scan, chest x-ray and renal function test were done.

Based on their medical history and clinical signs, the Federation of Obstetrics and Gynecology (FIGO) criteria was used to stage the newly diagnosed cervical cancer patients. Those that met the criteria of stage IB2 and below were offered a written informed consent in either English or Kiswahili by the principal investigator or a trained research assistant prior to enrollment into the study. After consenting, an interviewer (principal investigator or research assistants) administered questionnaire that included EQ-5D-5L was used to collect participant's clinical and reproductive

characteristics as well as assess their quality of life prior to surgery. After radical hysterectomy, the participants were followed up after three months (during their post-surgical visit or through a phone call) to determine their post-surgical quality of life.

The EQ-5D-5L consists of 2 pages – the EQ-5D-5L descriptive system and the EQ Visual Analogue scale (EQ VAS). The descriptive system comprises the same 5 dimensions as the EQ5D-3L (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Each dimension had 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The respondent were asked to indicate their health state by ticking (or placing a cross) in the box against the most appropriate statement in each of the 5 dimensions. This decision results in a 1-digit number expressing the level selected for that dimension. The digits for 5 dimensions can be combined in a 5-digit number describing the respondent's health state.

3.7 Patient recruitment schema

Study Procedure

Newly diagnosed participant with a histological confirmed cancer of the cervix → History, physical examination and radiological findings were used to exclude stage 1B3 and above → Eligible patient for surgery identified

Consent given

Administration of baseline (Pre-Op) questionnaire 1 social demographic and clinical characteristic data plus questionnaire 2 for QOL data

Thereafter 12 weeks post operatively, administration of questionnaire 2 of QOL data administered

Exit study

Figure 2: Patient recruitment schema

3.8 Data management and analysis

Data was collected using a structured questionnaire where both participants information and their quality-of-life score (pre- and post-hysterectomy) were documented. The data on the hard-copy questionnaires were entered into a password protected Microsoft Access electronic database. The data was then exported to STATA statistical software for analysis.

Descriptive results were computed and presented in the form of tables for the participants' sociodemographic characteristics, cervical cancer stage, treatment factors (surgery) and impact of treatment on quality of life.

Inferential statistical analysis using bivariate analysis using Pearson chi-square test was adopted to compare the difference in participants' social-demographic characteristics and quality of life indicators where a p-value ≤0.05 was considered to be statistically significant. Adjusted Odds Ratios were computed at 95% confidence intervals.

Each health state described by the EQ-5D-5L quality of life assessment tool was represented by a five-digit value, one for each of the five dimensions where by Level 1 indicating no problem, Level 2: indicating slight problem, Level 3: indicating moderate problems, Level 4: indicating severe problems and finally Level 5: indicating extreme problems. For instance, "21111" referred to a state in which a person had slight problems with walking, but no problems in the remaining four dimensions, whereas "54123" represented a person unable to walk about, with severe problems washing or dressing, no problem performing usual activities, slight pain or discomfort, and moderate anxiety or depression. The data collected using EQ-5D-5L

was presented with a basic subdivision according to the structure of the EQ-5D-5L as a descriptive system of the health profile and using European Quality of Life Visual Analogue. Scale (EQ-VAS) as a measure of overall self-rated health status.

The descriptive presentation of the results were on mobility, self-care, usual activities, pain or discomfort and anxiety or depression. These dimensions score compared the pre-radical hysterectomy and three months post radical hysterectomy mean scores, where an increase in the mean quality of life score was considered as an improvement. The scores were further dichotomized into level 1 and levels 2-5, where: Level 1 was indicative of a patient not having any problem while levels 2 to 5 signified that a patient has a problem. Visual analogue scale data were presented in means and corresponding standard deviation.

3.9 Quality control

The study team consisted the principal investigator and two research assistants (one per study site) who were trained by the principal investigator and tested on the study objectives, methods and data collection techniques prior to commencement of the study. Furthermore, they also underwent training on ethical research conduct with a particular focus on participant's privacy, confidentiality and autonomy of study participants.

Once all the data had been collected, the principal investigator reviewed all the questionnaires for both completeness and consistency prior to data entry. A double data entry approach was adopted to ensure both accuracy and reproducibility of the keyed data. The Principal Investigator conducted routine checks regarding data entry, storage and back-up procedure prior to the final dataset being transferred to the statistician for analysis.

3.10 Pilot Study

A pilot study, of seven patients was conducted at Chandaria Cancer Center in MTRH to test for the validity and reliability of the data collection tools. The objective was specifically to assess whether the research procedures, data collection tools, statistical and analytic processes could yield consistent information needed to achieve the study's objectives. Furthermore, it checked to clarify unclear or culturally sensitive questions that needed to be changed before the main study. The pilot study also assessed whether the research staff were adequately skilled to conduct the study. However, all the data collected during the pilot study were not included in the final study analysis.

3. 11 Ethical Considerations

The Moi University/MTRH IREC and KNH/IRB reviewed and approved the conduct of this study and no data collection took place prior to approval.

Respondents who agreed to participate in the study were given detailed information on the study and a chance to ask questions and/or to seek clarifications. Respondents were assured that their participation was voluntary and withdrawal from the study at any point with no penalty.

Respondents were required to sign an informed consent individually prior to participating in the study.

Confidentiality and anonymity of respondents was promoted by the use of respondent's codes during data collection.

The participants were not offered any incentives to participate in the research

3.11.1 Confidentiality

All electronic databases used in this study were protected by procedures consistent with applicable laws, directives, policies, regulations, and standard in Kenya. Each entry was assigned a unique identification number and all quantitative and qualitative data collected as part of the study was identified with this number. Data in tablets and computers was encrypted and password protected, and was only accessed by a user with a login and password. Participant files were accessible only to study investigators and were stored in a locked cabinet in a locked office. Prior to accessing any study data, study staff were asked to sign a Confidentiality Agreement (Appendix III).

3.11.2 Risks for participating in the study

This study carried minimum risk to participants. There was some risk that confidential information may be disclosed; however, all study staff underwent special training on confidentiality procedures and the importance of keeping personal information private. In addition, participant files were accessible only to the principal investigator and were stored away from clinic in a locked office. Databases did not include patient identifiers had been encrypted and password protected. The final study data only had the participant's unique identification number with no link to their name or other personally identifying information.

3.11.3 Benefits to Subject

Though no direct benefit to the patients will be realized from this study, the evaluation determined by treatment and their impact on QOL and identify ways to improve the quality of life among the surgically treated patients.

3.11.4 Study Implications

Findings from this study will be used to provide information on the impact of surgical treatment of patient with cancer of the cervix on QOL at two referral hospitals in Kenya and will be used to optimize care and treatment of these patients.

3.11.5 Publication Strategy

Authorship on publications, conference presentations, abstracts and other materials generated from this study will reflect contribution to design, execution and analysis of the study.

3.11.6 Funding

This study did not receive any funding.

CHAPTER FOUR

4.0 RESULTS

This section illustrates the data results from the research instruments and tools After

applying the eligibility criteria 75 patient were identified of which 4 declined consent.

The base line questionnaire 1 (which had the social demographic and clinical

characteristics) and 2 QOL data were administered followed later at 12 weeks with

administration questionnaire 2 of QOL data as shown in participant enrolment process

below
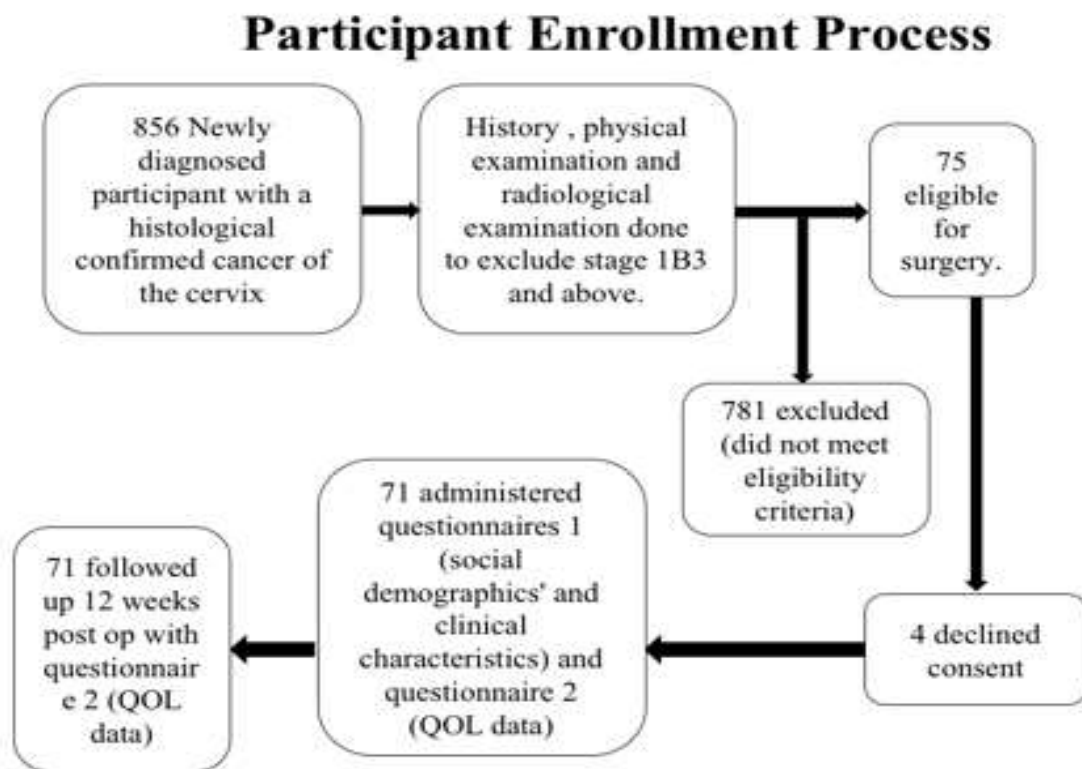
Figure 3: Participant Enrollment Process

4.1 Socio demographic characteristics of study participants

This study enrolled 71 women who were scheduled for radical hysterectomy and pelvic lymph node dissection for their surgically amenable stage of cervical cancer. Their mean age was 47.9 ($\pm$10.2) years with 62 (87.3%) of them aged more than 35 years. When the age of the participants was ranked, the youngest participant was 26 years old while the eldest was 68 years old. Nearly all (93%) of the participants were married, less than half (45%) had a minimum of secondary education, 37 (52.1%) were unemployed while 39 (54.9%) had a health insurance coverage. More than half of the study participants were recruited from Kenyatta National Hospital 40 representing 56.4% while the rest 31 representing 43.6% coming from Moi Teaching and Referral Hospital (Table 4.1).

Table 4. 1: Participants socio demographic characteristics (N=71)

Variable	N	Frequency (n)	Percent (%)
Age			
< 20		0	0
21-35	71	9	12.7
>35		62	**87.3**
Marital Status			
Single		5	7.0
Married	71	66	**93.0**
Education			
None/Primary	71	39	54.9
Secondary		16	22.5
Tertiary		16	22.5
Occupation	71		
Unemployed		37	**52.1**
Formal employment		12	16.9
Business		22	31.0
NHIF	71		
No		32	45.1
Yes		39	**54.9**
Study site	71		
MTRH		31	43.6
KNH		40	**56.4**

4.2 Clinical characteristics of the study Participants

Nearly two thirds (63.5%) of the study participants had a parity of four and above, with almost all (97.2%) the women reporting a negativefamily history of cervical cancer. None of the participants reported a history of smoking while 14 (19.7%) of the women enrolled were seropositive to human immunodeficiency virus (HIV) infection. The most prevalent cervical cancer stage was Stage IB2 among 34 (47.9%) participants followed by 28 (39.4%) Stage IB1 as shown on Table 4.2.

Table 4. 2: Clinical characteristics of patients with early-stage cervical cancer

Variable	N	Frequency (n)	Percent (%)
Parity			
One		4	5.6
Two to three	71	22	30.9
Four or more		45	**63.5**
Family history of Cervical cancer			
No		69	97.2
Yes	71	2	2.8
History of smoking			
No	71	71	**100**
Yes		0	0
HIV Status	71		
Negative		57	**80.3**
Positive		14	19.7
Cervical cancer stage	71		
Stage 1 A1		2	2.8
Stage 1 A2		7	9.9
Stage 1 B1		28	39.4
Stage 1 B2		34	**47.9**

4.3 Quality of life of patients diagnosed with cancer of cervix pre- and post-surgical treatment

A descriptive analysis using the EQ-5D-5L dimensions showed a positive improvement in the quality-of-life score before and after radical hysterectomy on all the five dimensions. This was further stratified into five levels namely: Level 1 (No problems), Level 2 (Slight Problems), Level 3 (Moderate Problems), Level 4 (severe problems) and Level 5 (unable to do anything) as shown on Table 4.3. 4.4, 4.5, 4.6 and 4.7.

Table 4. 3 Descriptive Comparison of Number of Patients in EQ-5D-5L Before and After Surgery in aspect of mobility.

Mobility	Pre	Post
Level 1	32 (45.1%)	65 (91.5%)
Level 2	23 (32.4%)	6 (8.4%)
Level 3	3 (4.2%)	0
Level 4	9 (12.7%)	0
Level 5	4 (5.6%)	0
Total	71	71

The mobility level of patients significantly improved after surgery as depicted in table 4.3 above. Sixty-five out of seventy-one of the patients were at level 1(91.5%) after surgery which was a good indicator as opposed to only 45.1% meaning more than half of the participants at a percentage of 54.1% who had a poor score (levels 2-5) prior to surgery as depicted in table 4.3 above.

Table 4.4: Descriptive Comparison of Number of Patients in EQ-5D-5L Before and After Surgery in aspect of self care.

Self-care	Pre	Post
Level 1	38 (53.5%)	70 (98.6%)
Level 2	9 (12.7%)	1 (1.4%)
Level 3	19 (26.9%)	0
Level 4	5 (7%)	0
Level 5	0	0
Total	71	71

In the aspect of self care as shown in table 4.4 above a total of 70 (98.6%) participants were able to take care of themselves without any assistance as opposed to only 38 participants prior to surgery at a percentage of 53.5% meaning 46.5% of participants had problems with taking care of themselves, however the percentage comes down to only 1.4% post operatively, representing a tremendous improvement as depicted in table 4.4 above.

Table 4.5: Descriptive Comparison of Number of Patients in EQ-5D-5L Before and After Surgery in aspect of Usual Activities

Usual Activities	Pre	Post
Level 1	16 (22.5%)	60 (84.5%)
Level 2	34 (47.9%)	11 (15.5%)
Level 3	9 (12.7%)	0
Level 4	2 (2.8%)	0
Level 5	0	0
Total	71	71

Eighty-four percent of participants had no problems conducting their usual activities after surgery, however, there was only 22.5% of participants at the same level pre operatively as shown in table 4.5 above. This indicates that 81.5% of participants had problems conducting their usual activities prior to surgery while that percentage significantly reduced to a paltry 15.5 5 post operatively, this phenomenon is shown in table 4.5 above.

Table 4.6: Descriptive Comparison of Number of Patients in EQ-5D-5L Before and After Surgery in aspect of Pain/Discomfort

Pain/Discomfort	Pre	Post
Level 1	3 (4.2%)	34 (47.9%)
Level 2	4 (5.6%)	27 (38%)
Level 3	43 (60.6%)	10 (14.1%)
Level 4	8 (11.3%)	0
Level 5	13 (18.3%)	0
Total	71	71

In the domain of pain/discomfort as shown in table 4.6 above only 4.2% of participants had no problems with pain or discomfort, meaning that 95.8% of participants had problems or complained of pain or discomfort prior to operation. However, post operatively 47.9% of participants had no problems with pain or discomfort while 52.1% still reported or complained of pain or discomfort twelve weeks' post operatively

Table 4.7: Descriptive Comparison of Number of Patients in EQ-5D-5L Before and After Surgery in aspect of Anxiety/Depression

Anxiety/Depression	Pre	Post
Level 1	11 (15.5%)	43 (60.6%)
Level 2	5 (7%)	14 (19.7%)
Level 3	27 (38%)	14 (19.7%)
Level 4	7 (9.9%)	0
Level 5	21 (29.6%)	0
Total	71	71

In the domain of anxiety or depression as shown in table 4.7 prior to surgery 15.5% of participant did not report pain or anxiety while 84.5% of the participants had problems or complained of anxiety or depression. Post operatively only 60.6% had no problems or reported no anxiety or depression, meaning that 39.4% of participants still had problems with anxiety and depression.

Therefore, a descriptive analysis using the EQ-5D-5L dimensions our results showed a positive improvement between the two time periods. The health state and quality of life of the interviewed patients was better after surgery with regards to mobility, self-care, usual activities, pain/discomfort and anxiety and depression as depicted in the figure 3 below asa summarized depiction of the aforementioned description.
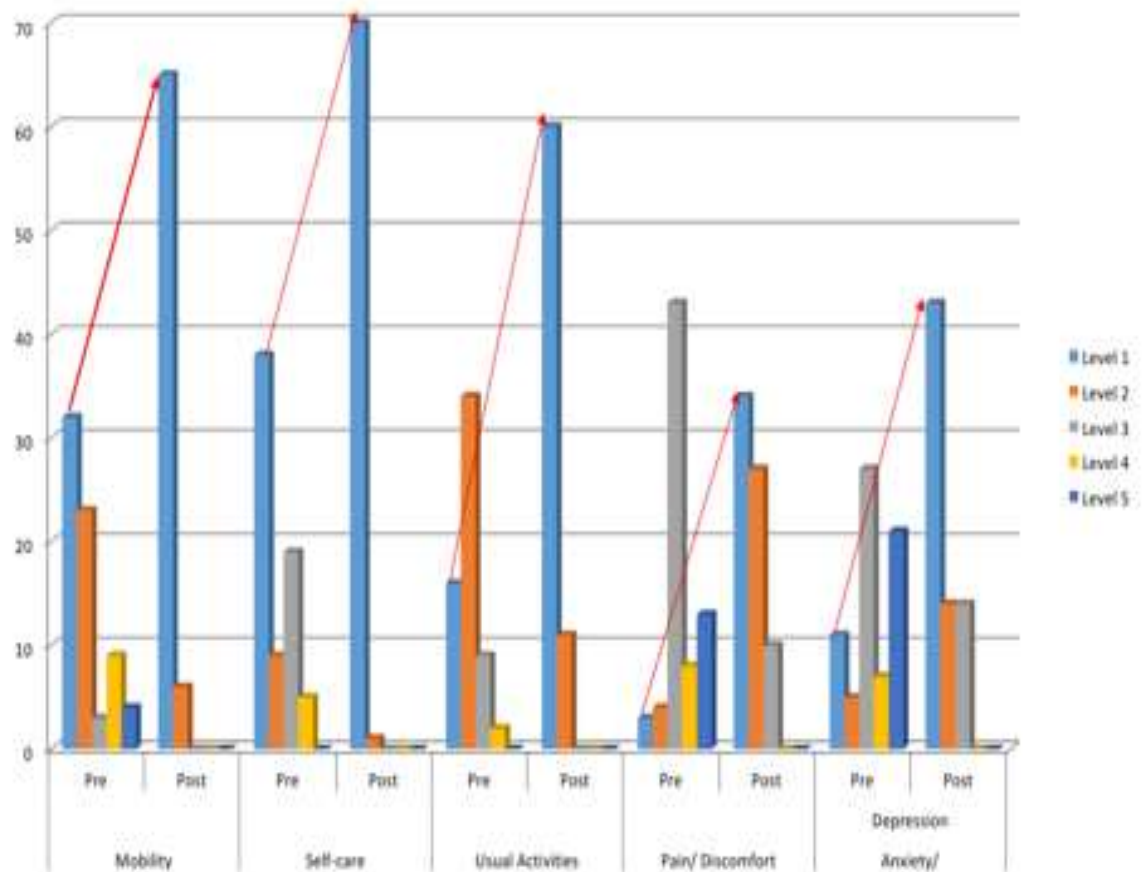
Figure 4:Descriptive Comparison of Number of patients in EQ-5D-5L Before and After Surgery

When a bivariate t-test was conducted, there was a statistically significant difference in the mean pre- and post-radical hysterectomy scores for three quality of life dimensions namely pain or discomfort (p=0.028), anxiety or depression (p=0.028) and the participants health on the day of assessment (p<0.001) as shown in the table (4.8) and bar graph below

Bivariate association of EQ-5D-5L scores before and after surgery
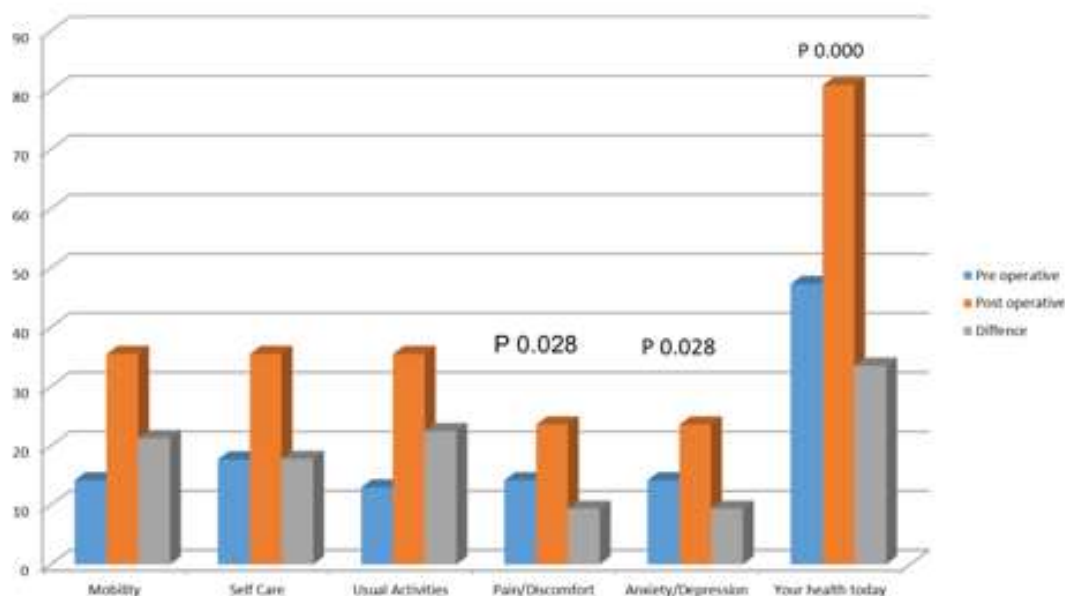
Figure 5: Bivariate association of EQ-5D-5L Before and After Surgery

Table 4.8: Bivariate association of EQ-5D-5L scores pre- and post-radical hysterectomy

Variable (N=71)	Pre-Operation	Post-Operation	p-value
	Mean (SD)	Mean (SD)	
Mobility	14.2 (12.7)	35.5 (41.7)	0.068
Selfcare	17.7 (14.7)	35.5(48.8)	0.095
Usual Activities	13.0 (12.9)	35.5 (34.6)	0.088
Pain/Discomfort	14.2 (16.5)	23.6 (12.3)	**0.028**
Anxiety/Depression	14,2 (9.44)	23.6 (16.7)	**0.028**
Your health today	47.32(8.9)	80.85(10.0)	**<0.001**

The study then conducted a bivariate comparison between participants' sociodemographic characteristics and quality of life improvement. Women aged 21-35 years were significantly (p=0.011) more likely to improve compared to the older counterparts aged 35 years or higher. Women with a tertiary level of education

significantly (p=0.004) reported an improvement in their quality of life compared to those with a secondary and primary level of education. Similarly, formally employed women were more significantly (p=0.012) more likely to report an improvement in their quality of life compared to those who were either unemployed or in self-employment as shown in table 4.9

Table 4.9: Bivariate association between Socio demographic characteristics and quality of life improvement

Variable	N	Frequency (n)	Percent (%)	P value
Age				
< 20		0	0	NA
21-35	71	9	12.7	**0.011**
>35		62	87.3	Reference
Marital Status				
Single		5	7.0	0.702
Married	71	66	93.0	0.062
Education				
None/Primary	71	39	54.9	0.245
Secondary		16	22.5	Reference
Tertiary		16	22.5	**0.004**
Occupation	71			
Unemployed		37	52.1	Reference
Formal employment		12	16.9	**0.012**
Business		22	31.0	0.103
NHIF	71			
No		32	45.1	Reference
Yes		39	54.9	0.460
Residence				
Uasin Gishu		7	9.9	0.101
Outside Uasin Gishu		24	33.8	Reference
Nairobi		21	29.6	0.312
Outside Nairobi		19	26.8	0.112

The study further compared whether there was any statistically significant association between the participants clinical characteristics and quality of life improvement. Women with Stage IA2 were more likely to report a significant (p=0.001) improvement in their quality of life compared to those presenting with all the other early clinical stages of cervical cancer (Table 4.10).

Table 4.10: Bivariate association between clinical characteristics and quality of life improvement

Variable	N	Frequency (n)	Percent (%)	P value
Parity				
One		4	5.6	0.303
Two to three	71	22	30.9	Reference
Four or more		45	63.5	0.782
Family history of Cervical cancer				
No		69	97.2	0.478
Yes	71	2	2.8	Reference
History of smoking				
No	71	71	100	NA
Yes		0	0	
HIV Status	71			
Negative		57	80.3	Reference
Positive		14	19.7	0.521
Cervical cancer stage	71			
Stage 1 A1		2	2.8	0.845
Stage 1 A2		7	9.9	**0.001**
Stage 1 B1		28	39.4	Reference
Stage 1 B2		34	47.9	0.058

The statistically significant sociodemographic and clinical characteristics of the study participants were then fitted into a logistic regression model where women aged 21-35 years had a two-fold (AOR=2.44; 95% CI: 1.30, 3.10) increased likelihood of reporting an improvement in their quality of life compared to their compatriots older than 35 years. Similarly, women with Stage IA2 reported a nearly six-fold (5.69; 95% CI: 3.55,6.89) improvement in their quality-of-life outcomes across all the five domains assessed compared to their colleagues with other early stages of cervical cancer. However, after adjusting for the confounders, level of education and being formally employed did not significantly increase the likelihood of better quality of life scores (Table 4.11).

Table 4.11: Logistic regression model on the sociodemographic and clinical characteristics associated with quality-of-life improvement.

Variable	Unadjusted OR (95% CI)	AOR (95% CI)	p-value
Age	3.16 (1.60, 3.80)	2.44 (1.30,3.10)	**0.026**
Education	0.39(0.10, 0.88)	0.20 (0.05,0.66)	0.143
Occupation	0.83 (0.06,0.99)	0.64 (0.21,1.28)	0.512
Cervical cancer stage	7.66 (6.44,10.71)	5.69 (3.55,6.89)	**0.001**

CHAPTER FIVE

5.0 DISCUSSION

5.1 Socio demographic and clinical characteristics of patients who underwent surgery for early-stage cervical cancer

This study determined that the mean age of women with early-stage cervical cancer undergoing radical hysterectomy was 47.9 ($\pm$10.2) years. This finding is comparable to that reported in an eighteen year (2000-2018) retrospective study conducted in Korea (Kim et al., 2019) where the mean age of the study participants was 49.1 ($\pm$ 11.1) years; and in a prospective study conducted in China (Xiao et al., 2016) between 2001 and 2014, the mean age of the study participants was 50.6 ($\pm$9.0) years. However, the mean age contrasts that reported in Hong Kong (Chan et al., 2012) at 62.11 ($\pm$15.5) years in a study which used a cross-sectional study design and also included palliative patients who often present with an advanced age. This mean age of 47.9 is also attributed to the fact that majority/most presentation of cervical cancer are locally advanced stage or advanced stage due to absence of robust screening, early treatment of precancerous lesions, and a lack of proper vaccination of girls at the eligible age where vaccination programs against HPV was only flagged off recently by President Uhuru Kenyatta.

Nearly all (93%) the women enrolled in this study were married, a finding that is comparable to that reported in Indonesia (Mahendra, 2016) where all the women enrolled were married, Ouagadougou-Burkina Faso (Adama et al., 2017) with a proportion of 89.8% and China at 81.2% (Xiao et al., 2016). However, the proportion of married women reported in this study contrasts that in from North Carolina in the United States of America (Doll et al., 2014) where 44% of the women enrolled stated that they were married while 44.5% could not confirm their marital status. This large

proportion of women who opted not to disclose their marital status could be a major reason for the proportionate variance in the number of married women enrolled in the current study and that conducted in North Carolina. Similarly in Ethiopia (Araya, Fenta, Sander, Gebremariam, & Gebretekle, 2020) there was a nearly equal proportion of women who were either married (51.7%) or single (49.3%). The least proportion of married women was reported in Hong Kong (Chan et al., 2012) at 34% a difference that could be attributed to sociocultural differences in the perception of marriage in Kenya and China. The high proportion of study participants being married in this study is attributable to the social cultural make up of both the Kenyan urban and rural setting where marriage institutions are revered and divorce/ separation are frowned upon in this settings.

More than half (55%) of this study's participants reported to have either attended a primary school or less, with an equal proportion of those who attended secondary schools and universities. This is in contrast with findings reported in China (Xiao et al., 2016) and Indonesia (Mahendra, 2016) where the least proportion of study participants only attended primary school or less at 25% and 35% respectively, compared to majority who had attained secondary level of education at 43.8% in China and 55% in Indonesia. This lower level of education in study participants is attributable to education majority of Kenyans remains uneducated or in lower level of education according to Kenya National Bureau of Statistics.

Because of the low level of education among the women enrolled in this study, 52.1% of them were unemployed, 31% of them engaged in private business while only 16.9% of them engaged in formal employment. This finding on unemployment among half of the study participants was also reported in the United States of America at 50.1% (Doll et al., 2014) but slightly higher than Ethiopia at 42.8% (Araya et al.,

2020). However, in the study conducted in North Carolina (Doll et al., 2014), 33.6% of the women were engaged in full-time employment while 15.8% were engaged on a part-time basis. In Ethiopia (Araya et al., 2020), 49% of the women were engaged in private business; a proportion that was much higher than that reported in this study.

Majority (63.5%) of the participants had a parity of four or more followed by those (30.9%) with two to three children. This finding is higher than that reported in Burkina Faso at 48% and 27% (Adama et al., 2017); while in Indonesia (Mahendra, 2016) 75% of the women had a parity of two to three and 20% had a parity of four or more. The parity of four or more is attributable to fertility rates of 3.9 births per woman in Kenya in 2014 according to the Kenya Bureau of Statistics.

Although infection with human immunodeficiency virus (HIV) has been previously reported as a risk factor for cervical cancer, 80.3% of the women enrolled in this study had a HIV-negative test result, a finding that contrasted to that reported in Kisumu-Kenya (Owenga & Nyambedha, 2018) at 22% in a study which targeted women referred to the county referral hospital for cervical cancer treatment and palliation. Furthermore, local statistics have also indicated that there is a higher prevalence of HIV infection in Kisumu at a proportion higher than that reported nationally (Maina et al., 2014).

Finally, this study adopted the FIGO staging criteria for cervical cancer where majority of the women undergoing radical hysterectomy had Stage IB2 (47.9%) and Stage IB1 (39.4%). The proportion of participants with Stage IB1 reported in this study compared to that in Texas-USA at 33% but was much lower than that reported in Korea at 88.3% (Kim et al., 2019) and China at 62.5% (Xiao et al., 2016). This study's Stage IB1 proportion is significantly higher than that reported in Indonesia (Mahendra, 2016) at 11.6% while 15.3% of them had Stage IB2. The difference in

the proportions by clinical staging could be attributed to the recent universal adoption of FIGO staging criteria for cervical cancer in 2018 after publication of both the studies conducted in China and Indonesia. Furthermore, difference in cervical cancer screening strategies across countries directly affect the stage at which women with the disease are identified. In this study, the locally advanced stages were majority as opposed to other stages. This late presentation is mostly due to an uneducated populace as indicated earlier, where educated women are bound to seek medical care earlier than their uneducated counterparts when early symptoms appear. Also the lack of education, in which most participants of this study fall into, makes some to give in to stigma associated with cancer, where the populace believe that such diagnosis or symptoms tend to come from bewitchment or witchcraft. For a more educated participant, say, those with tertiary education this beliefs do not hold as they are bound to act quickly based on available scientific evidence and seek medical care promptly of which they were not the majority in this study.

5.2 Quality of life of patients diagnosed with cervical cancer pre- and post-surgical treatment of surgically amenable stage

This study determined that majority of the study participants improved in all the five indicators on their quality of life. Specifically, nearly all participants were able to move (91.5%), take care of themselves (98.6%) and perform usual activities (84.5%) without any difficulty. However, less than half (47.9%) of the women enrolled did not experience any pain or discomfort, 60.6% did not report anxiety or depression symptoms.

Previous studies have indicated variability in the participants' perception to mobility, self-care and ability to perform usual activities; and this is often affected by the place a participant resides, their occupation and number of individuals living in her household (Hamming & De Vries, 2007). For instance, participants living in a bungalow or ground-floor of a story building will report less mobility challenges compared to those living in mansions or higher floors within a story building. The findings of this study match those reported in Indonesia (Endarti et al., 2015) where 77% of the women enrolled did not experience any difficulties with mobility, 83.9% were able to perform self-care activities without any problem while two-thirds (66.7%) performed their usual activities with ease. More than half of the participants enrolled in the Indonesian study (Endarti et al., 2015) experienced moderate to severe problems in their assessment of pain or discomfort as well as anxiety of depression. It is easier for participants to express pain or discomfort as well as anxiety compared to other quality of life indicators such as self-care and usual activities as these two are easily confounded by the nature of self-care and usual activity a participant is involved in. Furthermore, the assessment of the first three quality of life indicators (mobility, self-care and usual activities) are not significantly affected by the

assessment tool (whether it is EQ‑5D‑3L or EQ‑5D‑5L) as was demonstrated in a Polish general population (Młyńczak & Golicki, 2021) and a sample of patients with cancer in Korea (Lee et al., 2010).

The mean values for pre and post-radical hysterectomy quality of life indicators have also been demonstrated to differ based on the assessment tools. In a Dutch retrospective study (Korfage et al., 2009), the mean total EQ-5D utility post-radical hysterectomy score of 81.4 (±24.4) was nearly half that reported in the current study. This difference could be attributed to the differences in the study designs adopted by these two studies, one being retrospective while the other prospective, differences in the study duration and quality of life assessment questionnaire. This creates the need for massive adoption of a universal quality of life assessment tool for cervical cancer patients undergoing radical hysterectomy.

5.3 Socio demographic characteristics and quality of life improvement

This study determined that participants aged 35 years or less were significantly (p=0.011) more likely to report better quality of life outcomes across all the domains assessed. This finding is consistent with a recent study conducted in China (Zhao, Luo, Yuan, Gu, & Ding, 2021) where women aged 39 years or less were more likely to report emotional wellbeing, functional wellbeing and overall favourable quality of life outcome. Similarly, in Hong Kong (Chan et al., 2012) age was associated with good quality of life across physical, psychological, existential, support and intimacy domains. In Turkey (Goker, Guvenal, Yanikkerem, Turhan, & Koyuncu, 2011), being aged 60 years or older was significantly (p=0.016) associated with a high global quality of life score; while in California State of the United States of America (Li et al., 2018) being aged 55 years or more significantly (p=0.006) affected the women's

quality of life following radical hysterectomy. However, this finding on age was not found to be significantly associated with the participant's quality of life following radical hysterectomy in the Netherlands (Korfage et al., 2009). However, the Dutch study was on 10-year survival following cervical cancer treatment and not on radical hysterectomy as the only intervention for the early stage disease.

In this study participants who were younger significantly improved in their quality of life compared to their older counterparts. This is attributable to the fact that physiologically aging is associated with reduced physiological function of the body organs, hence hindering optimal recovery. Due to this, younger patient are bound to have quicker and better recovery leading to reports of a better quality of life after surgery, since the physiological function of their body organs are optimal (Lu et al., 2018).

The current study and that conducted in the Netherlands (Korfage et al., 2009) did not find any statistical association between a woman's marital status and quality of life perceptions following radical hysterectomy. However, this finding contrast that in China (Zhao et al., 2021) where being married was significantly associated with social wellbeing. As opposed to the current study which used the EQ-5D-5L tool, the Chinese study adopted the FACT-Cx questionnaire which could have caused the variance in the study findings.

The lack of association of marital status to improvement of quality of life is due to the fact that, the social cultural settings of this study in that, the populace are communal and come together to support each other during calamities and terminal diagnosis like cancer. Therefore whether one was married or not they were bound to get social support from both immediate family members to the extended family (Achiba, 2018).

Having a tertiary level of education among the participants enrolled in the current study was significantly associated with a good quality of life outcome. This finding is consistent to that reported in China where women with an advanced level of education reported better functional wellbeing and a high total FACT-Cx. However, in Turkey where majority of the women enrolled had lower level of education, a statistically significant difference was noted among those with a primary level of education reporting significantly (p=0.023) better quality of life outcomes compared to those with higher level of education. In Hong Kong, there was no statistically significant difference noted among those with a lower level of education compared to those with an advanced level of education.

This study further reports that a woman engaged in formal employment was significantly (p=0.012) more likely to report better quality of life outcomes after radical hysterectomy compared to those who are unemployed or in informal employment. This is comparable to a study conducted in China where formal employment was significantly associated with functional wellbeing. Formal employment has been attributed to having a steady monthly income, medical insurance amongst other health promoting benefits that could directly influence the recovery time of patients with chronic diseases and reduce the economic burden attributed to cost of healthcare. Furthermore, although a low proportion of participants enrolled in this study had national health insurance coverage making it not statistically associated with quality of life scores, this low proportion of women with cervical cancer having a health insurance is consistent with that reported in a study (Owenga & Nyambedha, 2018) conducted at the Jaramogi Oginga Odinga Teaching and Referral Hospital in Kisumu, Kenya where only 9% of the women enrolled had medical insurance coverage.

5.4 Clinical characteristics and quality of life improvement

In this study, parity was not associated with quality-of-life perception of the study participants. This finding is similar to that reported in Turkey (Selcuk et al., 2016) and the United States of America (Ye et al., 2014). In Turkey, the authors adopted a retrospective study design compared to the current prospective design. In the United States of America, a case-control among women who had undergone radical hysterectomy and vaginal extension. However, the findings contrast those reported in India (Shekhar & Jeyaseelan, 2019), China (Li et al., 2018) and Ethiopia . In Addis Ababa – Ethiopia (Ayana, Negash, Yusuf, Tigeneh, & Haile, 2018), parity was significantly (p=0.016) associated with social function while in a retrospective review conducted in China (Li et al., 2018), there was a statistically significant association (p=0.004) between parity and overall quality of life for the study participants.

The lack of association of parity and quality of life improvement after radical hysterectomy in this study is ascribable to the fact that the populace is communal and come together to support each other during calamities and terminal diagnosis like cancer. Therefore, whether one had more children or not they were bound to get social support, as a lot of the populace depends on the children for not only financial support, but also physical, spiritual and other aspect of social support. Despite this the community would still support the participants having had such a diagnosis like cancer.

The Stage I A2 cervical cancer staging for the study participants who underwent radical hysterectomy was significantly associated (p=0.001) with better quality of life compared to the other FIGO stages. This finding compared to a previous study conducted in China (Xie et al., 2013) where Lower stages associated with physical

functioning, role physical, bodily pain, general health; physical component summary and vitality. However, in a more recent study conducted in China among women with Stage IB of cervical cancer, there was no statistically significant association between FIGO staging and quality of life outcome. This could be attributed to the fact that all the study participants had a similar cervical cancer stage. Furthermore, in the case-control conducted in the United States of America (Ye et al., 2014) among women with FIGO stage IB1 and IB2, there was no statistically significant difference in the quality of life of these study participants. In Korea, there was no statistically significant association between cervical cancer and quality of life outcomes.

In this study those with earlier stages had a better quality of life, this can be due to the fact that the earlier stages involved less tissue invasion of the cancer leading to less radical surgery as described earlier, where stage 1A1 is prescribed for a simple extra fascial hysterectomy; type A/type 1 while the more locally advanced stages get radical hysterectomy (Bhatla et al 2019). The less tissue resection associated with the lower stages go hand hand with less operation time, shorter recovery period and less post operative complication translating to a better quality of life improvement.

5.5 Logistic regression of significant variables

After adjusting for the confounders, level of education and being formally employed did not significantly increase the likelihood of better quality of life scores. When a multivariate logistic regression was performed, it was determined that participants aged 35 years or less (p=0.026) and those with lower cervical cancer stages (p=0.001) were significantly more likely to report better quality of life outcomes compared to their older compatriots and those with more advanced cervical cancer stages. This is ascribable to the fact that physiologically younger participants had a better recovery than their older counterparts, where older people organ system are not at optimal and

presence of other comorbidities either identified or not identified leading to longer recovery time and as a result poor quality of life out-come/improvement (Qiang lu 2018)

However, the participant's level education and being formally employed did not significantly affect perception on post-radical hysterectomy quality of life.

This finding on age is comparable to that reported in China (Zhao et al., 2021) where age was significantly (p=0.006) associated with good quality of life outcomes following radical hysterectomy. Similarly, in Poland (Młyńczak & Golicki, 2021) and Hong Kong (Chan et al., 2012), age was significantly associated with the perception on post-radical hysterectomy quality of life across all the indicators. Despite the fact that this study adopted a 12-week prospective cohort design, the studies conducted in both Poland and Hong Kong were cross-sectional in design. In a different study conducted at Kenya's Kenyatta National Hospital (Ahamed & Degu, 2021), age was not significantly associated with quality of life outcomes. This difference could be due to the difference in age group stratification. As opposed to the current study which used 35 years as the cut-off, in Kenyatta National Hospital, the authors used 60 years of age as their preferred cut-off. Furthermore, studies conducted in the United States of America (Donovan, Boyington, Judson, & Wyman, 2014; Ye et al., 2014) and Austria (Greimel, Winter, Kapp, & Haas, 2009) did not find any statistical significance in the difference between age group and quality of life following radical hysterectomy. In the first study conducted in the United States of America (Ye et al., 2014), the authors enrolled thirty-one patients who had undergone vaginal extension following radical hysterectomy and a further 28 patients with matching factors after only receiving radical hysterectomy. This difference in sampling technique and study design to that adopted in the current study could be attributed to the difference in

association between the two groups. In the study conducted in Tampa, Florida (Donovan et al., 2014), the authors enrolled 104 cervical or endometrial cancer survivors who had completed one-year of treatment and measures of bladder and bowel symptoms. This is different to the current study where multiple quality of life markers were assessed and purely on cervical cancer patients. In Austria (Greimel et al., 2009), the authors conducted a 13 year retrospective study among 121 cervical cancer survivors who had undergone surgery only, surgery and chemotherapy as well as a combination of surgery and radiotherapy. This difference in selection criteria and a prolonged follow-up duration could explain the differences in the association between age as a predictor of post-radical hysterectomy quality of life.

Although this study did not find any association between level of education and quality of life, in Tampa-Florida, the authors (Donovan et al., 2014) reported a statistically significant association between having a college level of education and an improved quality of life. Furthermore, a participant's occupation although not associated with quality of life, the level of income attributed to the occupation was statistically associated with the participant's quality of life as was reported in China (Zhao et al., 2021) at p=0.033 and Tampa-Florida (Donovan et al., 2014) at p=0.004. This difference with the study in Florida could be attributed to the selection criteria of the study participants. In Florida, the authors (Donovan et al., 2014) only had 24 participants who had undergone radical hysterectomy out of 104 women enrolled. This small number of participants who had received the intervention of interest could further skew the study's findings.

Low cervical cancer stage significantly attributed to good quality of life perception following radical hysterectomy among this study's participants matches another study conducted in Kenya (Ahamed & Degu, 2021). The researchers at the Kenyatta

National Hospital determined that lower cervical cancer staging significantly (p<0.001) increased the likelihood of good quality of life seven-fold (AOR=7.3; 95% CI: 2.4, 21.7). A similar finding was also reported in Austria (Greimel et al., 2009) at p=0.007 and China (Zhao et al., 2021) at p=0.033. This finding could be attributed to the fact that radical hysterectomy is indicated for low surgically amenable cervical cancer stages according to the FIGO staging criteria for cervical cancer and recent universal adoption of FIGO staging criteria for cervical cancer in 2018 after publication of both the studies conducted in China and Austria. Furthermore, difference in cervical cancer screening strategies across countries directly affect the stage at which women with the disease are identified.

5.6 Study Strengths

Study done in 2 main referral hospitals in Kenya and data could be generalizable to the population.

Prospective design followed up participants for 12 weeks.

5.7 Study Limitation

This study had a shorter follow up period (12 weeks) to access the quality of life after such an extensive surgery where late complication might affect QOL.

CHAPTER SIX

6.0 CONCLUSION, RECOMMENDATIONS AND STUDY LIMITATIONS

This section presents the conclusions and recommendations of this study.

6.1 Conclusion

The quality of life among early stage cervical cancer patients after surgery was generally good, indicating of overall improvement of quality of life, especially with regards to pain/discomfort and anxiety/ depression.

Some of the factors that enhanced the QOL among patients in this study included employment, age and higher levels of education.

Based on the findings of the study the socio demographic factors that were identified as affecting QOL among cervical cancer patients were age, level of education and occupation.

The patients' cancer stage was the clinical characteristic identified in the study that affected QOL among cervical cancer patients.

Age and cervical cancer stage were the independent predictors of QOL reported in the study.

6.3 Recommendations

The researcher recommends that relevant authorities and stakeholders at MTRH and KNH consider improving on the following:

There should be more attention and clinical focus offered to cervical cancer patients who are >35years and with 1B and above to improve their quality of life by focusing more on addressing their pain/ discomfort and anxiety/depression, by using a multi-disciplinary approach in these patients care.

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APPENDICES

Appendix I: Questionnaire 1

Demographic information

Year of birth _____

Marital status

Married ☐

Single ☐

Divorced/separated ☐

Widowed ☐

Highest level of education

Primary ☐

Secondary ☐

College/Tertiary ☐

None ☐

Occupation (Can mark >1)

Home maker ☐

Business ☐

Government employee ☐

Farmer ☐

Employed ☐

Other ☐

Geographic area of residence

Uasin Gishu ☐

Others (specify county) ☐

Not indicated ☐

NHIF contributor

Yes ☐

No ☐

Not indicated ☐

Clinical information

Parity live _____

Parity abortion _____

Age at Menarche _____

Family history of ca cervix

Yes ☐

No ☐

History of smoking

Yes ☐

No ☐

If history of smoking Current

Past smoking

Not indicated

Stage of cervical cancer

Stage 1 A1 ☐

Stage 1 A2 ☐

Stage 1 B1 ☐

Stage 1 B2 ☐

HIV Status

Positive ☐

Negative ☐

Appendix 2:EQ -5D-5L

Health Questionnaire
English version for Kenya

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking	❑
I have slight problems in walking	❑
I have moderate problems in walking	❑
I have severe problems in walking	❑
I am unable to walk	❑

SELF-CARE

I have no problems washing myself or dressing myself (putting on my own clothes)	❑
I have slight problems washing myself or dressing myself (putting on my own clothes)	❑
I have moderate problems washing myself or dressing myself (putting on my own clothes)	❑
I have severe problems washing myself or dressing myself (putting on my own clothes)	❑
I am unable to wash myself or dress myself (putting on my own clothes)	❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities	❑
I have slight problems doing my usual activities	❑
I have moderate problems doing my usual activities	❑
I have severe problems doing my usual activities	❑
I am unable to do my usual activities	❑

PAIN / DISCOMFORT

I have no pain or discomfort	❑
I have slight pain or discomfort	❑
I have moderate pain or discomfort	❑
I have severe pain or discomfort	❑
I have extreme pain or discomfort	❑

WORRY (ANXIETY) / DEPRESSION

I am not worried or depressed ❑

The best health
you can imagine

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
  0 means the <u>worst</u> health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.
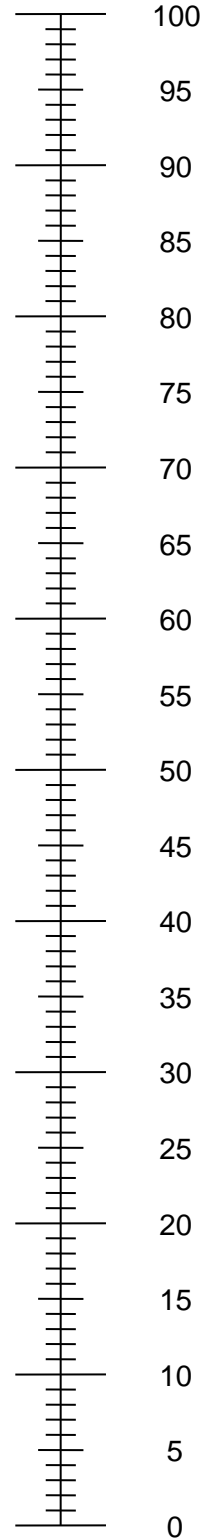
I am slightly worried or depressed ❑

I am moderately worried or depressed ❑

I am severely worried or depressed ❑

I am extremely worried or depressed ❑

YOUR HEALTH TODAY =

100
95
90
85
80
75
70
65
60
55
50
45
40
35
30
25
20
15
10
5
0

The worst health
you can imagine

Hojaji ya Afya

Toleo la Kiswahili cha Kenya
(Swahili version for Kenya)

Chini ya kila kichwa, weka tiki kwenye kisanduku KIMOJA kinachoelezea vizuri zaidi afya yako LEO.

UWEZO WA KUTEMBEA

Sina matatizo ya kutembea	❏
Nina matatizo kidogo sana ya kutembea	❏
Nina matatizo kiasi ya kutembea	❏
Nina matatizo makali ya kutembea	❏
Siwezi kutembea	❏

KUJIHUDUMIA

Sina matatizo ya kujiosha au kujivisha nguo	❏
Nina matatizo kidogo sana ya kujiosha au kujivisha nguo	❏
Nina matatizo kiasi ya kujiosha au kujivisha nguo	❏
Nina matatizo makali ya kujiosha au kujivisha nguo	❏
Siwezi kujiosha au kujivisha nguo	❏

SHUGHULI ZA KAWAIDA *(kwa mfano kazi, kusoma, kazi za nyumbani, shughuli za kifamilia au starehe)*

Sina matatizo ya kufanya shughuli zangu za kawaida	❏
Nina matatizo kidogo sana ya kufanya shughuli zangu za kawaida	❏
Nina matatizo kiasi ya kufanya shughuli zangu za kawaida	❏
Nina matatizo makali ya kufanya shughuli zangu za kawaida	❏
Siwezi kufanya shughuli zangu za kawaida	❏

MAUMIVU / KUTOJISIKIA VIZURI

Sina maumivu au sina kutojisikia vizuri	❏
Nina maumivu kidogo sana au najisikia vibaya kidogo sana	❏
Nina maumivu kiasi au najisikia vibaya kiasi	❏
Nina maumivu makali sana au najisikia vibaya sana	❏
Nina maumivu makali zaidi au najisikia vibaya zaidi	❏

WASIWASI / KUSHUKA MOYO

Sina wasiwasi au kushuka moyo	❏
Nina wasiwasi kidogo sana au nimeshuka moyo kidogo sana	❏
Nina wasiwasi kiasi au nimeshuka moyo kiasi	❏
Nina wasiwasi mkubwa au nimeshuka moyo kwa njia kubwa	❏
Nina wasiwasi mkubwa sana au nimeshuka moyo kwa njia kubwa sana	❏

Afya bora zaidi
unayoweza
kufikiria

— 100

— 95

— 90

- Tungependa kujua jinsi afya yako ilivyo nzuri au mbaya LEO.

— 85

- Kipimo hiki kina nambari kuanzia 0 hadi 100.

— 80

— 75

- 100 inamaanisha afya <u>bora zaidi</u> unayoweza kufikiria.
  0 inamaanisha afya <u>mbaya zaidi</u> unayoweza kufikiria.

— 70

- Weka alama ya X kwenye kipimo ili kuonyesha jinsi afya yako
  ilivyo LEO.

— 65

— 60

— 55

AFYA YAKO LEO =

— 50

- Sasa, tafadhali andika nambari uliyoweka alama kwenye
  kipimo katika sanduku hapa chini.

— 45

— 40

— 35

— 30

— 25

— 20

— 15

— 10

— 5

— 0
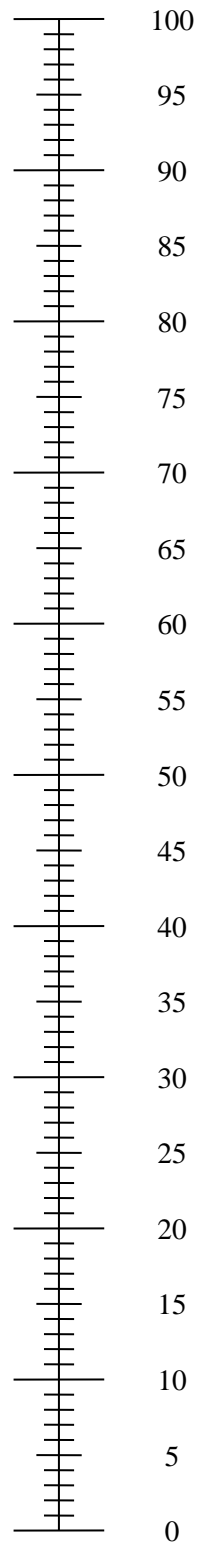
Afya mbaya
zaidi
unayoweza

Under each heading, please tick the **ONE** box that best describes your health **TODAY**

MOBILITY

I have no problems in walking about	❏
I have slight problems in walking about	❏
I have moderate problems in walking about	❏
I have severe problems in walking about	❏
I am unable to walk about	❏

SELF-CARE

I have no problems washing or dressing myself	❏
I have slight problems washing or dressing myself	❏
I have moderate problems washing or dressing myself	❏
I have severe problems washing or dressing myself	❏
I am unable to wash or dress myself	❏

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities	❏
I have slight problems doing my usual activities	❏
I have moderate problems doing my usual activities	❏
I have severe problems doing my usual activities	❏
I am unable to do my usual activities	❏

PAIN / DISCOMFORT

I have no pain or discomfort	❏
I have slight pain or discomfort	❏
I have moderate pain or discomfort	❏
I have severe pain or discomfort	❏
I have extreme pain or discomfort	❏

ANXIETY / DEPRESSION

I am not anxious or depressed	❏
I am slightly anxious or depressed	❏
I am moderately anxious or depressed	❏
I am severely anxious or depressed	❏
I am extremely anxious or depressed	❏

The best health
you can imagine

- We would like to know how good or bad your health is **TODAY**.

- This scale is numbered from **0** to **100**.

- **100** means the <u>best</u> health you can imagine.
  0 means the <u>worst</u> health you can imagine.

- Mark an **X** on the scale to indicate how your health is **TODAY**.

- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

| 100 |
| 95 |
| 90 |
| 85 |
| 80 |
| 75 |
| 70 |
| 65 |
| 60 |
| 55 |
| 50 |
| 45 |
| 40 |
| 35 |
| 30 |
| 25 |
| 20 |
| 15 |
| 10 |
| 5 |
| 0 |
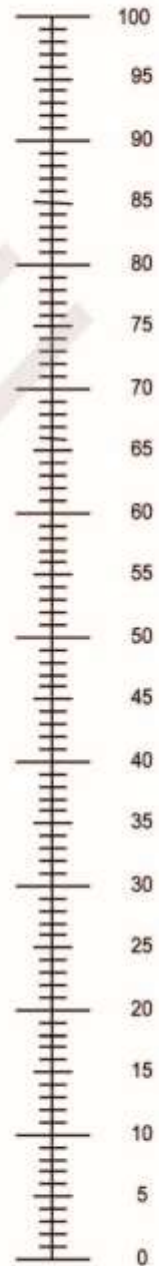
The worst health
you can imagine

Dear Dr. Ghalib Moseti ,

Thank you for your registration.
The study / project titled "Quality of life of patients undergoing surgical treatment for early stage cervical cancer at MTRH" you registered fulfils the conditions for you to use the requested version(s) free of charge.

Below you find our Terms of Use. We will provide you with the requested versions free of charge once we have received your agreement with our Terms of Use. You can indicate your agreement by pressing the green "Agree" button below. If you do not agree, please press "Disagree".

If you have any questions please contact us by sending an email to userinformationservice@euroqol.org.

Thank you in advance.

Kind regards,

Appendix 3: Consent Form

QUALITY OF LIFE STUDY

We want to know your view of how your life has been affected by cancer and its treatment.

This "quality of life" study looks at how you are feeling physically and emotionally during your cancer treatment. It also looks at how you are able to carry out your day-to-day activities.

This information will help doctors better understand how patients feel during treatments and what effects the medicines are having. In the future, this information may help patients and doctors as they decide which medicines to use to treat cancer.

You will be asked to complete 2 questionnaires at the following times:

☐ Before you begin treatment on this study,

☐ At 3 months after you have undergone surgery (radical hysterectomy)

It takes about 15 minutes to fill out each questionnaire.

If any questions make you feel uncomfortable, you may skip those questions and not give an answer.

If you decide to take part in this study, the only thing you will be asked to do is fill out the 3 questionnaires. You may change your mind about completing the questionnaires at any time. We will do our best to make sure that your personal information will be kept private.

Please circle your answer.

I choose to take part in the quality of life study. I agree to fill out the 3 quality of life questionnaires.

Yes ☐   No ☐   Thumb

Appendix 4: Fomu Ya Idhini

UTAFITI KUHUSU UBORA WA MAISHA

Tunataka kujua maoni yako kuhusu jinsi maisha yalivyoathirika na saratani na tiba yake.

Utafiti huu kuhusu "ubora wa maisha" unaangazia unavyojihisi kimwili na kihisia wakati wa matibabu ya saratani. Pia unaangazia jinsi unavyoweza kutekeleza majukumu yako ya kila siku.

Habari hii itawasaida madaktari kuelewa vyema jinsi wagonjwa wanavyohisi wakati wanapopokea matibabu na dawa zinavyofanya kazi. Katika siku za usoni, habari hii huenda ikawasaidia wagonjwa na madaktari pale wanapoamua dawa watakazo tumia kutibu saratani.

Utahitajika kujibu fomu tatu za maswali nyakati hizi:

*Kabla ya kuanza matiba

*Miezi 3 baada ya kukamilisha upasuaji

Itakuchukua dakika 15 kujaza kila fomu ya maswali.

Iwapo unahisi kuna maswali ambayo yanakutatiza na hautaki kuyajibu sio lazima uyajibu.

Iwapo umeamua kushiriki utafiti huu, utahitajika tu kujaza fomu hizo tatu za maswali.

Una uwezo wa kubadili nia kuhusu kujaza fomu hizo wakati wowote.

Tutahakikisha kuna usiri wa maelezo yako.

Tafadhali chora mduara katika jibu lako.

Nakubali kushiriki utafiti kuhusu ubora wa maisha. Nakubali kujaza fomu hizo 3 za maswali kuhusu ubora wa maisha.

Ndio ☐   Hapana. ☐   Alama ya kidole ☐

Appendix 5: Time Frame

Year 2018/19

PHASE	PERIOD	ACTIVITIES
I.	November 2018- October 2019	**Report Development** Problem Identification and Literature Review Preparation of Draft Report Consultation and Revision of Draft Report Approval of the Report
II.	October 2019- December 2020	**Pilot Survey** Identification of Survey Respondents Questionnaire Pre-Testing
III.	October 2020- February 2021	**Fieldwork** Administration of Questionnaires Interviews with Key Informants Review of Secondary Data and Information
IV.	February 2021 – April 2021	**Data Processing and Analysis** Data Cleaning and Tallying Processing and Analysis Interpretation of Results
V.	May 2021 – November 2021	**Report Writing** Preparation of Draft Report Consultation & Correction of Draft Report Submission of the Final Report & Examination.

Appendix 6: Budget

SN	ITEM	AMOUNT(Ksh)
1	Computer and internet	75,000
2	Flash disc	2,500
3	Printing	10,000
4	Typing services	8,000
5	Photocopy	5,000
6	Data collection and analysis	20,000
7	Transport and subsistence	20,000
8	Stationery	2,500
9	Research assistant	10,000
10	Miscellaneous	10,000
TOTAL		**163,000/=**

Appendix 7: IREC Approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference IREC/2019/105
Approval Number: 0003460

8th July, 2020

Dr. Moseti Ghalib,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH &
ETHICS COMMITTEE

0 8 JUL 2020

APPROVED
P. O. Box 4606-30100 ELDORET

Dear Dr. Moseti,

RE: APPROVAL OF AMENDMENT

The Institutional Research and Ethics Committee has reviewed the amendment made to your proposal titled:-

"Quality of Life of Patients Undergoing Surgical Treatment for Early Stage Cervical Cancer Treatment at Moi Teaching and Referral Hospital".
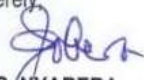
We note that you are seeking to make an amendment as follows:-

- To expand site of data collection.

The amendment has been approved on 8th July, 2020 according to SOP's of IREC. You are therefore permitted to continue with your research.

You are required to submit progress(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change(s) or amendment(s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc: CEO   -   MTRH   Dean   -   SPH   Dean   -   SOM
        Principal -   CHS   Dean   -   SOD   Dean   -   SON

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2019/105
Approval Number: 0003460

11th October, 2020

Dr. Moseti Ghalib,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Moseti,

RE: CONTINUING APPROVAL

The Institutional Research and Ethics Committee has reviewed your request for continuing approval to your study titled:-

"Quality of Life of Patients Undergoing Surgical Treatment for Early Stage Cervical Cancer Treatment at Two Referral Hospitals in Kenya".

Your proposal has been granted a Continuing Approval with effect from 11th October, 2020. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 10th October, 2021. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE

11 JAN 2020

APPROVED
P. O. Box 4606 - 30100 ELDORET

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc:	CEO	-	MTRH	Dean	-	SOD
	Principal	-	CHS	Dean	-	SPH
	Dean	-	SOM	Dean	-	SON

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

11th October, 2019

Reference: IREC/2019/105
Approval Number: 0003460

Dr. Moseti Ghalib,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Moseti,

QUALITY OF LIFE OF PATIENTS UNDERGOING SURGICAL TREATMENT FOR EARLY STAGE CERVICAL CANCER TREATMENT AT MOI TEACHING AND REFERRAL HOSPITAL

This is to inform you that *MU/MTRH-IREC* has reviewed and approved your above research proposal. Your application approval number is *FAN:0003460*. The approval period is 11th **October, 2019 – 10th October, 2020.**

This approval is subject to compliance with the following requirements;

  i.   Only approved documents including (informed consents, study instruments, MTA) will be used.
  ii.   All changes including (amendments, deviations, and violations) are submitted for review and approval by *MU/MTRH-IREC.*
  iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to *MU/MTRH-IREC* within 72 hours of notification.
  iv.   Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to *MU/MTRH-IREC* within 72 hours.
  v.   Clearance for export of biological specimens must be obtained from relevant institutions.
  vi.   Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
  vii. Submission of an executive summary report within 90 days upon completion of the study to *MU/MTRH-IREC.*

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and also obtain other clearances needed.

Sincerely,

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE

11 OCT 2019

APPROVED
P.O. Box 4606, 30100 ELDORET

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc   CEO   -   MTRH   Dean   -   SOP   Dean   -   SOM
        Principal -   CHS   Dean   -   SON   Dean   -   SOD

Appendix 8: Hospital Approval

MOI TEACHING AND REFERRAL HOSPITAL

An ISO 9001:2015 Certified Hospital

Telephone :(+254)053-2033471/2/3/4
Mobile: 722-201277/0722-209795/0734-600461/0734-683361
Fax: 053-2061749
Email: ceo@mtrh.go.ke/directorsofficemtrh@gmail.com

Nandi Road
P.O. Box 3 – 30100
ELDORET, KENYA
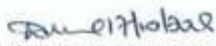
Ref: ELD/MTRH/R&P/10/2/V.2/2010

17th October, 2019

Dr. Moseti Ghalib,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"Quality of Life of Patients Undergoing Surgical Treatment for Early Stage Cervical Cancer Treatment at Moi Teaching and Referral Hospital".

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

DR. WILSON K. ARUASA, *MBS*
CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL

MOI TEACHING AND REFERRAL HOSPITAL
C E O
APPROVED
17 OCT 2019
SIGN......................
P. O. Box 3 - 30100, ELDORET

cc - Senior Director, (CS)
    - Director of Nursing Services (DNS)
    - HOD, HRISM

All correspondence should be addressed to the Chief Executive Officer
Visit our Website: www.mtrh.go.ke
TO BE THE LEADING MULTI-SPECIALTY HOSPITAL FOR HEALTHCARE, TRAINING AND RESEARCH IN AFRICA

Appendix 9: Hospital Approval KNH

KNH/R&P/FORM/01

KENYATTA NATIONAL HOSPITAL
Hospital Rd. along, Ngong Rd,
P.O. Box 20723, Nairobi.
Tel: 2726300-9Fax:2725272
Research &Programs: Ext. 44705
Email: k.reserch@knh.or.ke

Study Registration Certificate

1. Name of the PI .... MOSETI   GHALIB ....

2. Email address: gmosetiochared@gmail.com .....Tel No .0713428943..........

3. Contact Person (if different from PI)...

4. Email address: .... Tel No ....

5. Study Title

   QUALITY OF LIFE OF PATIENTS UNDERGOING SURGICAL TREATMENT FOR EARLY STAGE CERVICAL CANCER AT TWO REFERRAL HOSPITALS IN KENYA

6. Department where the study will be conducted ....CANCER TREATMENT CENTER.

7. Endorsed by Head of Department where study conducted:

   Name: For DR JOHN KINUTHIA Signature................ Date..02-03.2020...

8. KNH UoN Ethics Research Committee approval number 0003460 IREC/2019/105/NACOST/ (Please attach copy of ERC approval)

9. I   Moseti Ghalib ·A·   commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Research and programs.

   Signature................Date.. 4th March 2020.............

10. Study Registration number (Dept/Number/Year) CTC / 05 / 2020
    (To be completed by Research and Programs Department)

11. Research and Program Stamp_____

All studies conducted at Kenyatta National Hospital must be registered with the department of Research and Programs and investigators must commit to share results with the hospital