FACTORS ASSOCIATED WITH TIME TAKEN FROM HISTOLOGIC DIAGNOSIS TO INITIATION OF RADIOTHERAPY IN WOMEN WITH CERVICAL CANCER AT THE KENYATTA NATIONAL HOSPITAL;

Cross-sectional study

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2021

DECLARATION

I hereby declare that this dissertation is my original work and no other similar study has been done in the same institution.
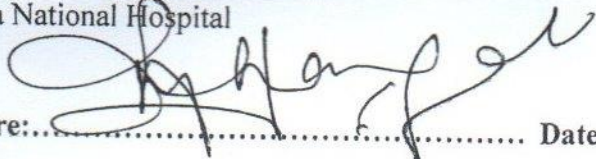
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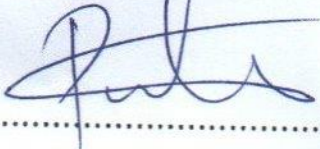
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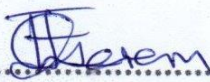Kenyatta National Hospital

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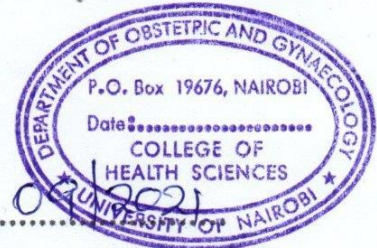
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DEDICATION

To my wife, Dr. Lydia Koila my children Jabali and Jayden for moral support and encouragement during my studies.

To my parents Samson and Hellen Moseti, for your continued support and guidance both spiritually and morally during my upbringing to date.

Thank you all.

LIST OF ABBREVIATIONS

AIDS   Acquired immunodeficiency syndrome

ASR   Age-standardized ratio

CIN   Cervical intraepithelial neoplasm

CIS   Carcinoma in situ

CCC   Comprehensive Care Clinic

CKD   Chronic Kidney Disease

CTC   Cancer Treatment Centre

Dept.   Department

EBRT   External Beam Radiation Treatment

E.T.C   Etcetera

EUA   Examination under anaesthesia

FIGO   International Federation of Gynecologic organization

HPV   Human papilloma virus

HSV   Herpes simplex virus

HSIL   High grade squamous intraepithelial lesion

HIV   Human immunodeficiency virus

ICC   Invasive Cervical Cancer

KNH   Kenyatta national hospital

LEEP   Loop Excision Electrosurgical Procedure

LLETZ   Large loop Excision of Transformation Zone

LSIL   Low-Grade Squamous Intraepithelial Lesion

M.MED   Masters in Medicine

N
NBCCEP National Breast and cervical cancer early detection program

OBS/GYN Obstetrics and Gynaecology

QOL Quality of Life

SHO Senior House Officer

STI Sexually transmitted infections

UON University of Nairobi

UK United Kingdom

VS Versus

WHO World Health Organization

DEFINITION OF TERMS

Delay: For purposes of this proposal, delay will be defined as time taken between histological diagnosis to initiation of radiotherapy of more than 60 days.

Treatment delay- Time from confirmation of diagnosis to initiation of treatment.

Patient delay – Period from patient awareness of her histological diagnosis to presentation to cancer treatment center at KNH.

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ABSTRACT

Background: Cervical cancer is the second most diagnosed cancers of women after breastcancer. Time taken from histological diagnosis to initiation of radiotherapy is considered as a measure of the quality of care. However, the wait time for initiation of radiotherapy after a histological diagnosis of cervical cancer has not been studied sufficiently in KNH.

Broad Objective: To determine factors associated with time taken between histologicaldiagnosis and initiation of radiotherapy in women with cervical cancer at the Kenyatta National Hospital.

Methodology: A cross-sectional study was conducted on 246 patients, presenting at KNH between September 2019 andNovember 2019. Face to face structured questionnaire was administered to capture patient characteristics i.e. age, education level,county of residence etc. and information on treatment pathway duration. Patient wait time from histological diagnosis to initiation of radiotherapy was collected from patient records as a continuous variable. Dates on histology diagnosis and the first time patient received radiotherapy session were collected. Knowledge of patients on radiotherapy was also evaluated. Data was extracted from questionnaire, fed into worksheet, and analyzed using version 23 of the Statistical Package for Social Scientists software. The demographics characteristics of participants were computed and presented on tables. Mean and median waiting time by the demographic characteristics of patients and hospital factors were computed using the Kruskall Wallis test. Analysis of Covariance (ANOVA) was used to control for confounding.

Results: The mean age of participants was 53.16, range of 18 to 84 years. A majority of participants were age group 51-60 years (32.2%). Married (65.5%),unemployed (54.3%), and those with stage IIB cervical cancer at diagnosis (60.8%). The Median wait time from

histological diagnosis to initiation of radiotherapy was 84 days, higher among 31-40 year old women (102), widows (93), employed women (111), and those using NHIF insurance cards (86). Patient factors and institution factors evaluated did not affect wait times. However, the distance to hospital explained 2.3% of the variation in wait times for radiotherapy that we reported.

Conclusion: Median wait time from cervical cancer histological diagnosis to initiation of radiotherapy was unacceptably higher at KNH than the recommended average of 30 days in UK. Health system should be strengthened by increasing more radiotherapy machines at KNH and decentralization of radiotherapy treatment centers to counties to improve health seeking behavior, shorten wait time, and improve prognosis.

1.0 INTRODUCTION

1.1: Background of the Study

Cervical cancer reported cases were 570,000 globally, which translated to 6.6% of cancer among women with 311,000 deaths occurring in the same year. Cervical cancer is the fourth commonly diagnosed cancerand ranked fourth in overall cancer mortality rates among women. In lower and middle income countries, it comes second in incidence and mortality rates after breast cancer with 90% of the mortality rates (1).

Figure 1: Global Distribution of Incidences and Mortality rates of Cancers in 2018 for Females (1).
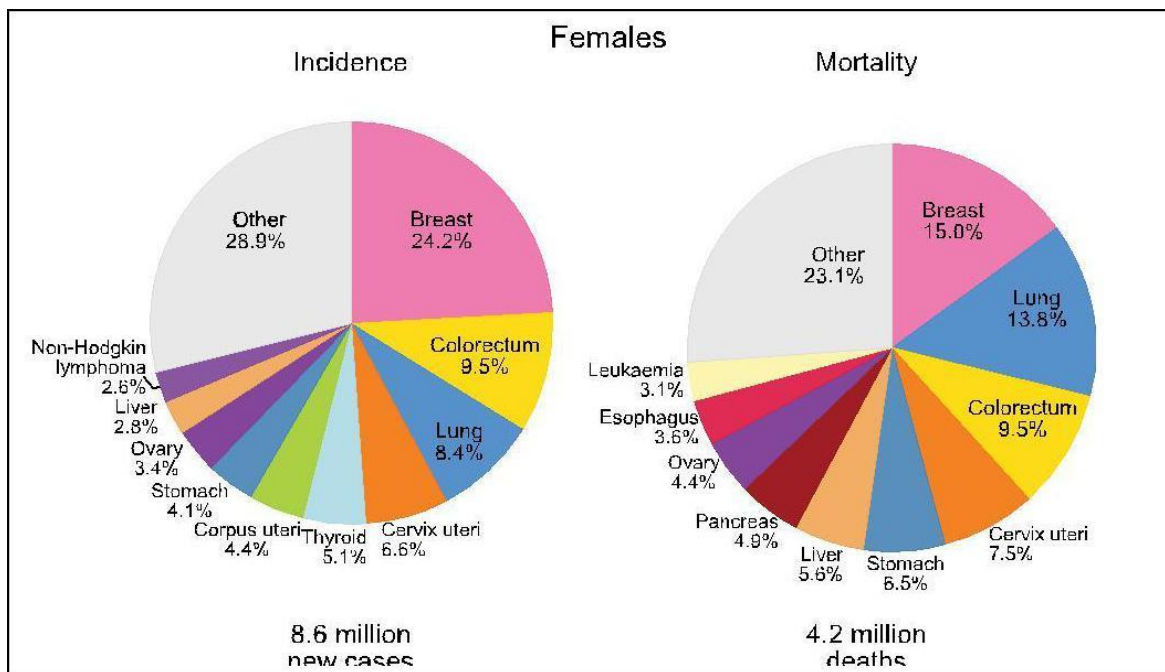
As shown in (Fig. 2), Africa ranks first in cancer incidence and mortality rate, higher in Southern parts of Africa (e.g., Swaziland, leads in cancer incidence rates), Eastern parts of Africa (Malawi, leads in cancer incidence rates), and Western parts of Africa (Mali, and

Burkina Faso). Comparatively, the rates of cancer are seven to ten times lower in Australia/ New Zealand, Western Asia and North America (1).

Figure 2: Global Age-Standardized, Incidence and Mortality Rates for Cervical Cancer in 2018(1)
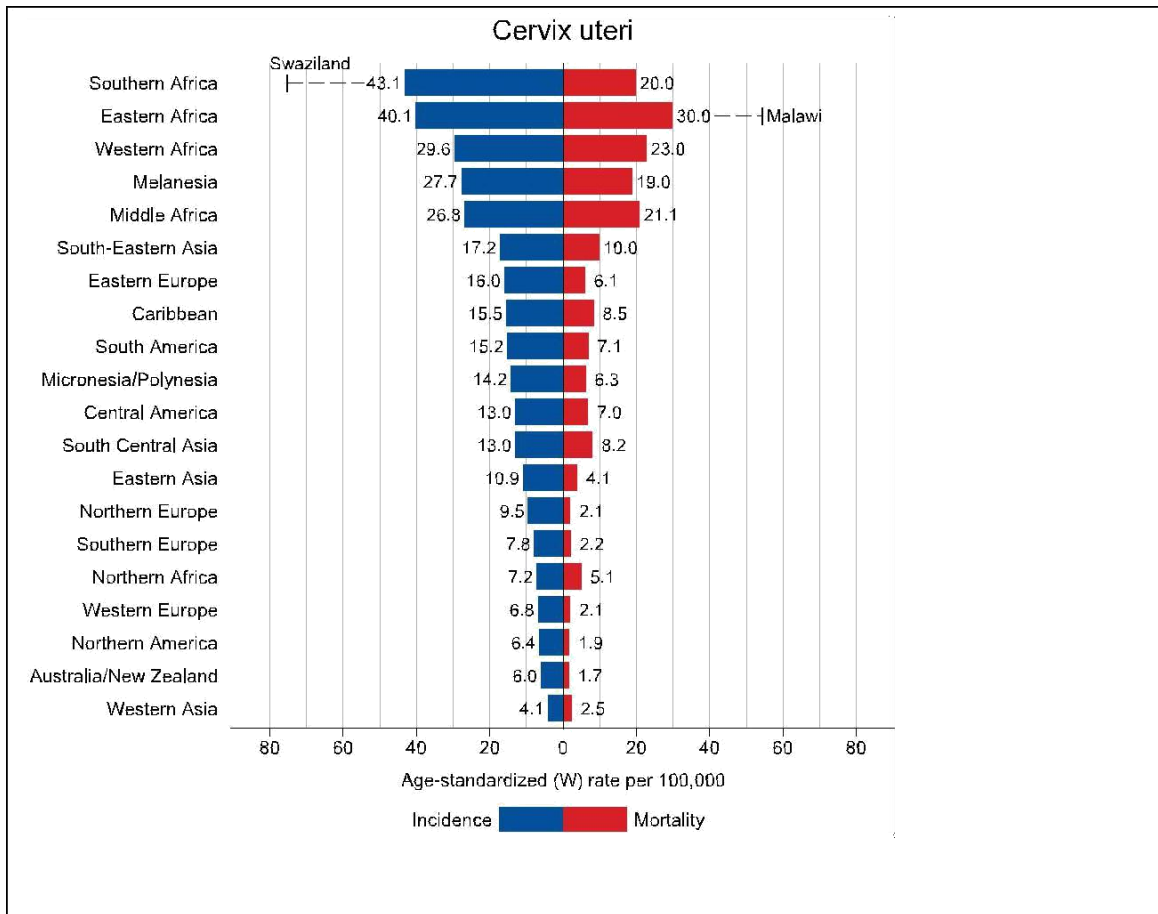
According to the HPV information Centre, Kenya, annual cervical cancer cases were 5250 translating to 18.3%. Annual cervical cancer deaths were 3286 translating to 10%. A five-year prevalence for all ages was reported to be 10963 which translated to 42.78%(2) as shown in the Table 1 below;

Table 1: Burden/Rates of Cervical Cancer Kenya (Estimates For 2018)

	Incidence	Mortality
Annual number of new cases/deaths	5250	3286
Crude Rate	20.5	12.8
Age Standardised rate	33.8	22.8
Cumulative Risk 0 -74 years (%)	3.7	2.6
Ranking of Cervical Cancer (All Years)	2nd	1st
Ranking of Cervical Cancer (15-44 Years)	1st	1st

Women in Nairobi with an ASR of 46.1 per 100,000,cervical cancer is ranked second commonest cancer making it less than numbers registered across the East Africa region. Advanced Cervical Cancer is a great burden at KNH, with the majority of these patients referred from all over Kenya,most are at an advanced stage with more than 80% in stage 2B and above as (3). This gives a direct reflection of the magnitude of the disease burden in the country. Due to these numbers, most of the patients present at the radiotherapy unit in late-stage clinical disease for radiotherapy treatment (31). Women who are HIV Positive are 2 to 12 times at risk of developing precancerous lesions which could upstage to cervical cancer eventually (14). They are also at a greater risk of recurrence and persistence of human papilloma virus (HPV), which causes 63.1 % of invasive cervical cancers (ICC), an AIDS-defining malignancy (2). Patients with lower social economic status have consistently poorer survival rates than those in a higher social economic state (11).

In Kenya just like other sub-Saharan countries, there are limited organized follow up programs for treatment for cervical cancer especially in rural areas, and whereas some radiotherapy services are available in some hospitals, mainly in urban cities and private hospitals, they are unaffordable to the majorities of the population (17). Early Cervical cancer diagnosis and

treatment has beenshown to have a 5-year survival rate of 92%, but overall, the 5-year survival rate for all cervical cancer stagesis72%, with variations dependent on disease stage at diagnosis (19). Women suspecting cervical cancer should report to health facilities early, receive prompt screening and appropriate diagnostic process so as to receive appropriate therapy before metastasis or complications occurs (20). Radiotherapy is one of the modes of treatment used to cure early cervical cancer and provide palliative treatment for advanced cervical cancer. Time spent by patients waiting for radiotherapy has an influence on the cancer treatment results and therefore is an indicator of quality of care (4). There is usually a delay from the diagnosis of the tumour to the commencement of radiotherapy treatment which is caused by factors such as referral delays and waiting lists. These delays lead to poor outcome, upstaging complication, obstructive uropathy and poor quality of life (9).

2.0 LITERATURE REVIEW

TIME TAKEN FROM DIAGNOSIS TO RADIOTHERAPY

Prolonged time taken between histological diagnosis and initiation of radiotherapy treatment has been shown to decrease survival rates and increase morbidity amongst cervical cancer patients.

In Brazil, The National Breast and Cervical Cancer Early Detection and Treatment Program indicator of timely follow-up, defined severe therapeutic care delay as a delay of 60 days or more from final cervical cancer diagnosis to the initiation of treatment (40). This was set to guarantee optimum treatment that would in turn affect disease outcome and survival rates. Evidence has shown that a waiting time that is more than 60 days from diagnosis to initial treatment could lead to poor survival rates as compared to cases where women start their treatment within 60 days after they are diagnosed with cervical cancer (38). Typically, 72.2% of women begin radiotherapy treatment sessions within two months from the time the diagnosis was confirmed with the median waiting time being 41 days. Over the years, this median waiting time has worsened, going from 11 days between 1995-1996 to 64 days a decade later, 2009-2010 (27).

In Canada, introduction of a Rapid Response Radiotherapy Program demonstrated persistent success in offering timely palliative radiotherapy and has continuously been improving to a median waiting time of 3 days from referral to consultation. Evidence supports that a waiting time of more than 60 days from cancer diagnosis to treatment initiation could lead to poorer survival compared with women who start treatment within 60 days after diagnosis, Patients with stage 2b and above who receive timely radiotherapy tend to have less severe burden of symptoms which improves their quality of life and therefore radiotherapy should be delivered in a timely manner to accord these patients improved quality of care (28).

PATIENT DELAY

Some delays were also caused by patient factors such as comorbidities, previous experiences, social influences and social demographic factors that were outside the patient's control (39).

Patient seeking second opinion on their cervical cancer histological diagnosis with the hope of getting different results prolonged waiting time to initiation of appropriate treatment. Other factors such as time-consuming pathologist reviews, previous experiences, strong social influences and co morbidities were also shown to increase time to treatment hence causing unnecessary delays (35). In Taiwan, long waiting time was associated with age, co morbidity, cancer stage, diagnosing hospital level, and hospital ownership. Delaying treatment for ≥4 months substantially raised mortality risk in cervical cancer patients(41).

Institutional factors and access

HEALTH SYSTEMDELAYS

A study done by Mackillop WJ et al, found out that long waiting time to radiotherapy were associated with poor access to health services due to either distance or cost.

In most cases, the long waiting times were correlated with poor access to healthcare services, request for second opinions by the patients, poor quality healthcare and pathologist reviews which were time consuming (37). In Nigeria, a study by Anakwenze et al., found that High patient volumes, Power outages, machine breakdown, health worker strikes, financial difficulty, and distance from radiotherapy centre are some of the factors that increase time to treatment significantly (9). In Kenya a study done by Tengeet.al on the burden of cancer in Western Kenya, shows that most healthcare facilities are not prepared to take the necessary measure when dealing with cancer patients. This is due to poor attitude, lack of skilled personnel and inadequate hospital infrastructure to handle cases efficiently (30).

Difficult access and long waiting lists may discourage patients and referrers from utilizing palliative radiotherapy. And in some circumstances compromise survival outcomes for the patient.Structured

timely hospital visits can minimise the number of patient visits between histological diagnosis and start of radiotherapy (24).

POVERTY, BIOLOGICAL AND CULTURAL FACTORS

Some negative beliefs like having cancer is the will of God or bad luck, cancer is caused by sexual intercourse or childbirth trauma (25) have an effect on the time it takes to start radiotherapy. These beliefs have also been observed in minority groups of Hispanics in the US as noted by Kingsley and Bandolin (28) with findings showing that cultural beliefs and poverty were hindrances to a cervical cancer screening test and preventive care for the disease was seen as a luxury. Similarly, a study conducted on Ghanaian women found that living in a rural area is a significant cultural factor in cervical cancer. For an intervention to be effective, Mupepi et al

(31) found that the cancer control interventions that target different cultural groups require a thorough understanding of culturally based beliefs, knowledge, and practices.

While the biological and cultural factors associated with proper management of cervical cancer, there is need to clearly define the role of the individual, cultural, social, and economic factors associated with late treatment of cervical cancer (22). This study, therefore, intends to establish the nature of these factors in Kenya.

2.1 CONCEPTUAL FRAMEWORK

Histology results

Ca cervix

PATIENT FACTOR

- *Social Economic Factors*
- Health insurance
- Out of pocket payments
- Age
- Education
- Marital status
- Employment status
- Residence
- *Cultural Factors*
- Family support
- Co morbidities i.eanaemia, CKD
- Stigma
- Fear of treatment procedure
- *Other Factors*
- Cervical cancer, signs,
- knowledge of radiotherapy
- Religion

- Fear of Stigmatization
- Beliefs and Practices
- Orientation to Alternative medicine,
- Cultural factors
- Poverty

INSTITUTIONAL AND INFRASTRUCTURE FACTORS

- Distance to health facility
- Adequate equipment
- Available information
- Affordability
- Accessibility
- appointment waiting period
- health workers strike
- Adequate Skilled Personell

Time taken to start radiotherapy (Mean, Mode,median)

Factors contributing to time taken to start radiotherapy

Development of protocol on patient navigation/flow During treatment

2.2 STATEMENT OF THE RESEARCH PROBLEM

Delayed initiation of radiotherapy can often lead to progression and upstaging of the disease. Other than individual patient factors, institutional and infrastructural factors such as distance to the health facility, inadequate radiotherapy facilities may be responsible for the late initiation of therapy. Level of training of health-care personnel, availability of radiotherapy services at the primary health systems and proximity to these facilities are some of the factors that may impact on diagnosis and treatment outcomes of cancer. Delayed communication of diagnosis by primary health care providers and failure to advice on referrals may contribute to delays leading to late treatment of cervical cancer (7).

Early cervical cancer detection can improve the success of a treatment regimen and prevents cell changes in the cervix from upstaging (22). In Africa, the treatment out comes for cervical cancer is still less optimal due to poor living standards. In Kenya, the high incident rates and the late stage presentation may be attributed to the lack of screening services at primary health care facilities. This is further compounded by issues of accessibility, affordability, and availability of health care services. Nevertheless, there is limited information about factors contributing to delay in radiotherapy especially for patients with advanced cervical cancer and late health seeking behaviour among patients. This study seeks to investigate and document waiting for time and factors associated with radiotherapy delay in women with cervical cancer at the Kenyatta National Hospital.

2.3 JUSTIFICATION OF THE STUDY

Advanced Cervical Cancer is a great burden at KNH (13), with the majority of these patients referred from all over Kenya. This gives a direct reflection of the magnitude of the disease burden in the country. Most of the patients present in late-stage clinical disease for radiotherapy treatment. Time spent waiting for radiotherapy sessions to begin is considered to be a good indicator of the quality of care and seems to have an influence on the treatment outcomes of cancer. The standards of care for cervical cancer cases need to be adopted to accommodate the unique circumstances of different persons and countries (12). To our knowledge, in Kenya, at KNH in particular, guidelines on patient navigation from time of diagnosis to radiotherapy are inadequate.

Locally, there is a paucity of information on detailed patient flow and time taken from diagnosis to receiving the first dose of radiotherapy and its related outcome. It is the hope of this dissertation to bring out the gap of what happens between histology diagnosis to radiotherapy and help in policy formulation, development of a guideline on patient movement from time diagnosed to first radiotherapy session and to add knowledge on cervical cancer care. Results from this dissertation will help in adjusting our protocol for quality of care among patients with advanced cervical cancer.

2.4 RESEARCH QUESTION

What are the factors associated with time taken between histological diagnosis and initiation of radiotherapy in cervical cancer among women at the Kenyatta National Hospital?

2.5 OBJECTIVES

2.5.1 Broad Objective

To determine factors associated with time interval between histological diagnosis and initiation of radiotherapy in women with cervical cancer at the Kenyatta National Hospital.

2.5.2 Specific Objectives

    a) To determine time interval between histological diagnosis to initiation of radiotherapy among patients who have undergone radiotherapy for cervical cancer at KNH

    b) To determine patient-related factors associated with time taken between histological diagnosis and initiation of radiotherapy

    c) To determine health system factors associated with the waiting time to initiation of radiotherapy

3.0 METHODOLOGY

3.1 STUDY DESIGN

These was hospital based cross-sectional study conducted at Kenyatta National Hospital Nairobi, Kenya.

3.2 LOCATION OF STUDY

The study was carried out at the Radiotherapy unit of Kenyatta National Hospital Nairobi. KNH offers both preventative and curative services for a variety of illnesses, to patients from all over Kenya. It has a bed capacity of approximate 2000. It is also the largest referral hospital in the country and the main public hospital that offers radiotherapy services in the entire country supplemented by other public and private facilities. The unit offers both external beam radiotherapy and brachytherapy to cervical cancer patients in addition to providing radiotherapy services to other disciplines. It is manned by radio-oncologists, postgraduate students, nuclear physicists, technicians and nurses. There's an outpatient clinic where newly diagnosed patients are seen and prepared for therapy and patients who have completed radiotherapy are followed up. It is estimated that averagely, 15 to 20 new patients with cervical cancer, are enrolled every Monday at the radiotherapy unit for radiotherapy. An average 120 patients receive radiotherapy per month in two session's i.e Morning and evening with an average of 60 patients per session. These patients receive 25 cycles over a period of 25days.

3.3 STUDY POPULATION

The study targeted population of women diagnosed with cervical cancer attending the KNH for treatment with advanced cervical cancer confirmed through histological diagnosis undergoing radiotherapy at the KNH. We concentrated on these particular groups because they were expected to have already undergone all diagnostic procedures necessary to make a confirmation of cancer diagnosis. Cervical cancer stage was crucial hence the reason for concentrating on

laboratory confirmed cases. The study was also interested in determining the period it took from a histological confirmation of cancer and date of commencement of radiotherapy treatment.

3.4: INCLUSION CRITERIA

Patients attending KNH radiotherapy clinic for treatment of cervical cancer were considered

- Patients who were willing to participate in the study (agree to the interview and to access of their medical records)
- Patients who had confirmed histological diagnosis of cervical cancer
- Patients diagnosed with cervical cancer who had already commenced radiotherapy and had had one or more radiotherapy sessions
- Patients who were able to communicate in either English or Kiswahili language.

3.5: EXCLUSION CRITERIA

- Patient who had disease recurrence
- Patients who had cancer of the cervix stage IIA and below.
- Patient who had known psychiatric illness.
- Patient who were too ill to consent

3.6: STUDY SAMPLE SIZE CALCULATION

The formula of means for sample size calculation was used to determine the sample size

$$n = (z^2 \times \sigma^2)/ (e)^2$$

Where:

n=sample size

Z=value of normal distribution = 1.96

σ = population std deviation = 39 {average of 119 days(Lohlun et al.)between diagnosis to treatment, sd = 39}

e=
  - = 5 (maximum error to be tolerated)

Therefore the calculated sample size was:

$$(1.96)^2 \times (39)^2 /(5)^2 = 233$$

With a mark up of 10%, the recalculated sample size = (0.1x233) + 233=**256**

3.7: SAMPLING METHOD

For the 246 participants, simple random sampling using random tables were used to select the study participants. Health talks were held by the principal investigator (PI) or Research Assistant (RA) at the respective clinics to sensitize the patients and healthcare workers about the study. Patients who satisfied the inclusion criteria were identified during the clinic visits and isolated for enrolment into the study. On average, 30 participants were enrolled on each of the clinic days.Upon verbally accepting to participate in the study following the health talk, all potential study participants were escorted to a private room within the clinic where the study was explained to them individually, including the benefits, harm and procedure including the final results dissemination. Written consent was then administered by either the PI or RA. Those who declined to further participate from the study were excluded from the study. All the women who consented and met the inclusion criteria were recruited until the sample size was achieved. The files of each participant interviewed were marked with a code to avoid re-interviewing.

3.8 STUDY INSTRUMENTS

Structured questionnaire (annex 2) which focused on the following areas: Social demographic characteristics such as age, parity, Residence, marital status, occupation, their level of education, and religion. Type of cervical cancer, date of the first visit to the clinic, stage at diagnosis, date of starting radiotherapy treatment, date of 1st consultation to radiotherapy unit and date of histological diagnosis.In addition, a data extraction section was included to review medical records to determine factors associated with time taken from histological diagnosis to commencing radiotherapy treatment. This was for purposes of capturing histological diagnosis, staging of the disease and dates of appointments. The files were obtained from the radiotherapy clinic and records office in the radiotherapy unit. Questionnaires for the patients were administered by the researcher with the help of two research assistants. A unique patient identification number was provided to each patient.

3.9 TRAINING OF THE STUDY TEAM

The study team including 1 clinical officer and 1 nurse, data manager and the principal investigator went through a half a day induction training on good clinical practice and review of the study protocol and data processes before undertaking to conduct the study.

3.10: STUDY VARIABLES

Table 2: Study variables

Variable	Definition
Independent	Age, Level of education Residence, Average distance from KNH, Occupation, insurance cover for radiotherapy,
Dependent	Median and mean duration of time between diagnosis and initiation of radiotherapy

3.11: ETHICAL CONSIDERATION

Informed consent was sought from all participants, with a careful explanation of the benefits of the study. No penalties for declining or financial incentives were offered for cooperating. Confidentiality was maintained, and no individual name appeared on the questionnaire. Interviews were conducted in a closed private room or an area with maximum privacy. Ethical approval was first sought from the Kenyatta National Hospital and University of Nairobi Ethics research committee and study number assigned prior to initiation of the study.

3.12 DATA COLLECTION PROCEDURES

A structured questionnaire was administered to the respondents by the principal investigator/ research assistants. Additional information on; type of cervical cancer, date of the first visit to the clinic, stage at diagnosis, co morbidities and the treatment the patient had received or currently receiving since diagnosis was extracted from patient's medical records; While ensuring anonymity, confidentiality and informed consent, a unique patient identification number was provided to each patient with the aim of capturing stage of cervical cancer stage of the disease and dates of appointments. Data completeness and accuracy was checked on a daily basis by the

data manager and the principal investigator. Data was uploaded into SPSS version 23 software for cleaning, coding, and analysis.

3.13: DATA MANAGEMENT AND ANALYSIS

MS Excel was used to enter and clean data for inconsistencies and data errors. The incomplete data was excluded from the analysis. These was stored in password protected hard drives and limited access computers. SPSS Version 23 was used to analyze the data. Data was analyzed and presented as per the following objectives and presented as per the dummy tables below:

1. Univariate analysis of the socio-demographic characteristics of the study participants will be presented in tables.

Table 3: Univariate analysis of the socio-demographic characteristics

Characteristic	Frequency	Percentage
Age (Mean, StdDev)		
Occupation		
Salaried		
Not salaried		
Business lady		
Marital status		
Single		
Married		
Divorced		
Level of education		
Primary		
Secondary		
Tertiary		
County of Residence		

2. **To determine the average waiting time from histological diagnosis to initiation of radiotherapy among patients who have undergone radiotherapy for cervical cancer at the KNH**

Univariate analysis was done and by calculating the mean and median duration of time taken in days and standard deviation around the mean. Median of 60days was used

3. To determine patient-related factors associated with time taken between histologicaldiagnosis and initiation of radiotherapy

Cross tabulation of factors associated with time to treatment and the time taken was done.

Further analysis was conducted using ANOVA to determine the association of the patient factors and the duration of time between histological diagnosis and initiation of radiotherapy.

This was presented in tables as shown below:

Table 4: Factors associated with time to radiotherapy treatment.

Patient factors	Frequency	Odds ratio	P value
Age			
Less than 49			
More than 49			
Occupation			
Salaried			
Business woman			
Not salaried			
County of Residence			

4. Health system factorsassociated with time interval from histology results toinitiation of radiotherapy

Cross tabulation of factors associated with time to treatment and the time take was done. Further analysis will be conducted using ANOVA to determine the association of the health system factors and the duration of time between histological diagnosis and initiation of radiotherapy.

This will be presented in tables as shown below:

Table 5: health system factors associated with the waiting time to initiation of radiotherapy

Patient factors	Frequency	Odds ratio	P value
Distance from the KNH			
Cost of radiotherapy			
Average time when machine not operational			
Insurance coverage for the procedure			

A p value of 0.05 was taken to be significant statistically.

3.14 STUDY LIMITATION

- Missing data in the files because of referrals from elsewhere or other hospital facilities

- We did not study staffing capacity in the radiotherapy unit and how it would have influenced waiting time and long queues at the radiotherapy unit

Participants whose files didn't meet the minimum documentation for extraction, were replaced by picking the most eligible randomly collected file for administration of the questionnaire and interviewing the patient..

3.15 DISSEMINATION

Results of this study were presented to the department of obstetrics and Gynaecology university of Nairobi and KNH department of reproductive health in form of a thesis book

4.0 RESULTS

4.1 SOCIO-DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF STUDY POPULATION

The mean age of participants was 53.16 ± 11.85 years [range of 18 to 84 years and median of 53 years. Of the 246 patients recruited, a majority (32.2%) were age group 51-60 and were married (65.5%). One hundred and thirty four were unemployed (54.3%), while 76 (31.0%) and 16 (6.6%) were business women and farmers. A majority had a primary level of education (54.5%), 98.5% were Christians, and 49.5% paid hospital bills using insurance policies such as theNational Hospital Insurance Fund (NHIF) card. Stage IIB cervical cancer was the commonest at diagnosis (60.2%) and at initiation of radiotherapy (41.8%) (Table 1). Nineteen women (9.6%) experienced discrimination because of cervical cancer. of these, 52.6% and 47.4% were discriminated by their neighbours and friends, while only three (15.8%) were discriminated by their husbands. The main support system for women was from their nuclear family members (94.5%) followed by their husbands (44.2%) and church members (34.2%). However, only 24.4% knew about radiotherapy prior to treatment, while 5.1% had access to radiotherapy services in their home county hospitals. Seventy five women (37.7%) reported that their radiotherapy treatment was delayed, mainly due to lack of enough finances (94.5%).

Table 6: Socio-demographic and clinical characteristics of study population

	N*		N	%
Age	246	51-60	79	32.2
		41-50	73	29.6
		61+	63	25.6
		31-40	23	9.5
		18-30	7	3.0
Marital status	246	Married	161	65.5
		Divorced	36	14.7
		Widowed	28	11.2
		Single	21	8.6
Occupation	246	Unemployed	134	54.3
		Business woman	76	31.0
		Informal with wages	16	6.6
		Farmer	16	6.6
		Formal employment	4	1.5
Level of education	246	Primary	134	54.5
		Secondary	63	25.8
		None	41	16.7
		Tertiary	7	3.0
		Missing	1	
Religion	246	Christian	242	98.5
		Muslim	4	1.5
Payment		Insurance	121	49.5
		Family	72	29.2
		Self	53	21.4
Stage at Diagnosis	222	IIB	135	60.8
		IIIA	60	27
		IIIB	19	8.6
		IVA	7	3.2
		IVB	1	0.4
Stage at Radiotherapy	242	IIB	103	41.8
		IIIA	50	20.3
		IIIB	31	12.6
		IVA	19	7.7
		NONE	43	17.4

N*: Some variables had missing data and thus the variable N

Table 7. Factors associated with time interval to receiving timely radiotherapy

	N*		n	%
Discriminated	198		19	9.6
		Neighbours	10	52.6
		Husband	3	15.8
		Friends	9	47.4
		Family members	1	5.3
Support system	199			
		Family members	188	94.5
		Husband	88	44.2
		Church members	68	34.2
		Friends	56	28.1
		Neighbours	7	3.5
Knew radiotherapy before treatment	196		48	24.4
Radiotherapy in county hospital	196		10	5.1
Delayed radiotherapy treatment	197		75	37.7
		No money for hospital	61	81.3
		Afraid of outcome	16	21.3
		Afraid of procedure	12	16.0
		Was told nothing was serious	7	9.3
		Alternative treatment	6	8.0

N*: some variables had missing data thus the variable N

4.2 Health system related factors.

A majority of the 246 women thought that KNH had adequate equipment for radiotherapy (99.0%) and that adequate information on cervical cancer was being provided in the course of their treatment (93.9%). Only 60.2% thought that radiology services were affordable, while 4.2% attested to having their treatment disrupted because of industrial strikes.

Table 8: Health system related factors influencing time interval between histological diagnoses to initiation of radiotherapy

	N*	N	%
Adequate equipment at KNH	246	244	99.0
Adequate information system on cervical cancer at KNH	245	230	93.9
Affordable radiotherapy services at KNH	240	144	60.2
Health workers strikes affecting treatment	246	10	4.1
Radiotherapy treatment satisfaction by patients at KNH	246	241	98.0

N*: Some variables had missing data and thus the variable N
KNH: Kenyatta National Hospital

4.3 TIME INTERVAL FROM HISTOLOGICAL DIAGNOSIS TO INITIATION OF RADIOTHERAPY

The median time interval from diagnosis to initiation of radiotherapy was 84 days with a range of two to 651 days. Diagnosis to first consultation at the radiology unit took a median time of 40 days (range of 1-640 days), while the median time from the first consultation at the radiology unit to initiation of the first radiotherapy was 28 days with a range of 1-380 days.

Table 9. Waiting times from diagnosis to initiation of radiotherapy

	Mean ± SD	MED	Min	Max
Diagnosis to Start of Radiotherapy	121.3 ±117.2	84	2	651
Diagnosis to Ist consultation at radiology unit	75.9 ±103.5	40	1	640
Consultation to radiotherapy	45.4 ±56.2	28	1	380

SD: Standard deviation
MED: Median

Patient Related Factors Affectingtime interval from diagnosis to initiation of radiotherapy

None of the patient related factors we evaluated influenced waiting time from histological diagnosis to first radiotherapy statistically significantly. Even though 31-40 year old women had a longer median wait time (102 days) than 40-50 year old women (88 days) and 18-30 year old women (59 days), no statistically significant difference was demonstrated ($X^2 = 7.30$, p=0.12).

Widows (93 days) had a longer wait time than single women (82 days), while women in formal employment (111 days) had a longer waiting time than unemployed women (84 days) by 27 days, but without statistical significance (p>0.05).Payments via insurance cards increased waiting times by nine days compared to self-payments (X^2=0.45, p=0.80).

Table 10. Association between patient factors and waiting time to radiotherapy

		N	Mean	SD	MED	X^2	P
	31-40	28	136.74	137	**102**	7.3	0.12
	61+	61	126.69	117.1	88		
Age	41-50	68	147.21	147.9	88		
	51-60	74	95.19	71.7	77		
	18-30	15	57.17	33.9	59		
Marital status	Widowed	34	132.4	117.7	**93**		
	Divorced	41	156.2	160.6	86	1.72	0.63
	Married	140	113.3	107.3	84		
	Single	29	115.9	107.2	82		
Occupation	Formal employment	13	122.3	65.7	**111**	2.25	0.69
	Farmer	23	109.1	48.3	102		
	Informal (wages)	23	110.4	65.7	84		
	Unemployed	116	125.6	131.4	84		
	Business woman	71	120.4	114.1	77		
Education	Tertiary	18	195.8	228.2	**105**		
	None	45	118.6	79.6	88	1.87	0.6
	Primary	120	120.2	123.5	84		
	Secondary	63	116.9	108	83		
Religion	Muslim	28	108	60.1	126	0.45	0.8
	Christian	218	122	118.3	84		
Payment	Insurance	113	127.6	128.9	**86**		
	Family	73	115	101	84		
	Self	60	118.7	116.4	77		
Stage	III	50	167.2	170.3	**99**	6.9	0.44
	IV	19	102.6	39.9	98		
	IIIB	31	144.1	155.1	83		
	IIB	103	89.5	58.8	77		
	None	43					

4.4 HEALTH SYSTEM RELATED FACTORS ON WAIT TIME

The four hospital-related factors reviewed did not influence waiting times for radiotherapy statistically significantly. Even though more women whose treatments were disrupted by industrial action had a longer median wait time (91 days) than those whose treatment was not disrupted (84 days), the difference was insignificant (Z=-1.87, p=0.38). Moreover, no significant difference in the wait times of women found information to be adequate (Z=-0.62, p=0.54) and who found radiotherapy to be affordable (Z=-1.19, p=0.23) was reported.

Table 11. Association between heath systems related factors and wait time to radiotherapy

		N	Mean	SD	MED	Z	P
Industrial action (strikes)	Yes	33	122.4	120.2	91	-0.87	0.38
	No	213	111.9	66.0	84		
Affordable radiotherapy	Yes	143	113.1	107.1	84	-1.19	0.23
	No	103	135.5	131.9	90		
Adequate information	Yes	209	86.1	61.7	76	-0.62	0.54
	No	37	123.3	119.2	84		

5.0 DISCUSSION

While designing this cross Sectional study at the Kenyatta National Hospital (KNH) radiotherapy unit, our intention was to demonstrate the wait time for initiation of radiology for cervical cancer in three levels – diagnosis to consultation, consultation to radiology, and diagnosis to radiology. We also intended to elucidate hospital and patient factors that influence wait time to radiotherapy of cervical cancer patients, with the aim of influencing policy around cervical cancer at the hospital level (KNH), county level (Nairobi), and nationally (Kenya). Data was retrieved from interviewing patient and patient files, abstracted, and analysed scientifically to draw meaningful conclusions on factors associated with time taken from histologic diagnosis to initiation of radiotherapy in women with cervical cancer at the Kenyatta National Hospital

Among the 246 participants analysed over the duration of the study, our data indicated that less than 30% were likely to initiate radiology within 60 days after histological diagnosis of cervical cancer. According to Cancer Research UK, the current targets for management of cervical cancer with a confirmed histology are initiation of treatment within a month of diagnosis - not more than 62 days - and initiation of treatment within 30 days after consultation with a radiologist (42) Our participants met the latter standard. The median wait time from consultation to radiotherapy was 28 days, which was within the acceptable limits at the United Kingdom(43). The median wait time from histological diagnosis to consultation was longer at 40 days, which might indicate poor health seekingbehavior by cervical cancer patients or a lack of access to affordable, quality radiotherapy services in far flung regions of Kenya. Majority acknowledged that they had sought radiotherapy service late after histological diagnosis mainly because of lack of finances and lack of radiotherapy services at the county level. Our median wait time from histological diagnosis to initiation of radiotherapy (84 days) was almost three times the recommended average of 30 days

almost two times the acceptable range of 62 days, and peaked among divorced women (156 days), women with advanced (FIGO stage III) disease (167 days), and women with a tertiary level of education (195.8 days). In Taiwan, consistent results were reported in a population-based study by Shen et al in 2017 in which the odds of treatment delay increased with the severity of cancer and increasing age(44). In Thailand, advanced disease with lymph node metastasis and stromal invasion was identified as a predictor for health seeking (45).

Patient-related factors evaluated over the duration of the study, did not explain the variability in wait times of cervical cancer that were statistically significant. Increasing age, a low level of educations, and being in employment increased the wait times of patients but not statistically significantly. Longer wait times were also associated with advanced disease and utilization of the NHIF insurance card as a treatment modality for consultations and treatment. This was attributed to long pre-authorization waiting times and frequent visits to NHIF offices for pre authorization of treatment before starting treatment and some investigations such as MRI or CT scans. Even though our data did not attain statistical significance, maybe because of our low sample size or randomization of participants during recruitment in to the study population, targeting such variables in controls can boost health seeking and treatment outcomes of patients. In the United States, near universal coverage of cervical cancer and breast cancer increase the health seeking behaviors of at-risk women by up to 7% in just three years (46). Moreover, apart from solving cost issues such as affordability of radiotherapy and patient level factors such as acceptability, the ready availability of physicians was identified as an important predictor for early screening and treatment of HPV in South Africa (47). In our study, discussions with a majority of cervical cancer patients revealed a dire need for radiotherapy services at the County level, since most level III and level four hospitals in most of the 47 counties in Kenya lacked such services.

Three of the hospital-related factors evaluated (perennial industrial strikes, affordability of radiotherapy, and access to radiotherapy services) influenced the wait times of cervical cancer patients, but not statistically significant. However, the distance to hospital explained 2.3% of the variation in wait times for radiotherapy that we reported. Women from far flung areas of Kenya have a significantly longer wait time, with every 10 kilometers women travelled out of Nairobi increasing wait times by approximately a day. Makau et al, while evaluating wait time to radiotherapy in Kenya in 2017 associated the centralization of cancer treatment in Nairobi as a barrier for health seeking. Confounded by the low socioeconomic status of cancer victims, the long travel to KNH impeded access to treatment, which affects the prognosis of patients. Our data was also consistent with the findings of Chidima et al in Nigeria, where distance to radiotherapy centers increased time to treatment statistically significantly. Decentralization of public radiotherapy centers to counties can increase access to treatment by women in need.

6.0 CONCLUSIONS

Time interval between histological diagnosis to treatment of advanced cervical cancer was unacceptably longer with median wait time of 84 daysalmost three times the recommended average of 30 days by united kingdom and almost two times the acceptable range of 62 days recommended in the USA by National breast and cervical cancer detection program (NBCCEDP). Distance to hospital explained 2.3% of the variation in wait times for radiotherapy significantly contributed to delay in initiation of radiotherapy.Further assessment of the impact of prolonged time ininitiation of radiotherapy and consideration of quality metrics to track Time to radiotherapy initiation are warranted to address these issues.

7.0 RECOMMENDATIONS

- KNH should come up with structured timelines protocol in various stages of follow up to make it easy and clear on follow up especially for patient with cervical cancer scheduled to have radiotherapy treatment.

- Patients should be encouraged to enroll in insurance schemes early enough to ease the burden of cost of treatment with radiotherapy and minimize time wasting.

- KNH should buy more radiotherapy machines and encourage Kenyan Government to decentralize radiotherapy services to county hospitals to reduce congestion at KNH.

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APPENDICES

Annex1: Consent Form/ FomuYaIdhini

a.) English

Study title:

FACTORS ASSOCIATED WITH TIME TAKEN BETWEEN HISTOLOGIC DIAGNOSIS AND INITIATION OF RADIOTHERAPY IN WOMEN WITH CERVICAL CANCER AT THE KENYATTA NATIONAL HOSPITAL; CROSS-SECTIONAL STUDY

Principal investigator: Dr. Victor MuleeMoseti.

Introduction:

I Dr. Victor MuleeMoseti, a postgraduate student at the Department of Obstetrics &Gynecology, University of Nairobi, am conducting a study on**FACTORS ASSOCIATED WITH TIME TAKEN BETWEEN HISTOLOGIC DIAGNOSIS AND INITIATION OF RADIOTHERAPY IN WOMEN WITH CERVICAL CANCER AT THE KENYATTA NATIONAL HOSPITAL** KNH. You are hereby requested to participate in the study.

The following information will help you make an informed decision on whether to proceed to participate in the study or not. Feel free to ask any questions about the study or anything in this form that is not clear.

Purpose of the study:

It is the hope of this study to bring out the time taken between laboratory diagnosis of cervical cancer to treatment with radiotherapy and what happens in between. This will help in policy formulation, development of guidelines on patient movement from the time of diagnosis to first radiotherapy sessions and to add knowledge on cervical cancer care.

Benefits:

Your participation in the study will help us obtain this information that will help in adjusting our protocol for quality of care among patients with cervical cancer. The knowledge generated from this study is expected to benefit other future patients, the local community, Kenya and women globally.

Possible risks:

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

Voluntarism:

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

Compensation:

No compensation will be offered for participation in the study.

Procedure:

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

Confidentiality:

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

Contact information:

If you have any questions regarding the study, you can contact Dr. Victor Moseti through telephone number 0723873075. You may also contact the KNH/UoN/ERC Commitee-0735-274288/0721-665077.

Or

The chairperson,

KNH/UON Ethics and Research Committee

P.O. Box 20723-00202, Nairobi.

Telephone number: (254-020) 2726300-9 Ext 44355

Email:uonknh_erc@uonbi.ac.ke

Your participation in the study will be highly appreciated.

Consent:

I_____ hereby voluntarily consent to participate in the study. I acknowledge that a thorough explanation of the nature of the study has been given to me by Dr./Mr./Mrs._____. I clearly understand that my participation is completely voluntary and that I can withdraw from the study at any time without any negative repercussion on my current treatment schedule.

Name of the Participant_____

Signature of Participant _____ Date _____

Name of the Research Assistant_____

Signature of Researcher/ Assistant _____ Date _____

Witness Name _____ Date_____

Witness Signature _____ Date _____

Annex 2: Questionnaire

FACTORS ASSOCIATED WITH TIME TAKEN BETWEEN HISTOLOGIC DIAGNOSIS AND INITIATION OF RADIOTHERAPY IN WOMEN WITH CERVICAL CANCER AT THE KENYATTA NATIONAL HOSPITAL:

A CROSS SECTIONAL STUDY

1. Serial number..............................

2. Age …………………Home County......................................

3. Marital status *(tick as appropriate)*

   Single ☐

   Married ☐

   Divorced ☐

   Separated ☐

4. Occupation

   Formal Employment ☐

   Informal with wages ☐

   Business woman ☐

   Unemployed ☐

   Others ☐   Specify_____

5. Level of education

   None ☐

   Primary ☐

   Secondary ☐

   Tertiary ☐

6. Religion

Christian ☐

Muslim ☐

Not religious ☐

Other ....   Specify_____

7. Who Pays your hospital bill?

Self ☐

Famiy ☐

Harambee ☐

Insurance i.e. NHIF ☐

Others _____

8. Date of histology diagnosis _____

9. Date of 1st consultation at radiotherapy unit _____

10. Date of first radiotherapy _____

11. At what stage of cancer of the cervix were you diagnosed? _____

12. At what stage of cervical cancer did you start radiotherapy _____

13. What are some of the risk factors that causes cervical cancer? (You can tick more than one answer)

Multiple sexual partners ☐

A curse for wrong doing ☐

A symptom of HIV ☐

Witchcraft ☐

Diet ☐

Don't Know [ ]

Others _____ Specify _____

14. Did the above risk factors and Perception delay you from seeking treatment in time?

Yes [ ] No [ ]

15. Do you think early stage of cervical cancer can be cured? Yes [ ] No [ ]

If yes How? _____

16. Did you experience any form of discrimination for having cervical cancer?

Yes [ ] No [ ]

If yes from whom?

Neighbors [ ] Husband [ ] Friends [ ]

Family member's [ ] Church members [ ]

Others _____ Specify _____

17. Where do you get your social support from as you receive your treatment?

Nuclear Family members [ ] Church members [ ]

Husband [ ] Friends [ ] Neighbors [ ]

Others _____ Specify _____

18. Did the people who support you make you come for treatment in time?

Yes [ ]

No [ ]

Knowledge of Radiotherapy

19. Did you have any prior knowledge on radiotherapy as a form of treatment for your disease?

Yes [ ]

No [ ]

20. Is it important to receive radiotherapy for your treatment?

Yes [ ]

No [ ]

21. Do you have radiotherapy services at your county hospitals?

Yes [ ]

No [ ]

22. Could you have reduced time taken to receive radiotherapy if you had radiotherapy services at your county?

Yes [ ]

No [ ]

23. In your opinion did you delay to get radiotherapy treatment?

Yes [ ]

No [ ]

24. What delayed you from receiving radiotherapy in time?

I was afraid of the outcome [ ]

I was afraid of treatment procedure [ ]

I went to a traditional herbalist for alternative treatment [ ]

I was told there was nothing serious [ ]

I dint have money to go to hospital [ ]

25. Do you think KNH have Adequate equipment to treat your condition

Yes ☐

No ☐

26. Were you given adequate information regarding cervical cancer within KNH?

Yes ☐

No ☐

27. Do you think this information made you seek treatment in time?

Yes ☐

No ☐

28. Were you able to afford radiotherapy treatment for your disease?

Yes ☐

No ☐

29. Did health workers strike affect your scheduled time to have radiotherapy?

Yes ☐

No ☐

30. Are you satisfied on how you receive radiotherapy treatment at KNH?

Yes ☐

No ☐

31. What areas do you recommend for improvement?

Annex 4: Letter to ERC

Dr. Victor Moseti (MBChB)

H58/87776/2016

June 6th, 2019.

The Chairperson,

Ethics, Research and Standards Committee,

Kenyatta National Hospital and University of Nairobi,

P.O. Box 20723,

NAIROBI

Dear Sir/Madam,

RE: SUBMISSION OF MASTERS DEGREE RESEARCH PROPOSAL FOR APPROVAL

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

Yours Sincerely,

Dr.Victor Moseti

CC:
Department of Obstetrics and Gynecology,

College of Health Sciences

University of Nairobi.

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/362

30ᵗʰ September, 2019

Dr. Victor Moseti
Reg. No. H58/87776/16
Dept. of Obstetrics and Gynaecology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Moseti

RESEARCH PROPOSAL: FACTORS ASSOCIATED WITH TIME TAKEN BETWEEN HISTOLOGIC DIAGNOSIS AND INITIATION OF RADIOTHERAPY IN WOMEN WITH CERVICAL CANCER AT THE KENYATTA NATIONAL HOSPITAL; CROSS SECTIONAL STUDY (P449/06/2019)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above research proposal. The approval period is 30ᵗʰ September 2019 – 29ᵗʰ September 2020.

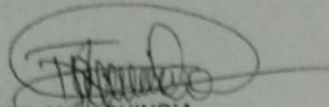This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 7 hours.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. 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).
g. Submission of an executive summary report within 90 days upon completion of the study.
This information will form part of the data base that will be consulted in future when processing related

Protect to discover

research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website http://www.erc.uonbi.ac.ke

Yours sincerely,

PROF. M. L. CHINDIA
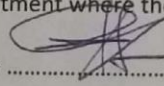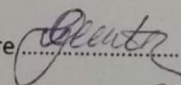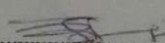SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
  The Director, CS, KNH
  The Chairperson, KNH- UoN ERC
  The Assistant Director, Health Information, KNH
  The Dean, School of Medicine, UoN
  The Chair, Dept. of Obstetrics and Gynaecology, UoN
  Supervisors: Dr. Beatrice Anne Kihara, Dept. of Obstetrics and Gynaecology, UoN
      Dr. Orora I. Maranga, Dept.of Reproductive Health, KNH
      Dr. Anne Pulei, Dept.of Obstetrics and Gynecology, UoN

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P.O. Box 20723-00202 Nairobi

Tel.: 2726300/2726450/2726565
Research & Programs: Ext. 44705
Fax: 2725272
Email: knhresearch@gmail.com

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
   DR VICTOR MULEE MOSETI

2. Email address: Victormoseti@gmail.com   Tel No. 0723887307

3. Contact person (if different from PI)

4. Email address: Tel No.

5. Study Title
   FACTORS ASSOCIATED WITH TIME TAKEN BETWEEN HISTOLOGICAL
   DIAGNOSIS AND INITIATION OF RADIOTHERAPY IN WOMEN
   WITH CERVICAL CANCER AT KENYATTA NATIONAL HOSPITAL
   CROSS SECTION STUDY

6. Department where the study will be conducted OBSTETRICS & GYNAECOLOGY WD
   (Please attach copy of Abstract)   10, clinic 18

7. Endorsed by Research Coordinator of the KNH Department where the study will be conducted.
   Name: DR. IKOL ADUNGO   Signature   Date 7/10/2019

8. Endorsed by KNH Head of Department where study will be conducted.
   Name: DR MAUREEN OWITI   Signature   Date 7/10/2019

9. KNH UoN Ethics Research Committee approved study number P449/06/2019
   (Please attach copy of ERC approval)

10. I DR VICTOR MULEE MOSETI 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 4/10/19

11. Study Registration number (Dept/Number/Year) Obs & Gynae / 341 / 2019
    (To be completed by Research and Programs Department)

12. 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.