FACTORS ASSOCIATED WITH CERVICAL CANCER STAGE AT DIAGNOSIS AMONG PATIENTS ATTENDING KENYATTA NATIONAL HOSPITAL, KENYA

BY:

KABURA WAMBURU

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DECLARATION

This thesis is my original work and has not been presented to any other university or institution.

Signature…… **Date……..….**

Kabura Wamburu
Reg No: SPH/PGH/1014/12

This thesis has been submitted to Moi University with our approval as university supervisors

Name: Dr Naftali Busakhala
Specialist Physician and Senior Lecturer
Moi University

Signature…… **Date……..….**

Name: Dr Josephat Nyagero
Technical Leader, Research Programme
AMREF Health Africa

Signature…… **Date……..….**

ABSTRACT

Background: The global burden of cervical cancer is considerable with nearly 527,600 new cancer cases and 265,700 cancer deaths resulting in cervical cancer being the second most frequently diagnosed cancer. In Kenya, cervical cancer is the second most common cancer among women, with almost half of all women with invasive cervical cancer having been diagnosed at a late stage. Lack of healthcare insurance and the user fees system for healthcare services can be an impediment to early diagnosis and treatment. Information regarding preventive care for cervical cancer is also wanting. Few women are aware of the symptoms and risk factors of cervical cancer and that its precursor lesions are detectable through screening procedures thereby causing most women to seek treatment when the cancer is at an advanced stage.

Objective: To determine factors associated with cervical cancer stage at diagnosis among patients receiving treatment at Kenyatta National Hospital.

Methods: The study was carried out at the cancer treatment centre and in the obstetrics and gynaecology department at Kenyatta National Hospital. A cross-sectional study method was adopted and 385 cervical cancer patients were recruited through convenience sampling. Histological information was obtained from patient files. Informed consent was sought and interviews were carried out by the researcher and by a research assistant using a semi-structured questionnaire. A pilot study was conducted in order to ensure reliability and validity of the instrument. Data collected was entered and analysed using SPPS 16. The outcome variable stage at diagnosis, was determined using the International Federation of Gynaecology and Obstetrics (FIGO) staging system. Chi-square, Fisher's exact and Wilcoxon ranksum tests were used to evaluate the association between stage at diagnosis of cervical cancer and factors that may bring about delays in diagnosis.

Results: Stage at diagnosis was advanced, 72.6% and 27.4% for women with early stage cancer. Of the women with advanced stage cancer, 145 (55.6%) and 62 62.6%) with early stage cancer had heard of cervical cancer prior to their diagnosis. Only 22% of women with early stage cervical cancer and 23.7% women with advanced stage cervical cancer were aware of the sexually transmitted nature of cervical cancer. Majority of the women were not aware of the causative link between cervical cancer and human papillomavirus (HPV), 8 (13.1%) in women with early stage cancer and 5 (3.5%) in women with advanced stage cervical cancer (p=0.036).

Conclusion: Most women presenting with advanced cervical cancer at Kenyatta National Hospital were not aware that cervical cancer is caused by HPV. They were also not aware that HPV can be sexually transmitted.

Recommendations: There is need to increase awareness of basic cervical cancer symptoms in order to allow for early detection. Women should be informed about the HPV virus, on its role in the cervical cancer aetiology.

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ACRONYMS AND ABBREVIATIONS

CCRT	Concurrent Chemo-radiotherapy
CDC	Centers for Disease Control
CIN	Cervical Intraepithelial Neoplasia
CTC	Cancer Treatment Center
DNA	Deoxyribonucleic Acid
EBRT	External Beam Radiotherapy
ECSA	East Central and Southern African Countries
ERC	Ethical Review Committee
HIV	Human Immunodeficiency Virus
HPV	Human Papillomavirus
HSV	Herpes Simplex Virus
IARC	International Agency for Research on Cancer
ICC	Invasive Cervical Cancer
KNH	Kenyatta National Hospital
NCCPSP	National Cervical Cancer Prevention Strategic Plan
Pap Test/Smear	Papanicolaou testing
STI	Sexually Transmitted Infection
SES	Socioeconomic Status
UoN	University of Nairobi
VIA	Visual Inspection using Acetic Acid
VILI	Visual Inspection using Lugol’s Iodine
WHO	World Health Organization

DEFINITION OF TERMS

Cancer – Is the unusual growth of abnormal cells in the body which occurs when the control mechanism in the body ceases to work and as a result old cells do not die but instead grow uncontrollably, developing new, abnormal cells.

Cancer staging – Staging can be defined as the process of appraising the anatomical extent of a tumour. Stages are subdivisions of the continuing disease process which is based on anatomical markers. Cancer staging is used to indicate the extent of disease at the time of diagnosis which is essential in the management of the patient.

Early diagnosis – is the recognition by the public or health professionals of early signs and symptoms of cancer so as to aid in diagnosis before the disease becomes advanced. This allows for more efficient and uncomplicated therapy.

Parity – Is the number of times a woman has delivered a foetus of more than twenty four weeks, regardless of whether that foetus was live of still born.

Papanicolaou smear test – A test that is done in order to check for cervical pre-cancerous lesions and cancer.

Precancerous lesions – are unusual changes that occur in tissues in an early stage of cancer progression which have the potential to develop into invasive cancer if left untreated. Cervical cancer screening aims to detect cancer at an early stage.

Screening – This is the presumptive identification of unrecognized disease by the application of a test that can be applied rapidly in an asymptomatic population.

Socioeconomic status – This is a descriptive term for a person's social standing in society which is measured by a combination of economic, occupational and educational criteria.

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CHAPTER ONE: INTRODUCTION

1.1. Background of the study

Cervical cancer impacts the lives of many women worldwide, especially those in developing countries. Approximately 527,600 new cancer cases and 265,700 cancer deaths occur in women worldwide making cervical cancer the second most frequently diagnosed cancer and the fourth leading cause of cancer deaths among women. Close to 90% of these new cases and deaths occur in developing countries (Torre *et al*., 2015). Sub-Saharan Africa has a disproportionately enormous burden of cervical cancer which is mostly due to scarce screening programs that allow for early detection of precancerous lesions and early stage cervical cancer. Moreover, the health infrastructure, financial and human resources in sub-Saharan Africa countries is inadequate to support the Papanicolaou testing or liquid based cytology techniques (Aleyamma and Preethi, 2009). The most efficient and cost effective methods for screening for cervical cancer in developing countries include, deoxyribonucleic acid (DNA) testing for human papillomavirus (HPV) and visual inspection using either acetic acid (VIA) or Lugol's iodine (VILI) (Sherris *et al.,* 2009). Cervical cancer incidence and mortality rates differ to a large extent in Africa, with the rates in East and West Africa being five times more than those in North Africa (Parkin, Bray, Ferlay and Jemal, 2014). In Kenya, cervical cancer is the second most prevalent cancer after breast cancer (MOPHS and MOMS, 2012a). The incidence of cervical cancer per year in Kenya is approximately 2,454 with about 1,676 annual deaths due to the disease (MOH, 2013).

The major underlying cause of cervical cancer is human papillomavirus (HPV) infection and its precursor lesions. Smoking has been found to be an independent risk factor for cervical cancer after altering the effects of HPV infection. Other risk factors

for cervical cancer include having many sexual partners, high parity, early age at first intercourse, co-infection with HIV and long term use of oral contraceptives (Munoz, Castellsagué, de González and Gissmann, 2006). Implementation of HPV vaccination programs in developing countries is challenging due to the high costs of vaccines and inadequate vaccine distribution platforms. The vaccine is administered in three doses that are spread over a six month period and platforms that reach out to preadolescent girls are non-existent (Sankaranarayanan, 2009).

Previous studies by Coughlin, King, Richards and Ekwueme (2006) have shown that, disparities in socioeconomic and demographic status are correlated to cervical cancer both in the developing and developed countries. In spite of a general downward trend in cervical cancer incidence in the United States, disparities in mortality rates still exist among certain age groups as well as in geographic, socioeconomic and racial groups. It has also been found that, various factors such as an age greater than sixty five years, race, ethnicity, poor health coverage, low levels of education, lack of knowledge and poverty are associated with inadequate preventive cervical cancer screening practices. High cervical cancer rates with regard to place of residence reflect to a great extent the health inequities in a particular area. For instance, there are vast disparities in terms of coverage of early detection programs for cervical cancer as well as limited access to health services in rural and urban areas. These factors therefore represent an indicator of the treatment prospects in these areas (Palacio-Mejía, Rangel-Gómez, Hernández-Avila, Lazcano-Ponce, 2003).

A study by Robinson, Christensen, Ottesen and Krasnik (2011) shows that, the imbalanced use of cancer health care services may be attributed to cultural and ethnic barriers. Co-infection and socio-demographic factors lend to the likelihood of delays in the diagnosis of cervical and ovarian cancers and the probability of extended delays

in referral for specialized treatment are generally greater in rural than in urban areas. Early diagnosis of cervical cancer has been found to be directly correlated with health insurance. Garcés-Palacio *et al*., (2010) found that, Columbian women who obtain cervical cancer screening services are more likely to have subsidized health insurance than women without health insurance. Moreover, a study by Kaku, Mathew and Rajan (2008) showed that late stage at diagnosis is more likely to occur if the patient is widowed, divorced or has a low level of education. This is attributed to lack of a support system which in turn discourages the patients from seeking treatment. Consequently, low levels of education make it difficult for the patients to understand the implications of the disease and to take note of the common symptoms. In African countries, approximately 95% of cancer patients are diagnosed with late stage or end stage disease. Culture, low level of cancer knowledge in the population, lack of specialized health care practitioners and limited access to health care facilities contribute to the delay in diagnosis for cancer patients (Pezzatini, Marino, Conte and Catracchia, 2007).

In Kenya, it is estimated that about 50 Kenyans die each day from various types of cancers with 10 to 15 new cases of cervical cancer reported in Nairobi each week (Kenya Departmental Committee on Health, 2011; Anorlu, 2008). Cervical cancer is simple to detect and cure in its early stages. The situation in Kenya however is quite dismal as only 3.5% of women between the ages of 25 and 49 years have been screened in a three year period (Bruni *et al*., 2017). In order to address the rising cases of cervical cancer, the government has set out national guidelines for the management of cervical, breast and prostate cancer that are to be implemented across all levels of the health care system in addition to, strengthening the referral systems in the country (MOPHS and MOMS, 2012b). However, Kenyatta National Hospital (KNH), MP

Shah Hospital, Texas Cancer Centre and Aga Khan Hospital are the only available radiotherapy centres in Nairobi that handle roughly 3,800 patients a year which is below the needs of the residents of Nairobi. Consequently, patients who are referred to KNH from other hospitals have to wait for several months to access services resulting in a majority of the patients progressing to late stage disease despite early diagnosis (Karanja, 2011). This study therefore sought to determine the magnitude of the identified barriers to health seeking behaviour including, socio-demographic aspects and lack of awareness of cervical cancer that causes women to obtain treatment when the disease is at an advanced stage.

1.2. Problem statement

Cervical cancer can be prevented at a minimal cost when screening services are available to detect precancerous lesions in asymptomatic women and when suitable treatment and follow up mechanisms are available (Lewis, 2003). In developed countries, the burden of cervical cancer is relatively low as Pap smear screening is a regular aspect in women's healthcare which is in sharp contrast to women in developing countries who have minimal or no access to screening or prevention services (Tsu and Levin, 2008). Studies have demonstrated that a bulk of cancer patients seek medical care when the disease is at an advanced stage. For instance, a number of hospitals in Zimbabwe reported that 80% of cervical cancer patients were diagnosed with advanced disease (Chirenje, Rusakaniko, Akino and Mlingo, 2000).

Poor access to health facilities, high levels of exposure to HPV and an absence of screening programs has resulted in high cervical cancer rates among sub-Saharan African women (Ferlay *et al*., 2011). Crossley-May, Vigneau, Brown and Banerjee (2003) demonstrate that, women of low socioeconomic status use medical services only when recommended to them by health practitioners and when they are available

to them resulting in delays in diagnosis. Thus, for women diagnosed with late stage cervical cancer, the disease will have progressed extensively for them to obtain viable treatment options such as radiation, surgery and chemotherapy. Health facilities in developing countries with the essential infrastructure are unable to function optimally due to irregular supplies of crucial materials such as laboratory reagents for staining smears and fixatives as well as the absence of cytology technicians resulting in missed screening opportunities thereby contributing to delays in diagnosis (Chirenje *et al*., 2001).

Early stage at diagnosis is crucial in effectively managing cancer. Achieving this is feasible in developing countries using low cost methods such as visual inspection using Lugol's iodine or acetic acid, and DNA testing for HPV (Denny *et al*., 2005). Studies that used simulation modelling showed that screening women between the ages of 35 and 55 years once or twice in their lifetime using any of the low cost methods can greatly reduce the incidence of cervical cancer by 30% (Goldie *et al*., 2005). Women at risk of developing cervical cancer require accurate information for them to understand prevention methods and to prompt them to use screening services (Abotchie and Shokar, 2009). Increasing public awareness of cervical cancer early signs and symptoms enhances its detection at an early stage when more effective alternatives for treatment are available resulting in better disease prognosis (World Health Organization, 2002). Therefore, concerted efforts should be made to enhance the capacity of health care delivery systems in providing timely treatment for women diagnosed with early stage cervical cancer and in their ability to increase awareness for improved patient outcomes. This study therefore sought to ascertain the factors influencing stage at diagnosis of cervical cancer among women attending Kenyatta National Hospital.

1.3. Justification

Cervical cancer is curable if precancerous lesions are diagnosed promptly through screening. However, in spite of the presence of a National Cervical Cancer Prevention Strategic Plan (NCCPSP) (2012), cervical cancer screening only takes place in certain locations and in fragmented projects rather than as an established national level program. As a result, women are more inclined to seek healthcare services when symptoms develop, when the cancer is at an advanced stage and difficult to treat (Mupepi, Sampselle and Johnson, 2011).Similarly, early detection of cancer is vital due to the documented relationship between stage at diagnosis and survival. Prevention amenities such as information on cervical cancer, screening services, vaccination against HPV, the causes of and treatment of pre-cancerous lesions are all vital in treating cervical cancer at its early stage (Thomson and Forman, 2009). Challenges in the management of cervical cancer may vary from individual to institutional related factors and technological factors. In Kenya, the prognosis for most cervical cancer patients is poor as there are inadequate health care delivery platforms. Similarly, population based registries in Kenya mostly have information on incidence and mortality rates with limited data on cancer stage at diagnosis. Therefore, this study sought to identify women who are more likely to be diagnosed at a late stage and thus aid in the development of prevention and control programs that will reduce the burden and mortality from cervical cancer in Kenya.

1.4. Objectives of the Study

1.4.1. General objective

To determine the factors associated with cervical cancer stage at diagnosis among patients receiving treatment at Kenyatta National Hospital.

1.4.2. Specific objectives

1. To determine the proportion of patients receiving treatment at KNH diagnosed with early and late stage cervical cancer.
2. To determine the demographic and socioeconomic factors of cervical cancer patients receiving treatment at KNH.
3. To determine the level of access to primary and secondary health care facilities among cervical cancer patients receiving treatment at KNH.
4. To determine the level of cervical cancer awareness in patients receiving treatment at KNH.

1.5. Research questions

1. What is the proportion of patients receiving treatment at KNH diagnosed with early and late stage cervical cancer?
2. How does stage at diagnosis vary with respect to demographic and socioeconomic factors in women being treated at KNH?
3. How does the availability of primary and secondary health care facilities affect the stage at diagnosis of cervical cancer?
4. How does cervical cancer awareness affect the stage at diagnosis in women being treated at KNH?

CHAPTER TWO: LITERATURE REVIEW

2.1. Introduction

Cervical cancer is curable if precancerous lesions are diagnosed promptly through screening. However, in sub-Saharan African countries disease screening is not routine as most individuals do not access screening services since the notion of check-ups is not common practice in the African way of life. Individuals instead, are more inclined to seek healthcare services when symptoms develop, when the cancer is at an advanced stage and difficult to treat (Mupepi, Sampselle and Johnson, 2011). Studies by Amarin, Badria and Obeidat (2008) showed that, there are discrepancies in incidence and mortality rates as well as differences in education and knowledge of cervical cancer and prevention methods between developing and developed countries. Moreover, socioeconomic factors such as education, income, poverty status, occupational group and cultural factors such as beliefs, knowledge and attitudes about disease have a graded influence on health (Baquet and Commiskey, 2000).

A hospital based study carried out in Sudan by Ibrahim, Rasch, Pukkala and Aro (2011) showed that, risk factors such as lack of health insurance, old age, rural residence and African ethnicity contribute to diagnosis of advanced cervical cancer with approximately 72% of the cervical cancer patients being diagnosed at an advanced stage. The inadequacy of screening programs in Kenya has led to most women with invasive cervical cancer being diagnosed at an advanced stage and the factors associated with late stage cervical cancer diagnosis are unknown. This chapter provides literature on pathology of cervical cancer, socio-demographic factors, knowledge on cervical cancer and availability of healthcare facilities and the extent to which these factors influence the stage at diagnosis.

2.2. Cervical cancer

Cancer of the cervix occurs when the cells surrounding the cervix begin to change. The two main types of cells found around the cervix are glandular cells that are on the endocervix, the part of the cervix adjoining the uterus. Squamous cells are found on the exocervix or ectocervix, the area that is adjacent to the vagina. Squamous cell carcinoma is the cancer that develops in the ectocervix and accounts for approximately 80 to 90% of the cervical cancer cases (Saslow *et al*., 2012). Whereas, adenocarcinoma develops in the endocervix, with few cases of mixed variants occurring that are referred to as adeno-squamous carcinomas or mixed carcinomas (Saslow *et al*., 2012). Epidemiologic studies have shown that several risk factors increase the chances of developing cervical cancer. Studies have further shown that independent of other risk factors, there is a strong association between genital HPV and cervical cancer. Thus, HPV is not a sufficient cause of cervical cancer and other risk factors are essential for the progression from HPV infection to cervical cancer (Bosch, Lorincz, Munoz, Meijer and Shah, 2002). The signs and symptoms of cervical cancer do not usually manifest in women with early stage cervical cancer and precancerous lesions. Nevertheless, the most common symptoms include abnormal vaginal bleeding such as post-coital bleeding, heavy and longer menstrual periods than usual, postmenopausal bleeding and bleeding or spotting in between menstrual periods, unusual vaginal discharge which may contain blood and pain during intercourse (Saslow *et al*., 2012).

2.3. Proportion of women with early stage cervical cancer

Variations in preventable disease incidence and mortality are as a result of differential access to screening services and treatment. In developed countries, Pap smear screening is a regular aspect in women's healthcare which is in sharp contrast to

women in developing countries who have minimal or no access to screening or prevention services (Tsu and Levin, 2008). Studies have shown that mortality from squamous cell cervical cancer which makes up approximately 90% of all cervical cancers has significantly reduced in the United States, ranking fourteenth of all cancer deaths due to increased prevalence in cervical cytology screening (Pap smear testing) (Siegel, Naishadham and Jemal, 2012). The reduction in mortality rates due to screening is as a result of enhanced detection of invasive cancer at the early stages when the five year survival rate is roughly 92% as well as the detection and treatment of pre-invasive lesions thereby resulting in a reduction in the overall incidence of invasive cervical cancer (Tarver, 2012).

In developing countries, the age standardised mortality rate for cervical cancer is 9.6 per 100,000 women which is double the rate in developed countries. The absence of efficacious screening programs in developing countries can be linked to the disparity in prevalence rates between developed and developing countries (Wright, Faseru, Kuyinu and Faduyile, 2011). Data from the National Cervical Cancer Prevention Strategic Plan (NCCPSP) (2012) shows, that the incidence of abnormal cervical cytology results is approximately 3.6% with a much higher percentage among HIV positive women (MOPHS and MOMS, 2012a). However, the number of cancer registries in many African countries is insufficient or non-existent and thus the true incidence of cervical cancer is unknown due to gross under reporting. Available data from these countries is obtained from hospital records which is representative of only a small fraction of women as most of them are unable to access hospital services (Ntekim, 2012).

The gains arising from cervical screening programs in developed countries have been undoubtedly substantiated. Denmark for example, registered a 25% decline in

mortality following 40% coverage. Whereas, Norway recorded a 10% drop in mortality after 5% coverage. It is therefore evident that in areas with well-organized Pap smear screening programs and where women are screened at regular intervals, cervical cancer incidence can be abridged significantly (Vallikad, 2006). Subsequently, health education aimed at augmenting public knowledge on risk factors, signs, symptoms and treatment of cervical cancer has been found to ameliorate early detection, compliance with therapy and survival from cervical cancer. In Sweden, there were improved outcomes of cervical cancer prior to the introduction of widespread cervical cancer screening programs thereby presenting additional experiential evidence of the efficacy of increased awareness of cervical cancer coupled with facilities for diagnosis and treatment (Sankaranarayanan, Budukh and Rajkumar, 2001).

Screening for cervical cancer however, necessitates human and financial resources, infrastructure, quality assurance and monitoring and evaluation measures. In developing countries, reducing mortality from cervical cancer is among the many health interests competing for scarce resources. Screening programs that assimilate visual inspection of the cervix with acetic acid (VIA) or DNA testing for HPV in one or two clinical visits are more economical options to the standard three day visit cytology based screening programs and should thus be considered (Denny, Kuhn, Pollack, Wainwright and Wright, 2000). Furthermore, screening of women aged thirty five years old or more with one or two visit visual inspection or through HPV DNA testing techniques could greatly diminish the risk of cervical cancer by 25% to 36%. Conversely, the relative increase in reduction of risk of cervical cancer in women who have been screened twice is roughly 40% with much lesser incremental gains from three screenings (Goldie *et al.*, 2005). Nevertheless, difficulties in implementing

effective screening programs in low resource setting results from the inability of the programs to focus on increased coverage, to employ effective and culturally acceptable tests to women and in the use of appropriate treatment methods on women who have positive screening tests and their follow up (Ali, Kuelker and Wassie, 2012).

2.4. Cancer staging and Pathology

The pre-malignant stage of cervical cancer can be detected by cytological inspection of exfoliated cervical cells which is then verified by histological assessment of the cervical material. The pre-malignant changes characterize a range of histological irregularities that range from mild dysplasia CIN1 to moderate dysplasia CIN2 to severe dysplasia or carcinoma in situ CIN3. However, the incertitude regarding the natural history of CIN has rendered the treatment of cervical pre-malignancies to be procedurally ineffective (Doorbar, 2006). In order to effectively manage any malignant disease, the location the disease originated from, the biology and the degree of the disease at the time of diagnosis that is, the stage of the tumour should be regarded (Gospodarowicz, Groome, O'Sullivan, Sobin and Koh, 2007).

The classification of cancers based on their anatomical extent is referred to as staging. A staging system measures certain characteristics of a tumour, which are then coded, resulting in ranked variables. Staging provides a wealth of knowledge that aids in the type of treatment employed in individual patients as well as providing a guide in the management of cancer control programs (Mackillop *et al*., 2004). Classification of gynaecological malignancies is organized in a way that the pathological spread is divided into four stages. Stage I refers to the extent of tumour restricted to the organ of origin. Stage II describes the local extension of disease away from the main organ of origin to neighbouring organs. Stage III refers to more extensive involvement of

neighbouring organs whereas, stage IV represents metastatic disease that is removed from the primary organ of origin (See appendix 1). The four fundamental stages are further classified into sub-stages which specify the precise biological, clinical or pathological prognostic factors in a particular stage (Odicino *et al*., 2008, p. 205).

2.5. Early and late stage cervical cancer

The most significant aspect used to determine the survival of cancer patients is the stage of disease at the time of diagnosis, so that differences in stage distribution of tumours among populations being evaluated are of concern (IARC, 2005). Information on survival provides indictors that are useful in the monitoring of cancer control activities. However, survival data should not be considered on its own as it does not provide adequate information on the efficacy of cancer control but must be regarded in the context of incidence and mortality data. Furthermore, studies on survival are carried out in order to assess the efficacy of cancer treatment and the availability and accessibility of high quality treatment which greatly influences patient survival (World Health Organization, 2010).

Early stage disease for cervical cancer includes patients diagnosed with stage IA1, IA2, IB1 and IIA. Stage IA1 diagnosis is by cone biopsy and the prognosis for these patients is outstanding with low risk (approximately 1%) for lymph node metastasis, recurrence and death. While the prognosis of patients with stage IA2 is also excellent, patients are faced with a greater likelihood of lymph node metastasis and treatment failure (Takeshima *et al*., 2000). Retrospective studies have put forward radical hysterectomy and pelvic radiation therapy as effective treatment options for stage IB1 cervical cancer. The age of the patient, concomitant medical issues (including obesity) and physician bias influence primary treatment options. Prospective studies that aimed to compare surgery with radiotherapy established the five year survival rate for

stage IB1 patients to be approximately 91% for surgery and 87% for radiotherapy (Peters *et al*., 2000). Differences in the anticipated survival rates in women with stage IB cervical cancer have been demonstrated. This is mainly due to the fact that increases in tumour size results in a subsequent risk in treatment failure. Consequently, stage IB2 patients require radiotherapy followed by extrafascial hysterectomy, radiotherapy plus concurrent chemotherapy, and neoadjuvant chemotherapy accompanied by radical pelvic surgery (Rocconi *et al*., 2005). Post treatment surveillance using Pap smears should follow for any early stage cervical disease. This should be done annually after two normal Pap smear results at four and ten month intervals.

Patients with invasive cervical carcinoma are those that are diagnosed with stage IIB, IIIA, IIIB, IVA and IVB disease (Pearcey *et al*., 2002). The five year survival rates for stage IIB, IIIB and IVA are roughly 66%, 42% and 22% respectively. Concurrent chemo-radiotherapy should be regarded as the standard treatment option for FIGO stage IIB and higher, in addition to nearly all stage IB2 patients in order to optimise local control and survival (Quinn *et al*., 2006).

2.6. Demographic and Socioeconomic Factors Influencing Stage at Diagnosis

2.6.1. Age specific Incidence of Cervical Cancer

The incidence of cervical cancer in developed countries displays an atypical profile with increased rates observed between the ages of twenty five and thirty years which subsequently level off after the ages of forty five to fifty years. On the other hand, data from cancer registries in developing countries have established that, there is a linear relationship between age and cervical cancer where screening services are lacking. Thus, the availability of screening services in developed countries may to

some extent elucidate the pattern observed (Bosch and de Sanjosé, 2003). The prevalence of HPV also differs worldwide among various age groups. In that, in developed countries, the prevalence of HPV is higher in women between the ages of twenty five and thirty years than in older women. Whereas, in developing countries, middle aged women have nearly as many HPV infections as younger women which can be attributed to differences in age specific sexual behaviour in women and their partners (World Health Organization, 2009).

Epidemiologic studies carried out in India by Paul, Tiwary and Choudhury (2011) demonstrated a strong association between age at marriage and the odds of developing carcinoma of the cervix. Out of the total number of cases in the study, 92% of them were found to have been married before the age of 20 years. An analogous correlation of increased risk of cervical carcinoma was observed among women who got children at an early age as well as those who had multiple child births. Those who became pregnant between the ages of 16 to 18 years were found to develop carcinoma of the cervix thus, the "high risk" group were considered as those with their first pregnancy age of up to 23 years.

A study carried out in Sudan found that, younger women were more likely to be diagnosed at an early stage of cervical cancer than older women. Accordingly, women aged fifty five years and older comprised approximately 46% of the advanced (stages III and IV) cervical cancer cases. The probable cause would be that most women in their post-menopausal years fail to seek gynaecological services especially women residing in rural areas where health care services are not available. Lack of awareness of cervical cancer could also contribute to diagnosis at a late stage (Ibrahim *et al*., 2011, p. 387).

In a majority of epithelial cancers, risk is enhanced as a power of age with the exception of cervical cancer where risk increases until about the age of menopause and subsequently declines. Thus, the underlying age pattern of cervical cancer may be attributed to the natural history of HPV infection and its associated carcinogenic mechanisms (Bray *et al*., 2005).

2.6.2. Type of Marital Union and Parity

A study by Castellsagué *et al*., (2002) found that, for a given woman, the risk of developing cervical cancer is contingent on the sexual behaviour of her partner as well as on her own sexual behaviour. Also, populations in which female monogamy is predominant, an increase in the transmission and maintenance of HPV infections occurs mainly through the populace of female sex workers. In polygamous marriages, the risk increases two fold and is further amplified with multiple wives. Besides prostitution, polygamy, history of other sexually transmitted infections (STIs), and lack of male circumcision are factors associated with the role men play in contributing to the high prevalence of HPV infection in Sub Saharan Africa (Bayo *et al*., 2002). The International Agency for Research on Cancer (IARC, 2005) demonstrated that, women with HPV infection who recounted having had seven or more full term pregnancies were four times more likely to develop cervical cancer compared to nulliparous women with HPV infection. Similarly, women who recounted having seven or more full term pregnancies were two times more likely to develop cervical cancer compared to HPV infected women who recounted having had one or two full term pregnancies (Muñoz *et al*., 2002).

2.6.3. Economic Factors and Level of Education

Health inequalities arise when various groups of individuals in the populace fail to benefit from a particular health status as those in other groups. These inequalities are quantified using health statistics such as, incidence (the number of new cases of disease or injury), survival (the proportion of individuals who pull through following diagnosis of disease) and mortality rates (the frequency of occurrence of death) (Taylor, 2007; Centers for Disease Control and Prevention (U.S.) Career Development Division, 2006). Health inequalities come about when health statistics differ amongst different groups of individuals with factors such as ethnicity, race, income, education, biological, environmental and behavioural elements contributing to the disparities (Ward *et al*., 2004). Eliminating cancer disparities in practice would therefore require a decrease in mortality and incidence rates and a subsequent increase in survival rates amongst individuals with low socioeconomic status to levels analogous to those in the general populace (Wilkinson *et al*., 2002).

Experiential differences occur along the entire cancer care continuum that encompasses primary prevention methods, diagnosis, treatment and follow up amenities. The aggregate cost of cancer health disparities to the patient, employer, kin, providers and the society needs to be evaluated so as to aid in the advancement of strategies for eliminating such disparities. According to Freeman (2004), besides the aspects pertaining to the healthcare delivery system that contribute to disparities, other factors external to the system such as gender, geographic location, ethnicity, race and socioeconomic status may be responsible.

Low socioeconomic status (SES), social injustice and culture are thought to be the three major determinants of cancer disparities. These determinants are essential in determining an individual's outcome measure. Braveman *et al*., (2005) established

that, SES is a construct that comprises of aspects such as, an individual's social standing in society and availability of resources such as education and income. Consequently, low SES has been found to enhance health disparities in excess of other factors as it is associated with insufficient resources and information, inferior living conditions and risk promoting lifestyle (Freeman, 2004). Also, underutilization of screening services and late stage at diagnosis of cancers has been associated with individuals residing in low SES regions. Therefore, SES may serve as an indicator of aspects such as access to healthcare facilities as well as literacy levels (Schwartz *et al*., 2003). Agurto, (2001) established that, it is often challenging for a woman to access screening services if she is physically fit, as she must talk her partner into giving her money for transport when she is not noticeably unwell. Therefore, a major factor influencing a woman's assessment on whether to obtain cervical cancer prevention services is her spouse's emotive and if necessary financial assistance.

2.7. Access to Healthcare Facilities

2.7.1. Health Insurance and Out of Pocket Expenses

In the United States, reduced healthcare utilisation is correlated with low SES even amongst individuals with health insurance. Low SES is further correlated with women obtaining fewer Papanicolaou tests, as well as poor quality ambulatory and hospital care services (Fiscella, Franks, Gold, and Clancy, 2000). Ferrante *et al*., (2000, p. 442) found that medically uninsured women were more likely to be screened for cancer infrequently and are often diagnosed with late stage cervical cancer unlike women insured under health maintenance organizations. Hiatt *et al*., (2001) further demonstrated that, cancer screening is undoubtedly an indicator of the availability of private health insurance and the regular uptake of medical services. It has been established that, the main cause for lack of insurance among individuals in

employment may be due to employers failing to offer health insurance benefits. Individuals working in small companies, those who are self-employed, part time workers and low wage workers are most unlikely to benefit from employer based health insurance (Clemens-Cope and Garrett, 2008).

Equitable access to healthcare services is hampered by the presence of user fees as well as by insufficient healthcare insurance with various households being unable to procure even the most rudimentary medical care leave alone, the added costs related to cervical cancer treatment (Castro-Leal, Dayton, Demery and Mehra, 2000). Similarly, cancer patients with health insurance incur additional treatment costs that are not covered by their insurance resulting in severe economic adversities. Some patients are therefore compelled to choose between other basic essentials and healthcare needs thereby resulting in adverse health outcomes (Smith, Cokkinides and Eyre, 2005). In addition to out of pocket expenses and the opportunity costs resulting from lost hours of productive work, individuals from rural areas are forced to travel lengthy distances for healthcare services causing them to use up scarce personal resources, thereby imposing a huge burden on the underprivileged (McIntyre, Thiede, Dahlgren and Whitehead, 2006).

Studies by Ward *et al.*, (2008) have shown that, insurance and cost related impediments to good quality cancer early detection, prevention and treatment services are increasing as a result of diminishing employer funded health insurance, upsurges in health insurance premiums and deductibles and soaring medical care costs. Moreover, a study carried out in Zimbabwe showed that, the likelihood of obtaining cancer screening services was greater in women who were economically self-reliant than in those who relied on their husbands or relatives for financial support (Mupepi, Sampselle and Johnson, 2011).

2.7.2. Availability of Healthcare Services

Healthcare systems in developing countries are more prejudiced towards curative services over preventive care in reaction to apparent demand. Additionally, health sector reforms aimed at cost recovery in these countries are biased towards curative care with the exception of immunisation and family planning services. Conversely, the existing preventive services that are available are mainly focused on pregnant, breastfeeding women and children under five (Tsu and Levin, 2008). Therefore, access to good quality healthcare services such as Pap smear screening services among marginalized and rural populations is often compromised resulting in late stage disease at the time of diagnosis (Garner, 2003). For most women residing in areas where access to healthcare services is minimal, there is need to factor in the location of health facilities as the use of these amenities is largely dependent on the distance to be covered. Geographic inaccessibility continues to be a major hurdle to healthcare services in most resource limited settings as a substantial number of women at risk of cervical cancer may be situated in areas where no treatment exists (Agurto, 2001). Furthermore, Bingham *et al*., (2003) found that, regional coverage rates were greater where healthcare services were situated in major community centres or where mobile campaigns availed services to women.

Farley *et al*., (2001) demonstrated that, Pap smear screening rates among African Americans in certain regions is high. However, a majority of the populace is diagnosed with late stage disease possibly due to poor follow up systems for abnormal Pap smears as well as inconsistencies in Pap smear results interpretations in several laboratories. Screening services in developing countries are primarily opportunistic typified by poor coverage, disproportionate screening among women with access to healthcare services and deficient quality control procedures (Arrossi, Paolino and

Sankaranarayanan, 2010). Screening services hardly ever gets to most at risk women specifically women aged between thirty five and sixty years particularly those residing in rural regions. Moreover, due to wanting healthcare infrastructure and scarcity of resources in sub-Saharan countries, it is difficult to implement the costly cytology based screening methods which are commonly used in developed countries. Similarly, another contributing factor is the limited number of cytoscreeners, cytopathologists and cytotechnicians some of whom may have inadequate training (Ntekim, 2012).

A multicentre cross sectional study carried out in east, central and southern African countries showed that, recurrent deficiencies in materials required for taking Pap smears, lack of policy guidelines, the lengthy distance and charges incurred when sending smears to processing centres as some of the causes listed for women not being screened frequently. In all the districts and in a majority of provincial hospitals surveyed, there was a palpable shortage of cytology technicians and histopathologists thereby necessitating the transfer of specimens to tertiary hospitals and private laboratories. The average time taken to obtain Pap smear results is four weeks and sometimes six to eight weeks (Chirenje *et al*., 2001).

An audit carried out at Kenyatta National Hospital in 2012 revealed that the average waiting time at the cancer treatment centre for new patients who needed to see a clinical specialist was sixty three days. Patients scheduled for radiotherapy treatment wait for close to four months to attend the initial session whereas those listed to receive brachytherapy (cervical cancer treatment) are forced to wait for five months. Patients awaiting chemotherapy take an average of one and a half months to receive treatment with only one out of two receiving treatment on time (Ouko, 2012).

2.8. Knowledge on Cervical Cancer and Stage at Diagnosis

Early detection of cancer is vital due to the documented relationship between stage at diagnosis and survival. Prevention amenities such as information on cervical cancer, screening services, vaccination against HPV, the causes of and treatment of pre-cancerous lesions are all vital in treating cervical cancer at its early stage (Thomson and Forman, 2009). Abridging cancer time of diagnosis is dependent on a patient presenting to a healthcare facility with probable cancer symptoms commonly referred to as patient delay, on primary healthcare providers reacting aptly to the symptoms, by either setting up additional investigations and or referring them to a specialist also known as doctor or practitioner delay and by minimising the interval between referral and diagnosis, referred to as hospital or system delay. However, patient delay is known to play a major role in most delays (Macleod, Mitchell, Burgess, Macdonald and Ramirez, 2009). Previous studies by Anorlu, Orakwue, Oyeneyin and Abudu (2004) have shown that only 4% of a total of 500 women receiving treatment at a maternal and child health clinic in Lagos, Nigeria were aware of cervical cancer. Similarly, in another study by Anorlu, Banjo, Odoemelun, Eghale and Abudu (2000) it was found that, out of 139 patients with advanced cervical cancer, 82% had never heard of cervical cancer with a majority of them assuming that the symptoms were as a result of a continuation of their menses, genital infections and irregular menses. Lack of adequate knowledge on cervical cancer is not only limited to patients, healthcare workers may also be ill informed about the disease. Women presenting with late stage disease in Nigeria cited referral delays by healthcare practitioners as a cause as it took them approximately nine to twelve months to obtain a diagnosis and to be referred to a tertiary hospital for specialised treatment (Anorlu *et al*., 2004).

In Ghana, a study carried out to establish the knowledge, beliefs and attitudes about cervical cancer and screening demonstrated that the level of awareness about screening was commendable, although knowledge about risk factors and screening interludes was minimal. The association between sex and cervical cancer for example was known, on the other hand, their understanding of other risk factors such as their partner's previous sexual experiences, smoking, diet, and family history was unknown to them. Also, the relationship between HPV and cervical cancer was not known. Conversely, it was also found that, women were unable to differentiate the types of cancer affecting women's reproductive organs and were therefore unable to recognize that cervical cancer is a preventable disease (Abotchie and Shokar, 2009). Therefore, in addition to educating women on the importance of screening for cervical cancer, there is need to inform them about the causal link between HPV and cervical cancer as well as other risk factors.

2.8.1. Early Sexual Onset

The risk of invasive cervical cancer is further increased among individuals who have sexual intercourse at an early age (Smith *et al*., 2003). Similarly the number of lifetime sexual partners increases the risk of developing invasive cervical cancer. Thus, individuals who have had six or more sexual partners are twice over more likely to develop cervical cancer than individuals who have had only one sexual partner.

2.8.2. Tobacco Smoking

The positive correlation between smoking and cervical cancer incidence and other tobacco related cancers was first hypothesized by Winkelstein (1977). Similarly, other studies such as the IARC multicentre pooled analysis of ten studies on invasive cervical cancer by Plummer *et al*., (2003), have found that smoking is a risk factor for

the advancement of HPV infection to cervical cancer. This study was however limited to HPV positive women as HPV is the necessary cause for cervical cancer. The presence of tobacco in vaginal and endometrial cells of women smokers' presented no noteworthy variation in risk in participants who were either HPV positive or negative. Other studies by Hildesheim *et al*., (2001) looking into the effect of smoking among HPV positive cases and controls observed a dose response relationship. After adjusting for confounding factors such as the number of lifetime sexual partners, high parity and age at first sexual intercourse the association between invasive cervical cancer and smoking is not altered considerably. Therefore, smoking is not likely to represent an alternative indicator for a woman's sexual behaviour. In developing countries, smoking among women is uncommon thus, focus on the relationship between smoking and cervical cancer should be in populaces where smoking among women is more frequent (Plummer *et al*., 2003).

2.8.3. Human Papillomavirus (HPV) Infection

The level of awareness of HPV infection has risen sharply over time but knowledge on the link between HPV and cervical cancer remains low. Studies carried out in the early nineties on HPV knowledge among women attending a south eastern university in the U.S found that only 13% had ever heard of HPV and only 8% of them recognised the association with cervical cancer. Furthermore, a population based survey carried out in the U.S on women aged between 18 and 65 years found that only 28% had heard of HPV and among those only 41% of them were familiar with the association of cervical cancer. Given that HPV DNA testing was only recommended for primary cervical cancer screening in the U.S in 2002 to 2003, the low levels of knowledge are not surprising (Holcomb, Bailey, Crawford and Ruffin, 2004).

Sexually active women are most likely to become infected with HPV at some point in their lifetime. The prevalence of HPV infection has been shown to decline markedly with age, with a higher prevalence in women shortly after sexual debut, compared to women aged forty five years or older. In women aged thirty or older, the prevalence is rather variable which may be related to the cervical cancer risk in the populace (Molano *et al*., 2002). However, most women do not exhibit symptoms and the infection resolves spontaneously in a few months. Conversely, in some women, re-infection may occur causing the virus to persist in the cervix. Thus, the risk of developing cervical lesions is amplified in women with persistent HPV infections (Bosch *et al*., 2008). In Africa, several factors have been found to increase the rate of infection and to advance the oncogenic effect of the HPV virus which is particularly widespread (Parikh, Brennan and Boffetta, 2003). These factors include marriage at an early age, high parity and polygamous marriages.

2.8.4. Infectious Agents other than HPV

Case control studies by De Sanjose *et al*., (1994) have demonstrated an association between cervical cancer risk with herpes simplex virus 2 (HSV-2) through serological studies, which confirmed a higher occurrence of antibodies to HSV-2 among cases of cervical neoplasia than in controls. Antibodies to HSV were also found to be associated with a moderate surge in risk of cervical cancer in women with HPV infection. Smith *et al*., (2002a) further demonstrated that while infection with HSV-2 may work in tandem with HPV infection to augment the risk of invasive cervical cancer, the influence of HSV-2 virus on squamous invasive cervical cancer is modest compared to the strong impact of HPV infection on invasive cervical cancer risk. Infection with Chlamydia trachomatis is similarly associated with an increased risk of squamous cell carcinoma as is HSV-2. Persistent HPV infection in women may be

associated with co-infection with C. trachomatis which may lead to an increased risk in clinical complications of HPV (Koskela *et al*., 2000). Smith *et al*., (2002b) demonstrated that, among women with HPV infection, there was a twofold increased risk of squamous invasive cervical cancer in those women who were sero-positive for C. trachomatis. A dose response effect was thus observed, that was due to increasing squamous invasive cervical cancer risk that was paralleled with increasing C. trachomatis titres.

The association between HIV and HPV infection and between HIV infection and cervical intraepithelial neoplasia has been systematically demonstrated. In HIV positive women, HPV infection is more likely to persist and infection with multiple HPV subtypes is also likely than in women who are HIV negative (IARC, 2007). Countries with routine cervical cancer screening programs have reduced incidence and associated mortality rates despite the fact that cervical cancer is considered to be an acquired immunodeficiency syndrome defining illness. Nevertheless, the prevalence of cervical intraepithelial neoplasia (CIN), the precursor lesions of cervical cancer are high in these countries.

The low cervical cancer rates can be explained by the rigorous screening programs for CIN in HIV positive women and the extended transition time from CIN to cervical cancer. In developing countries, the relationship between cervical cancer and HIV is unapparent probably due to a greater endemic rate of cervical cancer in the populace, with mortality cases arising from HIV related issues prior to the progression of cancer (Strickler *et al*., 2005).

2.8.5. Hormonal Contraceptives

Endogenous hormonal factors such as high parity and exogenous factors such as hormonal contraceptives are cofactors that play a role in the progression of cervical

adenocarcinoma (Castellsagué *et al*., 2006). The association between hormonal cofactors and the risk of squamous cell carcinoma has been observed. However, the evidence for adenocarcinomas has been scarce (Hildesheim *et al*., 2001). Castellsagué *et al*., (2006) provided further evidence that showed an increased risk of developing cervical adenocarcinoma in women with HPV infection who used hormonal contraceptives for extended periods of time. The use of oral contraceptives is correlated with risky sexual behaviour that conversely increases the risk of exposure to HPV infections that cause cervical carcinomas (Madeleine *et al*., 2001). Meta-analysis studies on hormonal contraceptives as a risk factor for cervical cancer demonstrated that with increasing use of oral contraceptives, the risk of invasive cervical cancer subsequently increases with an approximated twofold increased risk in women who have used it for 10 years or more compared those who have never used them (Munoz *et al*., 2006).

2.9. Knowledge gap

In the African context, the concept of cancer is peculiar which is evidenced by minimal preventive actions and defunct treatment programs. Delays in diagnosis stem from low levels of cervical cancer awareness in women and healthcare providers, cultural practices and constraints in access to healthcare services resulting in a majority of women being diagnosed at late or end stage disease. The most significant prognostic factor for cervical cancer is early detection and determining the extent to which the cancer has spread. Studies reviewed have shown that women who submit to annual pelvic examinations and Pap smears have a greater propensity of any irregularities or cancerous tissue being detected in the early stages. Also, the lack of or non-existent screening programs in developing countries is a major contributing factor to the advanced disease in women. Women from disadvantaged communities

tend to go without treatment due to financial constraints. Out of pocket costs and the indirect costs arising from the loss of productive hours from work due to ill health inflict a greater burden on women from disadvantaged backgrounds. Furthermore, women from rural areas are compelled to use up scarce resources by travelling protracted distances to seek healthcare services. Some women may also be unaware of cervical cancer, its risk factors and that its precursor lesions can be detected through screening procedures thus resulting in late stage disease at diagnosis. Conversely, women who are aware of cancer symptoms tend to pay more attention to symptoms and in turn are less likely to delay seeking help in the event that symptoms develop.

Most research has been centred on barriers to prevention and treatment methods and the level of awareness in women. Moreover, extensive literature exists on the influence of co-morbidity and socio-demographic factors that contribute to the likelihood of facing delays in the diagnosis of cervical cancer. This likelihood is further augmented by area of residence that is rural or urban, availability of health insurance and level of awareness in women. However, there is scanty information and no available detailed research which has been conducted on the factors that influence stage at diagnosis of cervical cancer in women receiving treatment at Kenyatta National Hospital.

2.10. Conceptual Framework

The following framework was used in this study pertaining to the relationship between the magnitude of women with early stage disease, socio-demographic factors influencing stage at diagnosis, access to healthcare services and knowledge on cervical cancer and stage at diagnosis.

Independent variables

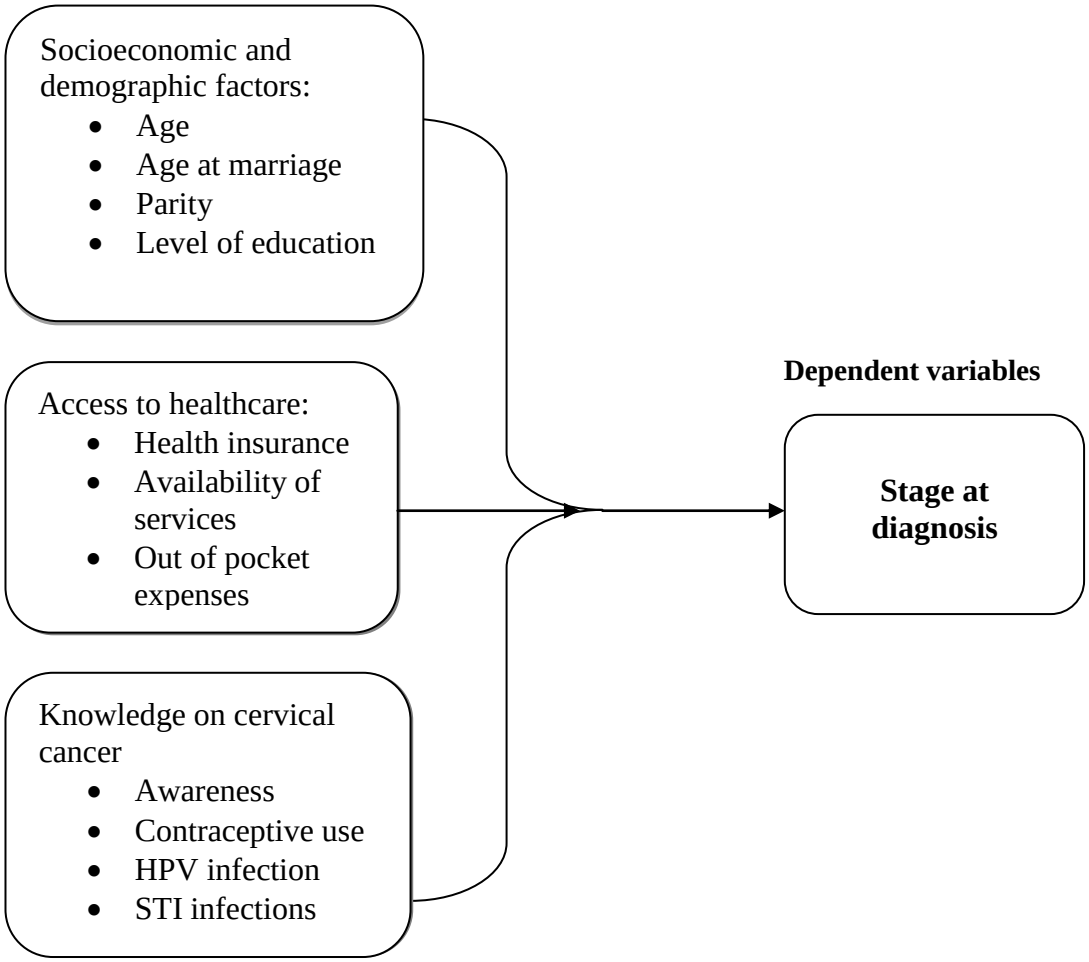

Figure 1: Conceptual framework

Stages in cancer are used as contrived subdivisions of the progressing disease that is based on the anatomical extent of a tumour. Thus, in order to optimally manage a cancer patient, the disease extent at the time of diagnosis is crucial to the outcome.

Magnitude of women with early stage disease

The precise incidence rate of cervical cancer in most African countries is unknown due to marked under reporting of cases. A number of the estimated figures in literature are hospital based which represents a small portion of women as there are few functional cancer registries in addition to poor documentation. In developing countries, screening for cervical cancer is opportunistic due to low coverage and the

absence of policies. Hence the need to develop guidelines aimed at reducing the number of women diagnosed with late stage disease.

Socio-demographic factors

Disparities in disease rates exist in developed and developing countries due to varying socio-demographic factors such as parity, education levels, age distribution of disease and type of marital union. Women in developing countries are at greater odds of suffering from cervical cancer at a younger age than women in developed countries. This could be attributed to early sexual debut, high parity rates and women in polygamous marriages which place them at greater risk of HPV infection. Consequently, health disparities are further exacerbated by low socioeconomic status as it is associated with insufficient resources and information, inferior living conditions and risk promoting lifestyles.

Access to healthcare services

The presence of user fees as well as lack of healthcare insurance hinders the equitable access to healthcare services. Majority of households are usually unable to obtain the most rudimentary medical care leave alone the additional expenses associated with cervical cancer treatment. Women from rural areas may be obliged to travel long distances in order to obtain healthcare services causing them to use up scarce personal resources. Improvements in healthcare infrastructure and resources including healthcare providers can greatly improve health outcomes in women with cervical cancer.

Knowledge on cervical cancer

Among the reasons for high cervical cancer incidence and mortality rates in African countries is the lack of awareness of cervical cancer and risk factors among the populace, healthcare providers as well as policy makers. Cervical cancer awareness programs have thus been shown to improve the knowledge of cervical cancer and increase acceptability of preventive measures against cervical cancer in women.

CHAPTER THREE: METHODOLOGY

3.1. Introduction

The aim of this chapter is to describe the methods used in the collection and analysis of the data. The chapter includes a description of the study design, the site of the study and the study population. It includes a description of the sampling method and the actual process of data collection as well as the instruments to be used for data collection and data analysis procedures. A description of the pilot study is included. Ethical clearance of the study is also discussed in this chapter.

3.2. Study Setting

The study was carried out in KNH, a state corporation mandated to be a regional centre of excellence in the provision of innovative and specialized healthcare. The hospital is located in Nairobi at the upper hill community area which is about 5 km from the Central Business District (Muthike, 2013). It is a national referral hospital and primary teaching hospital for the School of Medicine, University of Nairobi (UoN) with a bed capacity of 2000 beds (Irimu *et al*., 2014). Radiotherapy, neurosurgery, renal dialysis and kidney transplant surgeries, heart surgery, plastic and reconstructive surgery, orthopaedic surgery and management of burns are among the specialised healthcare services offered by the hospital (Ouko, 2012). The hospital's specialised services pertinent in the management of cancer include palliative care, medical oncology and haematology, surgical oncology, radiotherapy and pathology. The hospital receives approximately 89,000 inpatient and 500,000 outpatients annually. The cancer treatment centre an outpatient clinic receives between 2,000 and 3,000 new patients annually and approximately 70 to 80% of these patients are diagnosed at a late stage (Ouko, 2012). In addition, the hospital provides basic healthcare services to the populace of Nairobi and its environs. The cancer treatment

centre also receives patients from the East African region including Uganda, Ethiopia, Rwanda, Tanzania and Burundi (Muthike, 2013). However, it lacks a designated gynaecologic oncology unit (Cheserem, *et al*., 2013). The study was based at the at the cancer treatment centre (CTC), radiotherapy department and in the obstetrics and gynaecology department.

3.3. Target Population

The study population consisted of cervical cancer patients above the age of 18 years with a histological diagnosis of cancer receiving treatment at the cancer treatment centre, radiotherapy department and the obstetrics and gynaecology department. These patients may have obtained their diagnosis at either KNH or in other hospitals and referred to the hospital for further specialized treatment. Clinical records of patients with cervical cancer were reviewed to determine the referral cases as well as the treatment phase and the stage at diagnosis of cervical cancer to the clinic. The standard treatment options for patients presenting with cervical cancer are radiation therapy, surgery and adjuvant chemotherapy. Patients at KNH usually go through any of the three treatment phases during their scheduled visits including treatment preparations (pre-radiation assessment which involves complete physical examination and clinical staging of the disease among others) at the obstetrics and gynaecology department, treatment phase and post treatment follow ups at the radiotherapy department. In any given week, there are patients slated to attend the clinic for any of the three treatment phases (Maranga *et al*., 2013). The data was therefore collected from patients undergoing treatment preparations and post treatment follow ups at the clinics.

3.4. Research Design

A cross-sectional study design was used which according to Varkevisser, Pathmanathan and Brownlee (2003) is a survey method ideal for describing and quantifying the distribution of various variables in a study population at a single point in time. This design is appropriate as it can bring to light associations between variables in a given population. Semi structured questionnaires were used to gather information on demographic and socioeconomic factors, knowledge on risk factors and on access to healthcare services whereas information on stage at diagnosis was obtained from files of patients receiving treatment at the radiotherapy and obstetrics departments.

3.5. Sample Size Determination

Due to scanty data on the proportion of women with early stage cervical cancer in Kenya, it was assumed that the population proportion was 50%. Thus, the sample size that was required to estimate the true proportion of patients with early and late stage cervical cancer attending KNH, with a desired 95% confidence interval and a precision of 0.05, was computed using the following formula (Mugenda and Mugenda, 1999).

$$n = \frac{Z^2 (PQ)}{d^2}$$

Where:

n = desired sample size.

z = the standard normal deviate at the required confidence level usually 1.96 which corresponds to a 95% confidence interval.

p = the proportion in the target population estimated to have a characteristic being measured. (If there is no reasonable estimate then 50% is used).

q = 1 – p = the population without the desired characteristic.

d = the level of statistical significance usually set at 0.05

Therefore, p = 50% (0.5); Z = 1.96; d = (0.05); q = 0.5

Thus, the sample size is given by

$$n = \frac{(1.96 \times 1.96) \times 0.5 \times 0.5}{0.05 \times 0.05}$$

n = 384.16

Thus the total sample size for this study was 385.

3.6. Sampling Procedure

Copies of the KNH/UON-ERC (Ref No: KNH-ERC/A/142) and IREC (Ref No: IREC/2014/254) approval letters were presented to the head nurses at the departments of radiotherapy and obstetrics and gynaecology before data collection begun and additional copies were presented upon request. Physicians in both departments were also informed about the study. The nurses provided a separate room where the patients were interviewed.

New patients and patients on post treatment follow up are required to see an oncologist at the radiotherapy and obstetrics and gynaecology departments prior to receiving treatment. Those scheduled to receive chemotherapy were seen on Tuesday and Thursday whereas, those requiring radiotherapy were seen from Monday to Thursday. Approximately 50 to 60 cancer patients were seen each day from Monday to Thursday. Similarly, approximately 20 to 30 referral patients with gynaecological cancers from other hospitals are first seen at the obstetrics and gynaecology clinic every Friday. Clinical staging of cervical cancer and physical examinations are done

on patients attending the obstetrics and gynaecology clinic before they can receive treatment.

Patient files for all cancer patients scheduled to attend the clinics were made available from the registry on each day. The principal investigator and research assistant would work with the nurses to identify the cervical cancer patient files. The patient names and staging information were then recorded in a document checklist however the names were not indicated on the questionnaires. The patient names allowed for the easy identification of cervical cancer patients from the waiting area as well as identification of duplicates as some patients were on multiple treatment courses. The stages CIN I, II, III, IA, IA1, IA2, IB, IB1, IB2 and IIA were grouped as early and IIB, IIIA, IIIB, IVA and IVB as advanced based on the International Federation of Gynaecology and Obstetrics (FIGO) staging system.

Convenience sampling was used to recruit patients who had been identified from the patient files into the study. Patients who were eligible were identified on the clinic days and approached for consent between May and July 2015. Those willing to participate signed an informed consent form (see appendix 2). Patients were interviewed before or after being reviewed by the oncologist. On Tuesdays and Thursdays, the research assistant and principal investigator would work separately and interview patients on either chemotherapy or radiotherapy treatment. The patients were sampled during these doctor visits because they were either too weak or in too much pain to be interviewed while receiving treatment and only authorised personnel were allowed into the treatment areas during treatment sessions.

The questionnaire was administered by the principal investigator or by a trained research assistant. The research assistant was trained and a pilot study was carried out thereafter to ensure standardisation of the work. A total of ten cervical cancer patients

from the radiotherapy and obstetrics and gynaecology department were involved in the pilot study. Subsequently, the questionnaires were reviewed and adjustments made. A question that sought to determine if the women were in a monogamous or polygamous marriage was deleted as it made the patients uncomfortable. Some of the wording was changed such as inter-menstrual vaginal bleeding, age at menarche, age at first coitus also, the order of some of the questions was changed.

A total of 468 patients were enrolled. Those excluded included; 24 patients who refused to participate, 20 patients who were critically ill and 39 duplicates. Of the 385 eligible patients for this study, 24 were excluded from analysis. The response rate in this study was therefore 93.7% (see figure 2). The main reason why 24 questionnaires were missing staging information was; the researcher failed to note down the staging information in the questionnaires. This may have been available in the document checklist but because the questionnaires did not have the patient names it was difficult to match the questionnaire with the information in the checklist.

3.6.1. Inclusion Criteria

This study included women aged 18 years and above, who had a histological diagnosis of cervical cancer and staging information (Stage I-IV) as defined by the International Federation of Gynaecology and Obstetrics (FIGO) staging system, patients who had been informed about their cancer diagnosis, newly referred patients that is, those on pre-radiation assessment and those receiving radiotherapy and or chemotherapy treatment.

3.6.2. Exclusion Criteria

Patients who were critically ill thus unable to respond to questions, those in documented remission as they had no symptoms and those who were unwilling to take part in the study were excluded from this study.

3.6.3. Consort diagram showing the patient recruitment process

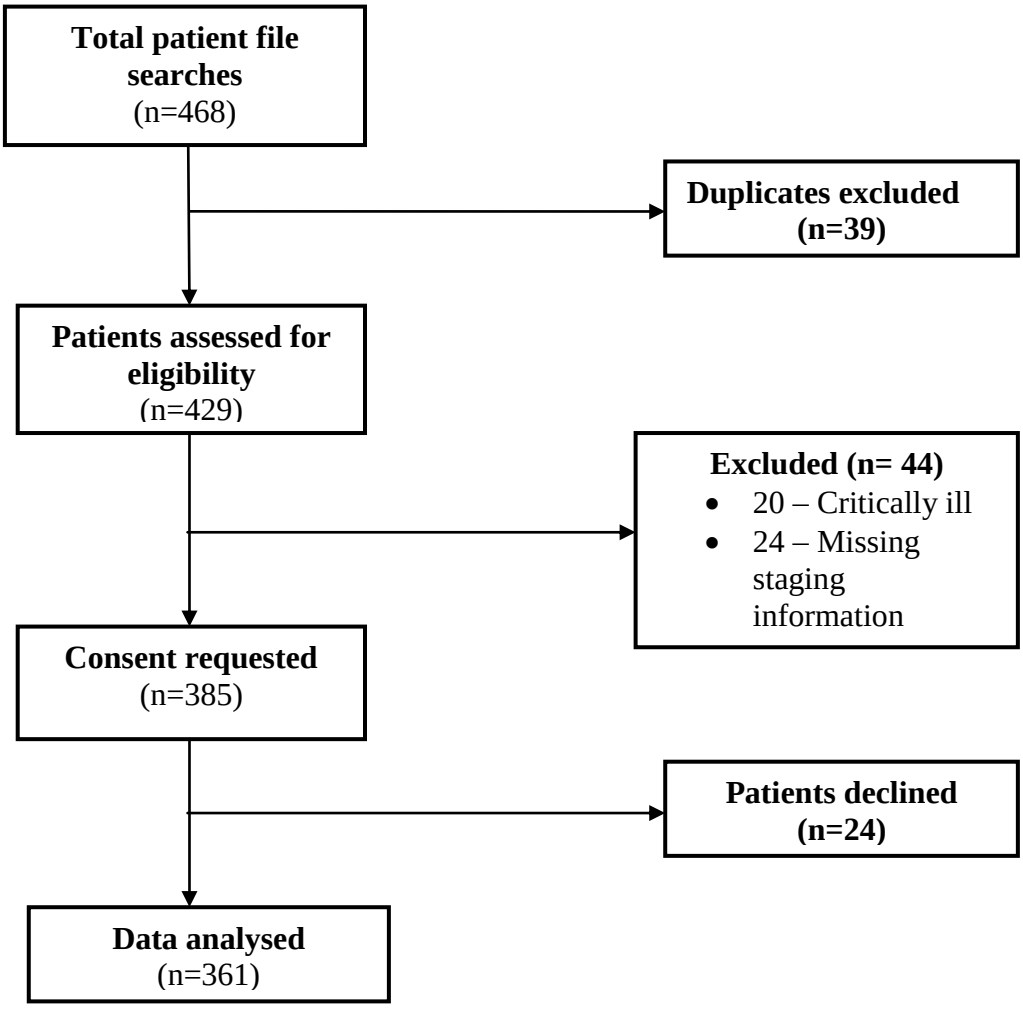

Figure 2: Consort diagram of patient recruitment

3.7. Data Collection Instruments

Information on stage at diagnosis was obtained from patient files and thereafter, personal interviews were carried out by the use of a semi-structured interviewer

administered questionnaire. The questionnaire was administered to the 385 respondents with the help of a research assistant who was identified and thoroughly briefed on the research objectives and trained on the data collection instrument. The use of a questionnaire allowed every respondent to get a similar assessing tool thereby resulting in standardized responses. A pilot study was carried out in order to ensure standardization of information to be obtained. For patients who do not understand English, a Kiswahili version of the questionnaire was available. A document review check list was also used to collect information on the enrolment and defaulter rate of the participants for triangulation purposes.

3.8. Delimitations of the Study

This study was carried out at the Kenyatta National Hospital cancer outpatient clinic, radiology department and the obstetrics and gynaecology department as it is among the few cancer treatment facilities in the country with affordable public cancer radiotherapy equipment and various medical specialties for cancer in Kenya.

3.9. Limitations of the Study

This study was limited by recall bias which may affect the validity and reliability of the information collected. It was also limited by self report data however this bias was minimal as behavioural factors were not mainly being assessed. Follow up of patients transferred from the cancer treatment centre to the obstetrics and gynaecologic ward for surgery was difficult given that the patients may have been discharged or opted out of surgery. As a result, the study mainly consisted of patients receiving treatment at the cancer treatment centre, radiotherapy department.

3.10. Assumptions of the study

It was assumed that the participants recruited gave honest responses. It is also assumed that they understood their prognosis and the stage of disease.

3.11. Validity and Reliability

A pilot study was carried out by administering ten questionnaires to respondents who were not among those selected for the study. The responses gathered were used to check for clarity in the questions and the necessary corrections were made. It also aided in determining the stability and consistency of the instrument in measuring the study concept.

3.12. Ethical Considerations

Approval to carry out research was sought from the Ethics and Research Committee at the Institutional Research and Ethics Committee at Moi University College of Health Sciences (MUCHS-IREC) (Ref No: IREC/2014/254) as well as from Kenyatta National Hospital/University of Nairobi (KNH/UON-ERC) (Ref No: KNH-ERC/A/142). Only patients who gave informed consent by filling out the form (in Appendix 2A) were recruited into the study and no patient was coerced into participating. Confidentiality was maintained by ensuring that no names were written on the questionnaires. Following completion of data collection and analysis, the results of the findings were used to compile a thesis which was then submitted to Moi University and to a peer review journal for publication. Furthermore, a report of the findings was forwarded to Kenyatta national hospital, University of Nairobi which will be made available to the participants. Moreover, the expected results may be used to inform public policy on the treatment and management of cervical cancer.

3.13. Data Analysis

Data from questionnaires was entered and cleaned in Microsoft Excel 2010 and analysed using Statistical Package for Social Sciences, ver. 16.0 (SPSS Inc., Chicago, Ill., USA) and. The main outcome variable, stage at diagnosis, was determined using the International Federation of Gynaecology and Obstetrics (FIGO) staging system. For these analyses, stage at diagnosis was grouped as early (CIN I, II, III, IA, IA1, IA2, IB, IB1, IB2 and IIA) or advanced (IIB, IIIA, IIIB, IVA and IVB). A confidence interval of 95% was used and a p-value of less than or equal to 0.05 was considered significant. Univariate analyses were carried out in order to describe the population under study through the use of descriptive statistics such as means, and proportions for the socioeconomic and demographic variables. Variables assessed as possible predictors of stage at diagnosis included age, age at marriage, age at first sexual intercourse, parity, marital status, education level, occupation, and income level. The relationship between independent variables and stage at diagnosis was assessed using the chi-square test, Wilcoxon ranksum test or Fisher's exact test as appropriate.

CHAPTER FOUR: RESULTS

4.1. Distribution of Cancer Stage at Diagnosis

Study participants were identified from the cancer treatment centre (CTC), radiotherapy department and the obstetrics and gynaecology department at Kenyatta national hospital between May and July 2015. Out of the 385 questionnaires administered, data from 361 participants was used in the analysis as 24 questionnaires did not have staging information. The proportion of women diagnosed with advanced stage cervical cancer was 72.6% while 27.4% were diagnosed with early stage cancer.

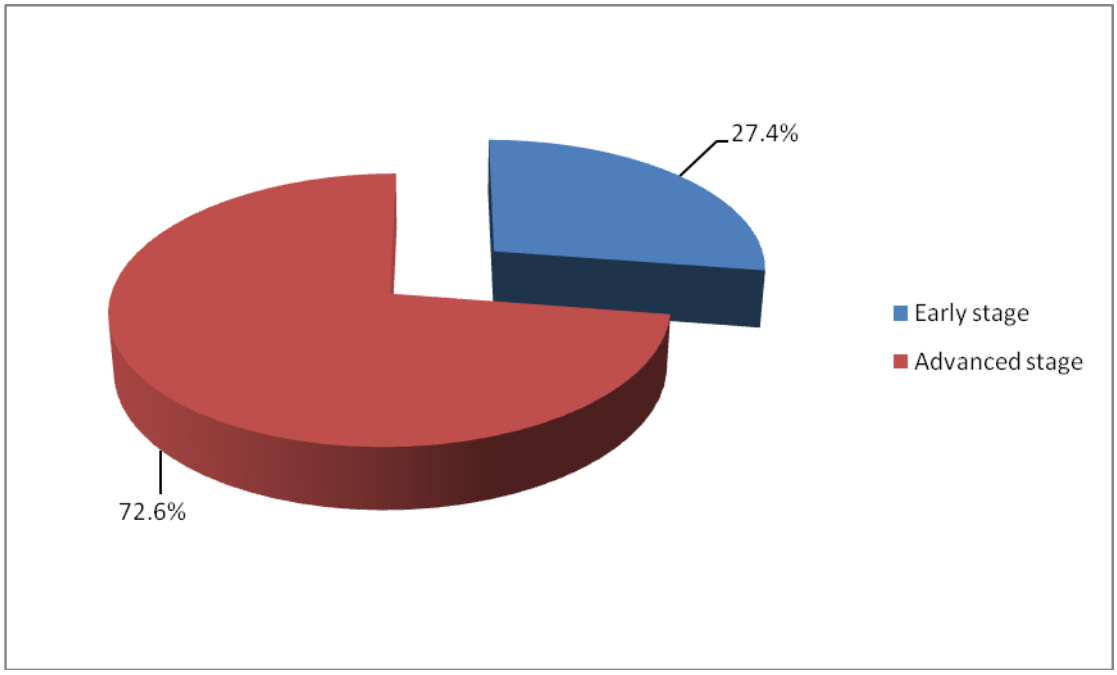

Figure 3: Stage at diagnosis of participants

4.2. Socio-demographic Characteristics of Participants

The mean age of participants was 49 years with 34.2% of the participants aged between 41 and 50 years while 21.4% were aged 40 years and below. Approximately 7% of the participants were married at the age of 15 and below, 48.4% were married between the ages of 16 and 20 years, 34.7% between the ages of 21 and 25 and only 10.2% were married at the age of 26 and above. Most of the women were married,

61.7% and about half of the women, 48.6% had between 4 and 7 children. About a third of the participants had attained secondary education 31.1% with 55% having attained primary education and only 0.6% had obtained a university degree. Out of the 221 participants who were married, 46.6% of their partners had attained secondary education, 42.1% primary education and only 0.5% of them had obtained a university degree. Majority of the participants were self-employed 65.7%, 19.1% were unemployed and 5.5% were permanently employed. The median monthly household income for the participants was Ksh 6,400 with a median range of Ksh 3,000 and 13,500.

Table 1: Socio-demographic characteristics of participants

Variable	No. of cases (n=361)	%
Age in years		
≤40	77	21.4
41-50	123	34.2
51-60	106	29.4
≥61	54	15
Age at marriage		
≤15yrs	21	6.7
16-20yrs	150	48.4
21-25 yrs	109	34.7
≥26yrs	32	10.2
Marital status		
Single	48	13.4
Married	221	61.7
Divorced	25	7
Widowed	64	17.9
Parity		
0-3	146	40.6
4-7	175	48.6
≥8	39	10.8
Education level		
No formal education	37	10.3
Primary education	198	55
Secondary education	112	31.1
Tertiary education	11	3.1
University education	2	0.6
Partner's education level		
No formal education	10	4.5
Primary education	93	42.1
Secondary education	103	46.6
Tertiary education	14	6.3
University education	1	0.5
Occupation		
Permanently employed	20	5.5
Casually employed (hairdresser/ house girl)	35	9.7
Unemployed (house wife/student)	69	19.1
Self-employed (farmer/business)	237	65.7
Monthly income		
HH income in Ksh. Median (IQR)	6400	3000-13500

4.3. Socio-demographic Differences in Stage at Diagnosis

There were observed differences in stage at diagnosis for women aged between 41 and 50 years, 42 (42.4%) for early stage compared to 81 (31%) with advanced stage cancer. Women aged 61 years and above were seen to be diagnosed with advanced stage cancer, 46 (17.6%) compared to 8 (8.1%) diagnosed with early stage cancer, however, without statistical significance (χ^2 =7.12, df=3, p=0.067). Twenty women (8.7%) married at 15 years and below were found have been diagnosed with advanced stage cancer compared to 1 (1.2%) with early stage cancer. Of the women who got married between the ages of 16 and 20, 111 (48.1%) were diagnosed with advanced stage cancer while 41 (49.4%) were diagnosed with early stage cancer. Twenty six (11.3%) women who got married aged 26 and above presented with advanced stage and 6 (7.2%) with early stage cancer. These differences were significance (χ^2 =7.87, df=3, p=0.049).

In women who had first had sex aged 15 and below, 15 (15.2%) had early stage cancer and 46 (17.6%) had advanced stage cancer. Of those who first had sex between the ages of 16 and 20, 62 (62.6%) had early stage cancer while 165 (63.2%) had advanced stage cancer. Twenty two (22.2%) women with early stage cancer and 50 (19.2%) with advanced stage cancer first had sex at the age of 21 years or above however, without statistical significance (χ^2 =7.148, df=3, p=0.067). Most of the women with less than 3 children were diagnosed with early stage cancer, 49 (49.2%) while, 97 (37.2%) were diagnosed with advanced stage cancer. Women who had between 4 and 7 children were seen to have been diagnosed with advanced stage cancer, 131 (50.2%) compared to 44 (44.4%) who were diagnosed with early stage cancer. Similarly, 33 (12.6%) women who had more than 8 children were diagnosed

with advanced disease compared to 6 (6.1%) who were diagnosed with early stage disease. These differences were significant (χ^2 =6.05, df=2, p=0.049).

One hundred and forty six (55.9%) women with primary education were diagnosed with advanced stage cancer compared to 52 (52.5%) diagnosed with early stage cancer. Women with no formal education showed slight differences in stage a diagnosis with 31 (11.9%) presenting with advanced stage cancer compared to women with early stage cancer, 6 (6%) but, without statistical significance (p=0.175). Among the married women whose partners had secondary level education, 70 (42.4%) were diagnosed with advanced stage cancer whereas 33 (58.9%) were diagnosed with early stage cancer. Twelve (7.3%) women whose partners had attained tertiary level education were diagnosed with advanced stage cancer compared to 2 (3.6%) with early stage cancer. There was no statistical difference in stage at presentation and partners' education level (p=0.088).

Only 9 (9.1%) of the women who were permanently employed were diagnosed with early stage cancer while 11 (4.2%) presented with advanced stage cancer. Twenty one (21.2%) of the unemployed women were diagnosed with early stage cancer compared to 48 (18.3%) diagnosed with late stage cancer. Among the self-employed women, 179 (68.3%) were diagnosed with advanced stage cancer compared to 58 (58.6%) diagnosed with early stage cancer. There was no statistical significance between stage at presentation and occupation (χ^2 =4.74, df=3, p=0.192). There was a noticeable difference in median household income in women with early stage cancer 8000, compared to 6000 in women who presented with late stage cancer, however without statistical significance (p=0.543).

Table 2: Socio-demographic differences in stage at diagnosis of participants

	Early Stage		Advanced Stage		
	Number (n=99)	**%**	**Number (n=262)**	**%**	**p value**
Age Category					
≤40yrs	21	21.2	56	21.5	
41-50yrs	42	42.4	81	31	0.067
51-60yrs	28	28.3	78	29.9	
≥61yrs	8	8.1	46	17.6	
Age at marriage					
≤15yrs	1	1.2	20	8.7	***0.049***
16-20yrs	41	49.4	111	48.1	
21-25yrs	35	42.2	74	32	
≥26yrs	6	7.2	26	11.3	
Age at first sexual intercourse					
≤15yrs	15	15.2	46	17.6	0.067
16-20yrs	62	62.6	165	63.2	
≥21yrs	22	22.2	50	19.2	
Parity					
≤3 children	49	49.5	97	37.2	***0.049***
4-7 children	44	44.4	131	50.2	
≥8 children	6	6.1	33	12.6	
Education Level					
No formal education	6	6.1	31	11.9	
Primary education	52	52.5	146	55.9	0.175
Secondary education	35	35.4	77	29.5	
Tertiary education	5	5.1	6	2.3	
University education	1	1	1	0.4	
Partner's Education Level					
No formal education	2	3.6	8	4.8	
Primary education	18	32.1	75	45.5	0.088
Secondary education	33	58.9	70	42.4	
Tertiary education	2	3.6	12	7.3	
University education	1	1.8	0	0	
Occupation					
Permanently employed	9	9.1	11	4.2	
Casually employed*	11	11.1	24	9.2	0.192
Unemployed†	21	21.2	48	18.3	
Self-employed	58	58.6	179	68.3	
Household Income Median (IQR)	8000	2000 - 15000	6000	3000 - 12000	0.543

*Casually employed (hair dresser/house girl)
†Unemployed (housewife/student)

4.4. The Relationship between Stage at Diagnosis and Access to Healthcare Facilities

Most of the women experienced more than one symptom. The most common symptom was vaginal discharge with 67 (72%) women with early stage and 207 (80.5%) women with advanced stage cancer having experienced it. Fifty three (57%) women with early stage and 126 (49%) with advanced stage cancer had experienced bleeding other than normal menstruation. Fifty four (58.1%) women with early stage and 177 (68.9%) with advanced stage cancer had experienced pelvic pain. Similarly, 51 (54.8%) women with early stage and 158 (61.5%) with advanced stage cancer had experienced lower backache. These differences were significant (p=0.002). This suggests that most women will experience one or more symptoms of cervical cancer. Therefore, knowledge of cervical cancer symptoms is important in order to influence health seeking behaviour.

Women who had experienced one or more symptoms of cervical cancer were asked what steps they took towards seeking treatment and two thirds of the women with early stage 62 (66.7%) and 153 (59.8%) with advanced stage cancer stated that they went to hospital immediately after observing their first symptoms, while 30 (32.3%) with early stage and 102 (39.8%) with advanced stage cancer stayed at home. These differences were however, not significant (p=0.244). The median duration of time it took for women to seek treatment after observing symptoms was between 2 and 10 months for women with early stage cancer and 2 and 12 months for women with advanced stage cancer but without statistical significance (p=0.91). The period of time taken for women with early and advanced stage cancer to seek treatment was almost the same implying that the level of awareness of symptoms was low. Of the women with early stage cancer 56 (57.7%) and 124 (47.9%) with advanced stage cancer had medication prescribed to them when they went to hospital, 50 (51.5%) with early

stage and 154 (59.5%) with advanced stage had a pelvic examination done and 32 (33%) with early stage and 100 (38.6%) with advanced stage cancer were given referral letters however without statistical significance (p=0.202). Referral of patients to tertiary hospitals was low for patients with early and advanced stage cancer suggesting that most patients were treated for the symptoms they presented with.

Four (80%) of the women with early stage cancer and 16 (80%) with advanced stage cancer cited lack of money as the reason for not honouring the referral to a tertiary hospital however, without statistical significance (p=0.884). Of the women who were not given referral letters when they were first seen at a health centre, 59 (89.4%) with early stage cancer and 135 (83.3%) with advanced stage cancer stated that they went to a number of dispensaries and private hospitals before being referred to KNH. Three (4.5%) with early stage disease and 15 (9.3%) with advanced stage disease cancer taken to KNH by their relatives who live in Nairobi. Four (6.1%) with early stage cancer and 8 (4.9%) with advanced stage cancer went to KNH without referral since their condition was deteriorating however, without statistical significance (p=0.253). This suggests that hospitals at the district or community level are not equipped with the human resources and or infrastructure needed to detect cervical cancer.

Table 3: The relationship between stage at diagnosis and access to healthcare facilities of participants

	Early Stage		Advanced Stage		
	Number (n=99)	**%**	**Number (n=262)**	**%**	**p value**
Symptoms experienced*					
Bleeding other than normal menstruation	53	57	126	49	
Vaginal discharge	67	72	207	80.5	
Pelvic pain	54	58.1	177	68.9	***0.002***
Postmenopausal bleeding	15	16.1	88	34.2	
Bleeding after sex	39	41.9	98	38.1	
Lower backache	51	54.8	158	61.5	
Steps taken after experiencing symptoms ‡					
Went to hospital/health centre	62	66.7	153	59.8	0.244
Attended to by a traditional healer	1	1.1	1	0.4	
Stayed at home	30	32.3	102	39.8	
Time taken to go to hospital after first symptoms in months (Median)	3	2.5 - 10	4	2 - 12	0.91
Measures taken at the hospital*					
Prescribed oral/injected medication	56	57.7	124	47.9	
Did a pelvic examination	50	51.5	154	59.5	0.202
Admitted you	21	21.6	46	17.8	
Gave a referral letter to a tertiary centre	32	33	100	38.6	
Other	2	2.1	2	0.8	
Reasons for late referral †					
I had no money	4	80	16	80	
Attended to by a traditional healer	1	20	0	0	0.884
The distance to the hospital was too far	0	0	1	5	
Other	0	0	3	15	
How did you get to KNH without a referral letter? †					
Went to a few more dispensaries/hospitals before being referred to KNH	59	89.4	135	83.3	
Taken to KNH by relatives living in Nairobi	3	4.5	15	9.3	0.253
Since my condition was deteriorating I decided to come straight to KNH without referral	4	6.1	8	4.9	
Other	0	0	4	2.5	

‡ *Numbers may not add up to total because of missing data.*

***** *Indicates a multiple response question numbers may not add up to total.*

† Indicates skipping patterns in the questionnaire, numbers may not add up to total.

4.5. Differences in Knowledge on Risk Factors for Cervical Cancer and Stage at Diagnosis

Of the women with advanced stage cancer, 145 (55.6%) and 62 (62.6%) with early stage cancer had heard of cervical cancer prior to their diagnosis while, 116 (44.4%) with advanced stage and 37 (37.4%) with early stage cancer had not heard of cervical cancer however, without statistical significance (χ^2 =1.468, df=1, p=0.226). This suggests that the women with advanced stage cancer may have heard of cervical cancer but they probably were not aware of the symptoms and risk factors that would enable them to obtain an early diagnosis. Eight (13.1%) of the women with early stage cancer and 5 (3.5%) with advanced stage cancer attributed the cause to human papillomavirus. Over ninety per cent of the women with advanced stage cancer, 136 (95.1%) and 52 (85.2%) with early stage cancer did not know what causes cervical cancer. These differences were statistically significant (p=0.036). This implies that knowledge on risk factors for cervical cancer was low in women with early and advanced stage cervical cancer. Among the women who had heard of cervical cancer, 15 (24.6%) with early stage and 43 (29.7%) with advanced stage cancer heard about it from neighbours, 28 (45.9%) with early stage and 62 (42.8%) with advanced stage had heard about it from the radio, whereas 32 (52.5%) with early stage and 87 (60%) had heard about it through health education but with no statistical significance (χ^2 =9.199, df=6, p=0.163). The women gave multiple responses on the source of cervical cancer information but public awareness on cervical cancer was minimal in women with early and advanced stage disease.

Over ninety per cent of women with early stage cancer 92 (93.9%) and 246 (93.9%) women with advanced stage cancer did not think that vaginal bleeding between periods was normal. Forty two (42.4%) women with early stage and 93 (35.8%)

women with advanced stage cancer thought that vaginal bleeding between periods was due to infection, 13 (13.1%) with early stage and 35 (13.5%) with advanced stage thought it was due to cancer and 43 (43.4%) with early stage and 127 (48.8%) with advanced stage cancer attributed it to other causes such as use of contraceptives. These differences were not statistically significant (χ^2 =5.288, df=7, p=0.625). While majority of the women did not think that vaginal bleeding was not normal, only 13% of women with advanced and early stage disease attributed it to cancer.

Ninety two (92.9%) of the women with early stage and 243 (93.5%) women with advanced stage thought it was not normal to bleed after having sex while 4 (4%) women with early stage and 8 (3.1%) with advanced stage thought it was normal but, without statistical significance (p=0.934). Of the women with early stage cancer, 48 (49%) and 107 (40.8%) with advanced stage cancer attributed the cause of bleeding after sex to infection. Eleven (11.2%) women with early stage cancer and 34 (13%) women with advanced stage thought it was due to cancer. Thirty (30.6%) women with advanced stage cancer and 103 (39.3%) women with advanced stage cancer attributed bleeding after sex to other causes however, there was no statistical significance (p=0.537). Knowledge on cervical cancer symptoms was low as very few women attributed bleeding after sex to cancer with most of the women associating it to infection.

Ninety seven (98%) women with early stage cancer and 251 (96.2%) women with advanced stage cancer thought having vaginal discharge was not normal but with no statistical significance (p=0.86). More than half of the women with early stage cancer 67 (67.7%) and 153 (54.6%) women with advanced stage cancer thought infection was the major cause of vaginal discharge. Only 7 (7.1%) women with early stage cancer and 32 (12.2%) women with advanced stage cancer thought that vaginal

discharge was caused by cancer. These differences were significant (p=0.04). These findings suggest that despite excessive vaginal discharge being one of the symptoms of cancer, most women commonly associated it to vaginal infections. Ninety one (91.9%) women with early stage cancer and 249 (95%) women with advanced stage cancer did not think that post menopausal bleeding was normal but, with no statistical significance (p=0.283). Fifty eight (59.2%) women with early stage cancer and 134 (51.9%) women with advanced stage cancer thought infection was the major cause of post-menopausal bleeding. Those who thought post-menopausal bleeding was due to cancer were sixteen (16.3%) women with early stage cancer and 42 (16.3%) women with advanced stage cancer. Nevertheless, with no statistical significance (p=0.166). This finding further shows that knowledge on cervical cancer is minimal as most women attributed the symptoms to infections.

Table 4: Differences in Knowledge on risk factors for cervical cancer and stage at diagnosis

	Early Stage		Advanced Stage		
	(n=99)	**%**	**(n=262)**	**%**	**p value**
Have you ever heard of cervix cancer? ǂ					
Yes	62	62.6	145	55.6	0.226
No	37	37.4	116	44.4	
Causes of cervical cancer †					
Human immunodeficiency virus (HIV)	1	1.6	2	1.4	***0.036***
Human papillomavirus (or genital warts)	8	13.1	5	3.5	
I don't know	52	85.2	136	95.1	
How did you learn about cervical cancer?*					
From neighbours	15	24.6	43	29.7	
Through the radio	28	45.9	62	42.8	0.163
Through the television	11	18	13	9	
From the newspaper	3	4.9	1	0.7	
Through health education	32	52.5	87	60	
Other	1	1.6	2	1.4	
Causes of abnormal vaginal bleeding ǂ					
Infection	42	42.4	93	35.8	
Cancer	13	13.1	35	13.5	0.625
Injury	0	0	4	1.5	
Other	43	43.4	127	48.8	
What causes bleeding after sex? ǂ					
Infection	48	49	107	40.8	
Cancer	11	11.2	34	13	0.537
Injury	8	8.2	16	6.1	
Other	30	30.6	103	39.3	
What causes vaginal discharge? ǂ					
Infection	67	67.7	143	54.6	
Cancer	7	7.1	32	12.2	***0.04***
Injury	1	1	2	0.8	
Other	23	23.2	80	30.5	
What causes bleeding after menopause? ǂ					
Infection	58	59.2	134	51.9	
Cancer	16	16.3	42	16.3	0.166
Injury	0	0	1	0.4	
Other	23	23.5	80	31	

ǂ *Numbers may not add up to total because of missing data.*

***** *Indicates a multiple response question numbers may not add up to total.*

† Indicates skipping patterns in the questionnaire, numbers may not add up to total.

4.6. Comparison between Knowledge of Infectious and Non-Infectious Risk Factors and Stage at Diagnosis

Majority of the 76 (76.8%) women with early stage cancer and 217 (83.1%) women with advanced stage cancer had never had genital warts. Only twenty three (23.2%) women with early stage cancer and 37 (14.2%) women with advanced stage cancer had developed genital warts while, 7 (2.7%) women with advanced stage cancer said that they did not know if they had ever had genital warts. These differences were statistically significant (χ^2 =6.55, df=2, p=0.038). This finding could be influenced by recall bias as most women were not sure what a genital wart was or if they had developed it at an earlier age. None of the twenty three women with early stage cancer who had developed genital warts had ever smoked tobacco while, 35 (94.6%) out of the 37 women with advanced stage who had developed genital warts had ever smoked tobacco. Only one (2.7%) of the women with advanced stage cancer was a smoker. These differences were not statistically significant (χ^2 =1.286, df=2, p=0.526). The effect of tobacco use in the advancement of HPV infection to cervical cancer was not observed as very few women smoked tobacco.

Seventy (71.4%) women with early stage and 227 (87%) women with advanced stage cancer cited not having had regular gynaecological examinations while, only 28 (28.6%) women with early stage and 34 (13%) women with advanced stage cancer had had frequent gynaecological examinations. These differences were statistically significant ((χ^2 =12.05, df=1, p=0.001). This implies that screening for cervical cancer was not common in women with early and advanced stage cancer. Over sixty percent of women with early stage cancer 68 (69.4%) and 163 (62.2%) women with advanced stage cancer thought that gynaecological examinations assisted in the early detection of cervical cancer. Sixteen (16.3%) women with early stage and 70 (26.7%) women

with advanced stage cancer cited other reasons however, these differences were not significant ((χ^2 =5.536, df=3, p=0.137). Seventy three (75.3%) women with early stage cancer and 155 (59.8%) with advanced stage cancer knew what a pap smear test was whereas, 24 (24.7%) women with early stage cancer and 103 (39.8%) women with advanced stage cancer did not know what a pap smear test was. These differences were significant ((χ^2 =7.458, df=2, p=0.024). This implies knowledge on screening methods is more in women with early stage cancer than in those with advanced stage cancer.

Most of the women with advanced stage cancer 127 (48.5%) and 46 (46.9%) women with early stage cancer cited that they did not know if cervical cancer was a sexually transmitted disease. Sixty two (23.7%) women with advanced stage cancer and 22 (22.4%) women with early stage cancer thought that cervical cancer was a sexually transmitted disease whereas, 73 (27.9%) women with advanced stage and 30 (30.6%) women with early cancer disease thought that cervical cancer was not a sexually transmitted disease however, without statistical significance (χ^2 =0.27, df=2, p=0.874). The sexually transmitted nature of cervical cancer was not known in women with early and advanced stage cancer as only 23% of women with early and advanced stage cancer were aware that it could be sexually transmitted. Almost half of the women with early stage cancer 46 (46.5%) and 116 (44.3%) with advanced stage cancer thought that promiscuity is a risk factor for developing cervical cancer. About a third of the women with early stage 39 (39.4%) and 88 (33.6%) women with advanced stage cancer did not know if promiscuity is a risk factor for developing cervical cancer still, without statistical significance (χ^2 =3.07, df=2, p=0.216). While close to half of the women with early and advanced cancer cited promiscuity as a risk factor for developing cervical cancer, their level of awareness on risk factors was low.

Seventy two (72.7%) women with early stage and 189 (72.4%) with advanced stage cancer had used hormonal contraceptives. While, 27 (27.3%) women with early stage and 72 (27.6%) with advanced stage cancer had never used hormonal contraceptives. There was no statistical significance (χ^2 =0.004, df=, p=0.953).

For women who used contraceptives for less than a year, 8 (11.1%) had early stage cancer and 23 (12.2%) had late stage cancer. Twenty seven (37.5%) women with early stage and 72 (38.1%) with advanced stage cancer had used contraceptives between 2 and 8 years. Of the women who had used contraceptives between 9 and 15 years, 22 (30.6%) had early stage and 74 (39.2%) had advanced stage cancer. Only 15 (20.8%) with early stage and 20 (10.6%) with advanced stage cancer had used contraceptives for 16 years and more however, without statistical significance (χ^2 =5.188, df=3, p=0.159). The median interval of contraceptive use was between 4 to 15 years for women with early stage cancer and 4 to 12 years for women with advanced stage cancer however, without statistical significance (p=0.657). Although these difference were not statistically significant, the results suggest that the use of hormonal contraceptives places women at risk of developing cervical cancer.

Table 5: Comparison between knowledge of infectious and non-infectious risk factors and stage at diagnosis

	Early Stage		Advanced Stage		
	(n=99)	%	(n=262)	%	p value
Have you ever had genital warts? ǂ					
Yes	23	23.2	37	14.2	***0.038***
No	76	76.8	217	83.1	
I don't know	0	0	7	2.7	
Tobacco use †					
Never	23	100	35	94.6	0.526
Smoker	0	0	1	2.7	
Ex-smoker	0	0	1	2.7	
Regular gynaecological examinations ǂ					
Yes	28	28.6	34	13	***0.001***
No	70	71.4	227	87	
Use of regular gynaecological examinations ǂ					
Early detection of carcinoma of the cervix	68	69.4	163	62.2	
To detect STIs	14	14.3	27	10.3	0.137
None of the above	0	0	2	0.8	
Others	16	16.3	70	26.7	
What is a pap smear test? ǂ					
It is a smear from the cervix used to rule out the presence of cancer cells	73	75.3	155	59.8	***0.024***
I don't know	24	24.7	103	39.8	
Others	0	0	1	0.4	
Is cervical cancer sexually transmitted? ǂ					
Yes	22	22.4	62	23.7	0.874
No	30	30.6	73	27.9	
I don't know	46	46.9	127	48.5	
Is promiscuity a risk factor ǂ					
Yes	46	46.5	116	44.3	0.216
No	14	14.1	58	22.1	
I don't know	39	39.4	88	33.6	
Hormonal contraceptives use ǂ					
Yes	72	72.7	189	72.4	0.953
No	27	27.3	72	27.6	
Duration of contraceptive use categories †					
≤1yr	8	11.1	23	12.2	
2-8yrs	27	37.5	72	38.1	0.159
9-15 yrs	22	30.6	74	39.2	
≥16yrs	15	20.8	20	10.6	
Duration of contraceptive use in years median	9	4 - 15	9	4 - 12	*0.657*

ǂ *Numbers may not add up to total because of missing data.*

***** *Indicates a multiple response question numbers may not add up to total.*

† *Indicates skipping patterns in the questionnaire, numbers may not add up to total.*

CHAPTER FIVE: DISCUSSION

5.1. Demographic and Socioeconomic Factors

This study looked into the impact of demographic and socioeconomic factors, knowledge on cervical cancer and access to healthcare on the stage of diagnosis of cervical patients attending Kenyatta national hospital. This study found that about 72% of the women were diagnosed with advanced stage cervical cancer. This is consistent with findings from a study carried out in Sudan that showed that stage at diagnosis in women was mostly advanced (Ibrahim *et al*., 2011). Similarly, this study showed that women above 50 years were more likely to be diagnosed with advanced stage disease. Previous studies have reported that factors such as increased age are directly correlated with advanced stage at diagnosis of cervical cancer (Palacio-Mejía *et al*., 2003). Other studies have also shown that, women older than 65 years appear to be at a greater risk of being diagnosed at an advanced stage (Ferrante *et al*., 2000). In this study, more women aged above 61 years presented with advanced stage cancer than those with early stage cancer.

This study shows that early age at marriage placed more women at risk of developing advanced stage cervical cancer. A study by Bosch *et al*., (2002) found that age at first sexual intercourse is closely associated with early age at marriage and that early age at marriage places women at a greater risk of developing advanced cervical cancer although HPV is necessary for the progression of disease.

It was observed that women who had had more than four pregnancies were more likely to be diagnosed with advanced stage cervical cancer than those who had less than three pregnancies. The International Agency for Research on Cancer (IARC, 2007) illustrated that, regardless of other known risk factors of cervical cancer, age at first sexual intercourse and increased number of pregnancies provides a greater risk

for developing invasive cervical cancer. They argue that, in addition to age at first sexual intercourse, early pregnancies increase the risk of cervical carcinogenesis due to the stress exerted on the cervix which is further exacerbated by increased number of pregnancies.

It was further observed that most of the women and their partners had only attained a primary level education and that these women were more likely to be diagnosed with late stage disease. This is consistent with studies that have shown that patients are more likely to be diagnosed with advanced stage cervical cancer if they have minimal or no education as they are unable to understand their prognosis and to take note of common cancer symptoms (Kaku *et al*., 2008). Furthermore, a woman's ability to obtain treatment is further influenced by her partner as she must persuade her partner to provide her with financial assistance when she is not noticeably ill (Bingham *et al*., 2003).

5.2. Access to Healthcare Services

In this study, it was observed that health seeking behaviour in women was wanting as the average time taken by women with early and advanced stage cervical cancer to visit a hospital after the onset of symptoms was between 3 and 4 months. This is consistent with findings that showed that cognisance of symptoms and mostly, the manner in which a patient interprets symptoms influences delays in seeking treatment. A patient's inability to recognise the gravity of symptoms, which may be due to lack of knowledge on the illness, is the major risk factor for patient delays in health seeking behaviour (Macleod *et al*., 2009).

The study sought to identify measures taken by health practitioners at hospitals which subsequently influenced the stage at diagnosis of cervical cancer. It was observed that more than half of the women with early and advanced stage cancer were given

medication and had a pelvic examination done. Studies have shown that the most predominant practitioner related issue linked to delays in referral to a tertiary health care centre is misdiagnosis (Chirenje *et al*., 2001). This could occur if the health practitioner prescribed medication symptomatically to patients or by associating symptoms to a health issue other than cancer. Furthermore, health practitioners add to a patient's delay by carrying out ineffective or unsuitable tests, neglecting to examine patients sufficiently and failing to look into false negative or indeterminate test results (Arrossi *et al*., 2010).

This study also found that, more women with advanced stage cervical cancer were given referral letters and that some of the women failed to honour the referral due to lack of money. This is consistent with other findings that show that the main barriers to health care services in most resource limited settings are opportunity costs and geographic inaccessibility and that a substantial number of women at risk of cervical cancer may be situated in areas where no treatment exists (Agurto, 2001).

It was also observed that, approximately 80% of women with early and advanced stage cervical cancer went to a number of dispensaries and private hospitals before being referred to KNH. This was probably due to lag times in processing smears or due to lack of skilled technicians in district hospitals. Ntekim, (2012) demonstrated that, insufficient resources and inferior health infrastructure in developing countries poses a challenge in implementing cytology based screening techniques. Conversely, in these countries the number of adequately trained health care practitioners is wanting in addition to poor quality control systems.

5.3. Knowledge on Cervical Cancer

The most striking finding in this study was the low knowledge on cervical cancer and HPV as a risk factor. This study showed that even among women presenting with

early stage cancer not more than 65% had heard of cervical cancer prior to their diagnosis and that health education was the common source of information on cervical cancer for the women. This is consistent with studies that showed that there is much uncertainty concerning the link between HPV and cervical cancer (Holcomb *et al*., 2004). Other studies have also shown that about 40% of women had heard of HPV, but not more than half were aware that it caused cervical cancer (Sherris *et al.*, 2001). This study assessed awareness of HPV through the patient's history of having had genital warts. Their capacity to mention HPV as a cause of cervical cancer was used as an indicator for awareness. Similarly, studies have indicated the importance of national screening programmes as an aspect of women's routine care but have cautioned that in the absence of relevant cues from the media, health educational messages are not sufficient in improving health seeking behaviour. A combination of outreach programmes, health education and media messaged have been shown to raise awareness in developed countries (Abotchie and Shokar, 2009).

A study carried out by the World Health Organization (WHO, 2009) illustrated that the most common cervical cancer symptoms that would allow for early diagnosis are excessive vaginal discharge and post coital bleeding. This study showed that majority of women had inadequate knowledge of the rudimentary symptoms of cervical cancer which augmented their risk of being diagnosed with advanced stage disease. This is consistent with a study carried out in Nigeria that showed that most of the women attributed their symptoms to other causes such as genital infections, erratic menses, contraceptive use and resumption of menses in menopausal women (Anorlu *et al*., 2004).

5.3.1. Knowledge on Infectious and Non-Infectious Risk Factors

The need for regular gynaecological examinations as a measure for the early detection of cervical cancer has been well documented. More specifically, studies have illustrated that preventive health behaviour such as routine cancer checkups are to a smaller extent observed in women from low socioeconomic backgrounds (Kaku *et al*., 2008). In this study it was observed that, knowledge on the importance of regular checkups for early detection of cervical cancer was low. Consequently, the frequency of gynaecological examinations in women with early and advanced stage disease was low. This finding is consistent with other studies that have demonstrated that screening services in developing countries are characterised by poor coverage and are mostly opportunistic (Anorlu, 2008).

The study illustrated that most of the women were not aware of the sexually transmitted nature of cervical despite the fact that some women regarded promiscuity to be a risk factor. This is consistent with findings from a British study that showed similarly low levels of awareness of the sexually transmitted nature of cervical cancer (Waller *et al*., 2004). Studies have shown that areas of sexual health and cervical cancer screening continue to remain relatively distinct in spite of the well established link between cervical cancer and sexual activity and that public health messages have not stressed the role of a sexually transmitted virus in cervical cancer aetiology (Molano *et al*., 2002). Additionally, studies have shown that the number of lifetime sexual partners increases the risk of developing invasive cervical cancer (Smith *et al*., 2003). Therefore, information regarding the link between cervical cancer and sexual activity is necessary in order to allow women to make informed choices concerning their sexual behaviour (Molano *et al*., 2002).

CHAPTER SIX: CONCLUSION AND RECOMMENDATION

6.1. Conclusion

This study revealed that stage at diagnosis among women attending Kenyatta national hospital is considerably advanced. Women who are most at risk of presenting with advanced stage cervical cancer are those with low education levels, women whose partners' education level is low, those who married early and those who had multiple child births. Inability to recognise symptoms, lack of money, distance to hospitals and poor healthcare infrastructure caused delays in seeking treatment. It was further observed that there was limited knowledge on risk factors for cervical cancer particularly on the link between HPV and cervical cancer. Similarly, there was poor understanding of promiscuity as a risk factor, on the sexually transmitted nature of cervical cancer and on the risk of prolonged contraceptive use.

6.2. Recommendations

There is need to increase the coverage of screening programs and increase awareness of basic cervical cancer symptoms in order to allow for early detection. Healthcare facilities offering cancer preventive and treatment services need to be increased and should be equipped with the appropriate equipment and trained personnel in order to reduce the time of diagnosis of cervical cancer. Women should be informed about the HPV virus and its role in the cervical cancer aetiology and on the importance of frequent gynaecological examinations. They should also be educated on the sexually transmitted nature of cervical cancer as this will allow women to make appropriate choices regarding their sexual behaviour. Therefore, any educational materials targeted towards most at risk women should clearly highlight these aspects.

6.3. Recommendations for Further Research

There is need to carry out a larger study that would further elucidate the differences in education level and socioeconomic status such as occupation and monthly household income that influence the stage at diagnosis. This study sought to establish factors that would cause patients to delay seeking care and factors within the health care system that could also cause delays resulting in advanced stage at diagnosis however factors within the health care system that caused additional delays were not clearly demonstrated. Therefore, there is need to carry out further research that would bring to light the factors within the health care system that would lead to advanced stage at diagnosis.

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APPENDICES

Appendix 1: Staging of Cervical Cancer

Stage I

The carcinoma is strictly confined to the cervix (extension to the uterine corpus should be disregarded).

- **Stage IA:** Invasive cancer identified only microscopically. (All gross lesions even with superficial invasion are Stage IB cancers.) Invasion is limited to measured stromal invasion with a maximum depth of 5mmb and no wider than 7mm.
- **Stage IA1:** Measured invasion of stroma ≤3mm in depth and ≤7mm width.
- **Stage IA2:** Measured invasion of stroma >3mm and <5mm in depth and ≤7mm width.
- **Stage IB:** Clinical lesions confined to the cervix, or preclinical lesions greater than stage IA.
- **Stage IB1:** Clinical lesions no greater than 4 cm in size.
- **Stage IB2:** Clinical lesions >4 cm in size.

Stage II

The carcinoma extends beyond the uterus, but has not extended onto the pelvic wall or to the lower third of vagina.

- **Stage IIA:** Involvement of up to the upper 2/3 of the vagina. No obvious parametrial involvement.
- **Stage IIA1:** Clinically visible lesion ≤4cm.
- **Stage IIA2:** Clinically visible lesion >4cm.
- **Stage IIB:** Obvious parametrial involvement but not onto the pelvic sidewall.

Stage III

The carcinoma has extended onto the pelvic sidewall. On rectal examination, there is no cancer free space between the tumor and pelvic sidewall. The tumor involves the lower third of the vagina. All cases of hydronephrosis or non-functioning kidney should be included unless they are known to be due to other causes.

- **Stage IIIA:** Involvement of the lower vagina but no extension onto pelvic sidewall.
- **Stage IIIB:** Extension onto the pelvic sidewall, or hydronephrosis/non-functioning kidney.

Stage IV

The carcinoma has extended beyond the true pelvis or has clinically involved the mucosa of the bladder and/or rectum.

- **Stage IVA:** Spread to adjacent pelvic organs.
- **Stage IVB:** Spread to distant organs.

Source: FIGO Committee on Gynecologic Oncology and IGCS Guidelines Committee (2009).

Appendix 2: Map of Kenyatta National Hospital

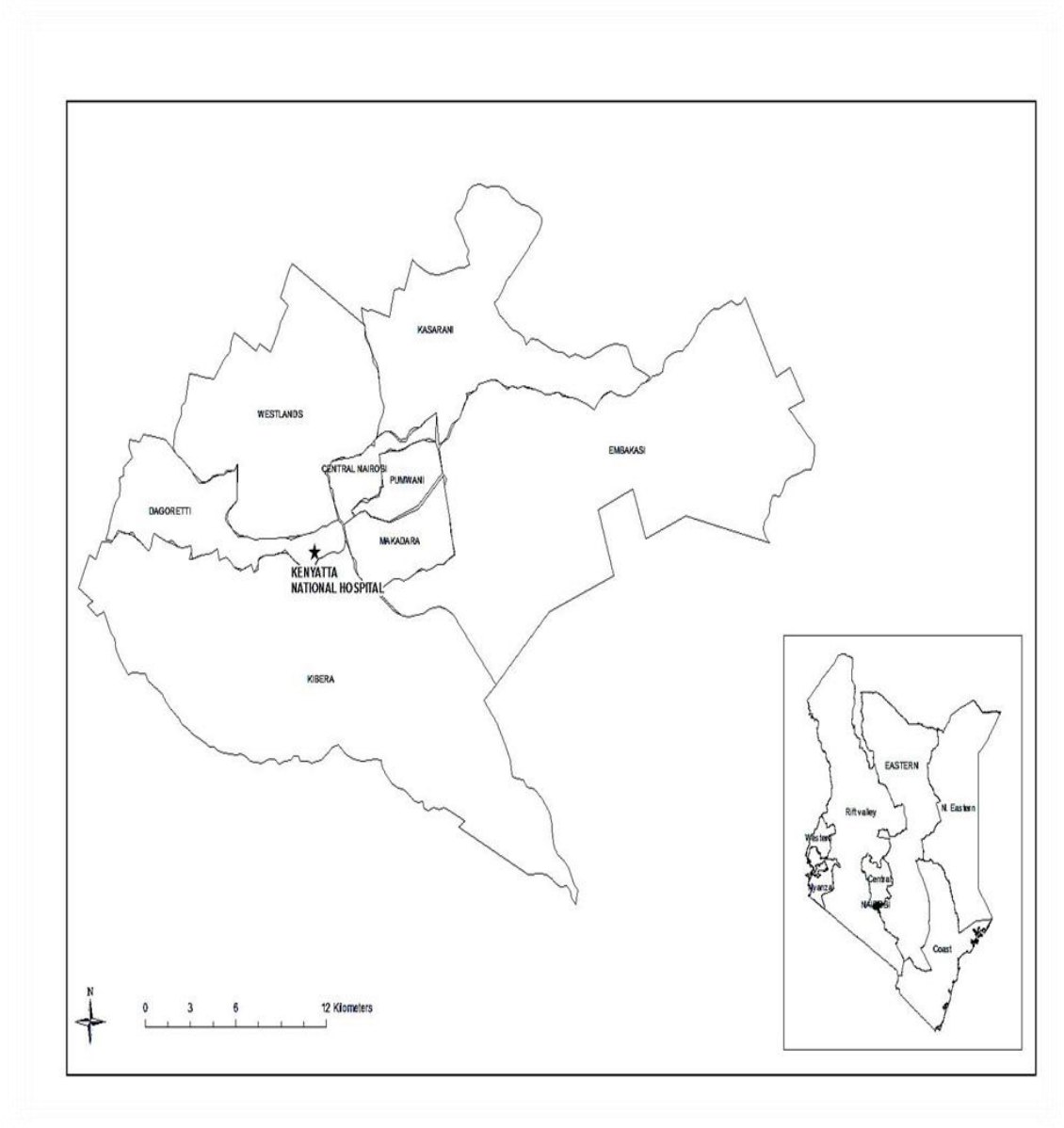


Figure 4: Map showing Kenyatta national hospital

Appendix 3A: Consent Form

Consent Form for Participation in a Research Study, Moi University

Title of Study: Factors associated with cervical cancer stage at diagnosis among women attending Kenyatta National Hospital, Kenya.

Description of the research

You are invited to participate in a research study conducted by Kabura Wamburu, from Moi University. The purpose of this research is to identify reasons such as age, level of education, distance to healthcare facilities and the understanding of cervical cancer symptoms that make women look for treatment for cervical cancer. The results from this study will assist in identifying women who are most likely to look for treatment when the disease is very serious and will provide information on women who are at risk of developing cervical cancer for educational and screening programs.

I would therefore like to invite you to be part of this research as information on the extent of disease is important in determining how serious the illness is and determining the type of treatment required. You do not have to decide today on whether or not you wish to participate in the research. However, before making a decision, feel free to talk to anyone you feel comfortable with about the research.

This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain further. If you have questions later, you can ask me or any research assistant in my team.

Risks and discomforts

There are no known risks associated with this research. We shall just engage you in a discussion as well as request you to fill a questionnaire related to the study.

Potential benefits

There will be no direct benefit to you, but your involvement will assist us in finding out more on the number of women who receive treatment before and after the disease becomes serious and find out which women can easily develop cervical cancer. This will therefore inform programs aimed at preventing cervical cancer.

Protection of confidentiality

Information obtained in this research study will not be shared with anyone external to the research team. The questionnaires used to obtain information from you will not contain your name but will instead be coded with a number that is unique to you. Only the researchers will know what your number is and the questionnaire will be kept under lock and key in a cabinet. It will not be shared with or given to anyone except me, the main researcher and the research assistant.

Voluntary participation

Your participation in this research study is voluntary. You may choose not to participate and you may withdraw your consent to participate at any time. You will not be penalized in any way should you decide not to participate or to withdraw from this study.

Contact information

If you have any questions or concerns about this study or if any problems arise, please contact the principal investigator, Kabura Wamburu at 0721215241. If you have any questions or concerns about your rights as a research participant, please contact the Moi University Board of Ethics, IREC at 0787723677.

Consent

I have read this consent form and have been given the opportunity to ask questions. I give my consent to participate in this study.

Participant's signature_____ Date: _____

If illiterate[1]

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____

Signature of witness _____ Date _____

Day/month/year

NB: A copy of this consent form should be given to you.

_____

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the purpose of the study.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability.

I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this informed consent form has been provided to the participant.

Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

Appendix 3B: Fomu ya kukubali/ kuridhia

Fomu ya kurifhia kushiriki katika utafiti, Chuo kikuu cha Moi

Anwani ya utafiti: mambo yanayoathiri hatua katika kujitokeza kwa saratani ya mlango wa uzazi miongoni mwa wanawake wanaotembelea hospitali kuu ya Kenyatta.

Maelezo ya utafiti na kushiriki kwako.

Umealikwa kushiriki katika utafiti unaofanywa na Kabura Wamburu, kutoka chuo kikuu cha Moi. Azma ya utafiti huu ni kutambua mambo yanayoathiri hatua katika kujitokeza kwa saratani ya mlango wa uzazi miongoni mwa wanawake wanaotembelea hospitali ya Kenyatta kwa matibabu. Matokeo ya utafiti huu yatasaidia katika kutambua wanawake ambao wana uwezekano mkubwa wa kutambuliwa kuwa katika hatua za mwisho za ugonjwa huu na hivyo kutoa habari kwa kundi lengwa kuhusu elimu na vilevile mipango ya kuwafanyia ukaguzi.

Ningependa hivyo basi kukualika kushiriki katika utafiti huu kwani ujuzi kuhusu hatua yake wakati wa udondosi(diagnosis) ni muhimu katika kuamua aina ya matibabu yanayohitajika. Si lazima uamue leo iwapo utashiriki katika utafiti huu au la. Hata hivyo, kabla hujafanya maamuzi , uwe huru kuongea na yeyote ambaye unamwamini kuhusu utafiti huu.

Fomu hii ya kuridhia huenda ikawa na maneno mengine ambayo ni magumu. Tafadhali niulize nisite kidogo na nitachukua muda kukuelezea. Iwapo utakuwa na maswali baadaye, unaweza kuniuliza au mtafiti msaidizi aliye katika timu yangu.

Hatari na kero.

Hakuna hatari zinazojulikana na ambazo zinahusishwa na utafiti huu. Tunakuhusisha tu katika mjadala na tunakuomba utujazie hojaji ya utafiti huu.

Manufaa yanayoweza kupatikana.

Hutupatia manufaa moja kwa moja. Lakini kushiriki kwako kunaweza kutusaidia kugundua idadi ya wanawake ambaohutambuliwa katika hatua za mwanzo mwanzo au za mwisho mwishoza ugonjwa huu na kutuwezesha kugundua ni kundi lipi la wanawake ambalo liko katika hatari ya kupata ugonjwa huu wa saratani ya mlango wa uzazi.

Kulindwa kwa usiri.

Habari ambazo zitapatikana katika utafiti huu hazitapatiwa yeyote ambaye hahusiki katika utafiti huu. Hojaji ambazo zitatumika kupata habari kutoka kwenu hazitakuwa na majina yenu lakini zitapewa nambari zenu za siri. Ni watafiti pekee ambao watajua nambari hizi na hojaji zenyewe zitawekwa salama katika sefu. Hazitapewa mtu mwingine isipokuwa mimi; mtafiti mkuu na mtafiti msaidizi.

Kujitolea kushiriki

Kushiriki kwako katika uaafiti huu ni kwa kujitolea. Unaweza kuchagua kutoshiriki na unaweza pia kuondoa kuridhia kwako wakati wowote. Hutaadhibiwa kwa njia yoyote ile iwapo utaamua kutoshiriki au kujiondoa katika utafiti huu.

Nambari za mawasiliano

Iwapo una swali lolote au hangaiko/sikitiko lolote kuhusu utafiti huu au iwapo kutazuka tatizo lolote, tafadhali wasiliana na mtafiti mkuu; Kabura Wamburu kwa nambari hii: **0721215241.** Iwapo una swali zozote au hangaiko lolote kuhusu haki zako kama mshiriki, tafadhali wasiliana na Bodi ya Maadili ya Chuo kikuu cha Moi IREC.

Ridhaa (consent)

Nimesoma fomu hii ya kuridhia/kukubali na nimepewa nafasi ya kuuliza maswali. Ninatoa ridhaa yangu kushiriki katika utafiti huu.

Sahihi ya mshiriki.....
Tarehe.....

Iwapo hujui kusoma

Nimeshuhudia usomaji sahihiwa fomu ya kuridhia/ kukubali kwa mshiriki na amekuwa na nafasi ya kuuliza maswali. Nathibitisha kuwa ametoa idhini kwa kupenda kwake.

Jina la shahidi..... **Alama ya kidole**

Sahihi ya shahidi.....

Tarehe.....

Shahidi ambaye amesoma ni lazima atie shahidi (ikiwezekana achaguliwe na mshirika na asiwe na uhusiano wowote na). Washiriki ambao hawajasoma watie alama za vidole pia.

Tanbihi: Upewe nakala ya fomu hii ya kuridhia/ kukubali.

Taarifa ya mtafiti/yule anayechukua ridhaa.

Nimesoma kisahihi habari za utafiti huu kwa mshiriki na kwa uwezo wangu wote nimehakikisha kuwa mshiriki anaelewa lengo/nia ya utafiti huu.

Nadhibitisha kuwa mshiriki alipewa nafasi ya kuuliza maswali kuhusu utafiti huu na maswali yote aliyouliza yameyajibu vizuri kwa uwezowangu wote.

Nadhibitisha pia kuwa mshiriki hajashawishiwa kutoa ridhaa na kuwa ameitoa kwa kupenda kwake.

Nakala ya fomu hii ya kuridhia /kukubali imetolewa kwa mshiriki.

Chapisha jina la mtafiti/ mtu anayechukua ridhaa

.....

Sahihi ya mtafiti/mtu anayechukua ridhaa .....

Tarehe.....

Siku/mwezi/mwaka

Appendix 4A: Questionnaire

FACTORS ASSOCIATED WITH CERVICAL CANCER STAGE AT DIAGNOSIS AMONG WOMEN ATTENDING KENYATTA NATIONAL HOSPITAL, KENYA

This questionnaire consists of four parts. Please answer all the questions by ticking (√) on the spaces provided or use the blank spaces left for you.

Place of residence

A. COUNTY	B. DIVISION	C. LOCATION/ESTATE

PART A: SOCIOECONOMIC AND DEMOGRAPHIC DETAILS

1. How old are you? (Which year were you born?) …… years
2. What is your marital status?
   a) Single
   b) Married (If married, is it a monogamous or polygamous marriage)
   c) Divorced
   d) Widowed
   e) Others……..
3. What was your age at marriage? …… years
4. Do you live with your partner? Yes ☐ No ☐
5. How many children do you have?
   ……...
6. What level of education have you completed?
   a) No formal education
   b) Primary education
   c) Secondary education
   d) Tertiary education
   e) University education
   f) Others (please specify)……
7. If yes to question 4, what is your partner's highest level of education?
   a) No formal education
   b) Primary education
   c) Secondary education
   d) Tertiary education
   e) University education
   f) Others (please specify)……

8. What is your occupation?
    a) Permanently employed
    b) Casually employed
    c) Unemployed/house wife/student
    d) Self-employed (If self-employed explain the type of business you are involved in)……

9. If you are unemployed, what is your source of income?

……

10. If you are employed, what is your total house hold income per month? Ksh……

PART B: ACCESS TO HEALTHCARE ON HEALTH SEEKING BEHAVIOUR

11. Have you ever heard of cancer of the cervix?

    Yes ( ) No ( )

12. If yes to question 11, do you know what causes cervical cancer?
    a) Human immunodeficiency virus (HIV)
    b) Human papillomavirus (or genital warts)
    c) Bacteria
    d) I don't know

13. If yes to question 11, how did you get to learn about it? (Multiple response)
    a) From neighbours
    b) Through the radio
    c) Through the television
    d) From the newspaper
    e) Through health education
    f) Other (please specify)……..

14. Have you ever experienced any of the following symptoms?
    a) Bleeding other than during normal menstruation [ ]
    b) Vaginal discharge [ ]
    c) Pelvic pain [ ]
    d) Postmenopausal bleeding [ ]
    e) Bleeding after sex [ ]
    f) Coughing up blood [ ]
    g) Lower back ache [ ]

15. If yes to question 14, what steps did you take?
    a) Went to hospital/health centre [ ]
    b) Attended to by a traditional healer [ ]

c) Stayed at home [ ]

16. How long did it take you to decide to go to hospital after first symptom in months? ……

17. If you did not go to the health centre/hospital immediately after having the first symptom what was the reason? (Multiple response)
    a) Thought it was abdominal pain in women [ ]
    b) Denied permission by my husband [ ]
    c) 1 went to a tradition healer [ ]
    d) 1 had no money [ ]

18. What did the person who attended to you do?
    a) Prescribed oral/injected medication [ ]
    b) Did a pelvic examination [ ]
    c) Admitted you [ ]
    d) Gave a referral letter to a tertiary centre [ ]
    e) Other (Please specify)
    ……

19. If you were given a referral letter how long did it take you to decide to honour the referral in months? ……

20. If you were late to honour the referral what was the reason?
    a) I had no money [ ]
    b) I was being attended to by a traditional healer [ ]
    c) It was during rainy season and the roads were impassable [ ]
    d) Found it unnecessary since I was not told about the diagnosis [ ]

21. If you were not given a referral letter when you were first seen at the health centre how did you manage to reach the referral centre?
    a) I went to a few more dispensaries/hospital before being referred to KNH [ ]
    b) I was brought to KNH by my relatives living in Nairobi [ ]
    c) Since my condition was deteriorating I decided to come straight to KNH without referral [ ]

22. What was your duration of symptoms in months?
    ……

PART C: KNOWLEDGE ON RISK FACTORS FOR DEVELOPING CERVICAL CANCER

23. What was your age when you had your first menstrual period in years?
    ……

24. What was your age when you first had sexual intercourse in years?
    ……

25. Do you think vaginal bleeding between periods is normal?
    Yes ( ) No ( ) I don't know ( )

26. What do you think causes abnormal vaginal bleeding? (Multiple response)
    a) Infection [ ]
    b) Cancer [ ]
    c) Abortion [ ]
    d) Injury [ ]
    e) Witchcraft [ ]
    f) Male promiscuity [ ]
    g) Others (Please specify)……..
27. Is bleeding after sex normal?
    Yes ( ) No ( ) I don't know ( )
28. Which of the following do you think causes bleeding after having sex?
    a) Infection [ ]
    b) Cancer [ ]
    c) Abortion [ ]
    d) Injury [ ]
    e) Witchcraft [ ]
    f) Male promiscuity [ ]
    g) Others (Please specify)……..
29. Is vaginal discharge normal?
    Yes ( ) No ( ) I don't know ( )
30. What do you think causes vaginal discharge?
    a) Infection [ ]
    b) Cancer [ ]
    c) Abortion [ ]
    d) Injury [ ]
    e) Witchcraft [ ]
    f) Promiscuity of your husband [ ]
    g) Excessive coitus [ ]
    h) Husband crossing over you in bed [ ]
    i) Others (Please specify)……..

31. Is bleeding after menopause normal?
    Yes ( ) No ( ) I don't know ( )
32. What do you think causes bleeding after menopause?
    a) Infection [ ]
    b) Cancer [ ]
    c) Abortion [ ]
    d) Injury [ ]
    e) Witchcraft [ ]
    f) Promiscuity of your husband [ ]

g) Others (Please specify)……..

33. Have you ever had genital warts?
Yes ( ) No ( ) I don't know ( )

34. If yes to question 33, have you ever smoked tobacco?
a) Never ( ) b) Smoker ( ) c) Ex-smoker ( ) d) I don't know ( )

PART D: HISTORY OF INFECTIOUS AND NON-INFECTIOUS AGENTS

35. Do you have gynaecological examinations frequently?
Yes ( ) No ( )

36. What do gynaecological examinations help with?
a) Early detection of carcinoma of the cervix
b) To detect STIs
c) None of the above
d) Others (Please specify)……..

37. What is a Pap smear test?
a) It is a smear from the cervix for examination that is used to rule out the presence of cancer cells
b) It is a disease
c) I don't know
d) Others (Please specify)……..

38. Is cervical cancer a sexually transmitted disease?
Yes ( ) No ( ) I don't know ( )

39. Is promiscuity a risk factor for developing cervical cancer?
Yes ( ) No ( ) I don't know ( )

40. Do you use hormonal contraceptives?
Yes ( ) No ( ) I don't know ( )

41. If yes to question 40, how long have you used them for in years? ……

STAGE

Insitu	Stage I	Stage II	Stage III	Stage IV	Unknown

HISTOLOGY……..
RESULTS……

Appendix 4B: Hojaji

MAMBO YANAYOATHIRI HATUA KATIKA KUJITOKEZA KWA SARATANI YA MLANGO WA KIZAZI MIONGONI MWA WANAWAKE AMBAO WANATEMBELEA HOSPITALI KUU YA KENYATTA 2014.

Hojaji hii ina sehemu nne. Tafadhali jibu maswali yote kwa kuweka mkwaju(√) katikanafasi zilizotolewa au utumie nafasi zilizoachwa wazi kwa ajili yako.

Mahali unapoishi

A. KAUNTI	B. TAARAFA	C. JANIBU/MTAA

SEHEMU YA A: HABARI ZINAZOONYESHA HALI YA MTU KIJAMII

1. Una miaka mingapi? (ulizaliwa mwaka gani?) miaka .....
2. Hali yako ya kindoa?
   a) Mseja(single)
   b) Umeolewa(iwapo umeolewa, ni mke mmoja au zaidi ya mmoja?)
   c) Mtalaka (divorced)
   d) Mjane (widowed)
3. Uliolewa ukiwa na miaka mingapi? Miaka .....
4. Unaishi na mwenzako? Ndio ☐ La ☐
5. Una watoto wangapi?.....
6. Kiwango chako cha elimu ni kipi?
   a) Sina masomo yoyote
   b) Kiwango cha msingi
   c) Shule ya upili
   d) Chuo kikuu
   e) Viwango vingine(tafadhali onyesha).....
7. Iwapo jibu la nne ni ndio, mwenzako amesoma mpaka kiwango gani cha elimu?
   a) Hana masomo yeyote
   b) Kiwango cha msingi
   c) Shule ya upili
   d) Chuo kikuu
   e) Viwango vingine (tafadhali onyesha)
8. Unafanya kazi gani?
   a) Kazi ya kudumu
   b) Kazi ya vibarua
   c) Sina kazi/ mke nyumbani/ mwanafunzi
   d) Nimejiajiri (iwapo umejiajiri, eleza ni aina gani ya biashara unayofanya)

.....

9. Iwapo hujaajiriwa, unatoa wapi mapato yako?
   .....
10. Iwapo umeajiriwa, unapata ya kiasi gani cha pesa kwa mwezi? Shilingi
    .....

SEHEMU YA B: KUPATA MATIBABU KWA TABIA YA KUTAFA AFYA

11. Umewahi kusikia kuhusu saratani ya mlango wa kizazi?
    Ndio ( ) La ( )
12. Iwapo jibu la nambari 11 ni ndio, unajua nini huasbabisha saratani ya mlango wa kizazi?
    a) Ukimwi
    b) k
    c) Bacteria
    d) Sijui
13. Iwapo jibu la nambari 11 ni ndio, uliisikia kuhusu saratani ya mlango wa kizazi vipi?
    a) Kutoka kwa majirani ( )
    b) Kupitia kwa redio? ( )
    c) Kupitia kwa televisheni?( )
    d) Kutoka kwa gazeti?( )
    e) Kupitia kwa mafunzo ya kiafya( )
    f) Mengine (Tafadhali onyesha).....
14. Umewahi kuwa na dalili mojawapo ya hizi?
    a) Kutokwa na damu kupitia kwa uke wako katikati ya wakati wako wa hedhi( )
    b) Kutokwa na uchafu kupitia kwa uke( )
    c) Uchungu kwenye nyonga( )
    d) Kutokwa na damu baada ya hedhi kusita( )
    e) Kutokwa na damu baada ya ngono( )
    f) Kukohoa damu kutoka kwa njia ya pumzi( )
    g) Kuumwa na mgongo upande wa chini( )
15. Iwapo jibu la 13 ni ndio,ulichukua hatua gani?
    a) Kwenda hospitali/zahanati? ( )
    b) Kushughulikiwa na mgnga wa kienyeji( )
    c) Kukaa nyumbani ( )
16. Ilikuchukua muda gani kufikiria kwenda hospitalini baada ya dalili za kwanza?.....
17. Iwapo hukuenda hospitalini/zahanatini mara moja baada ya dalili za kwanza; ulikua na sababu gani? (majibu mengi)
    a) Nilifikiria ni uchungu wa tumbo la uzazi tu( )

b) Nilinyimwa ruhusa na mume wangu( )
c) Nilienda kwa mganga wa kienyeji( )
d) Sikuwa na pesa( )

18. Yule aliyewashughulikia alifnya nini?
    a) Alinipa dawa za kumeza/sindano ( )
    b) Alini nyonga( )
    c) Alinilaza hospitali( )
    d) Alinipa barua ya kunituma kwa hospitali ya juu ( )
    e) Mengineyo(tafadhali onyesha)
19. Iwapo ulipewa barua ya kutumwa hospitali ya juu, ilikuchukua miezi mingapi kufikiria kutii barua hiyo?.....
20. Iwapo ulichelewa kutii barua hiyo, ulikua na sababu gani?
    a) Sikuwa na pesa ( )
    b) Nilikuwa nashughulikiwa na mganga wa kienyeji ( )
    c) Ilikuwa wakati wa mvua na njia zilikuwa hazipitiki ( )
    d) Sikuona haja kwani sikuambiwa ulikuwa ugonjwa upi ( )
21. Iwapo hukupewa barua ya kutumwa kwa hospitali ya juu mara ya kwanza, ulipoonwa katika zahanati, uliwezaje kufika kwa hospitali ya juu?
    a) Nilienda kwa zahanati zingine/ hospitali kabla ya kutumwa KNH ( )
    b) Nililetwa KNH na jamaa zangu wanaoishi Nairobi ( )
    c) Kwa vile hali yangu ilikuwa inazorota, nilifikiria kuja moja kwa moja hapa KNH bila barua ( )
22. Ulikuwa na dalili kwa muda gani? (miezi).....

SEHEMU YA C: UJUZI WA HATARI ZA KUWA NA SARATANI YA MLANGO WA UZAZI

23. Ulikuwa na umri gani(kwa miaka) ulipoacha kuona hedhi ya kwanza.....
24. Ulikuwa na umri gani uliposhiriki ngono kwa mara ya kwanza?.....
25. Je, unafikiria kutokwa na damu bila mpango ni jambo la kawaida?

    Ndio ( ) La ( )

26. Unafikiria kutokwa na damu kupitia kwa njia ya uzazi bila mpango kunasababishwa na nini? (majibu mengi)
    a) Maambukizi ( )
    b) Saratani ( )
    c) Kuavya mimba ( )
    d) Kujeruhiwa ( )

e) Uchawi ( )
f) Mme kutokuwa na mwaminifu ( )
g) Mengine (tafadhali onyesha).....

27. Je, kutokuwa na damu baada ya baada ya ndono ni kitu cha kawaida?
Ndio ( ) La ( )

28. Je, ni yepi miongoni mwa haya ambayo unafikiria yanasababisha kutokuwa na damu baada ya ngono?

a) Maambukizi ( )
b) Saratani ( )
c) Kuavya mimba ( )
d) Kujeruhiwa ( )
e) Uchawi ( )
f) Kutangatanga kwa mwanamme ( )
g) Mengineyo (tafadhali onyesha).....

29. Kutokuwa na uchafu kwa njia ya uke ni kawaida?

Ndio ( ) La ( ) Sijui ( )

30. Unafikiria ni kipi ambacho humfanya mwanamke atokwe na uchafu kwa njia ya uke?

a) Maambukizi ( )
b) Saratani ( )
c) Kuavya mimba ( )
d) Kujeruhiwa ( )
e) Uchawi ( )
f) Kutangatanga kwa mumeo ( )
g) Ngono nyingi ( )
h) Mume kuja upande wako wa kitanda ( )
i) Mengine (tafadhali onyesha).....

31. Kutokwa na damu baada ya ukomo wa hedhi (menopause) ni kitu cha kawaida?

Ndio ( ) La ( ) Sijui ( )

32. Unafikiria ni kitu gani kinachosababisha kutokwa na damu baada ya ukomo hedhi?

a) Maambukizi ( )
b) Saratani ( )
c) Kuavya mimba ( )
d) Kujeruhiwa ( )
e) Uchawi ( )
f) Kutangatanga kwa mumeo ( )
g) Mengineyo (tafadhali onyesha).....

33. Umewahi kuwa na chujua (warts) kwenye viungo vya uzazi?

    Ndio ( ) La ( ) Sijui ( )

34. Iwapo jibu la swali la 32 ni ndio umewahi kuvuta tumbaku?

    Sijawahi ( ) Navuta ( ) Niliacha ( ) Sijui ( )

SEHEMU YA D: HISTORIA YA MAAMBUKIZI NA NGUVU ASILI ZISIZO ZA MAAMBUKIZI (Non- infectious agents)

35. Umewahi kuwa na desturi ya kuangaliwa na daktari mwenye elimu uzazi(gynachologist)?

    Ndio ( ) La ( ) Sijui ( )

36. Desturi ya kukaguliwa na mwanajinakologia(gynachologist) husaidia vipi?

    a) Uvumbuzi wa mapema wa visababishi vya saratani (carcinoma) vya mlango wa uzazi
    b) Uvumbuzi wa maambukizi ya kingono (STIs)
    c) Hakuna miongoni mwa zilizotajwa.
    d) Mengine (Tafadhali onyesha).....

37. Je, ukaguzi wa ‘pap smear’ ni nini?

    a) Ni kutoa umaji kutoka kwa mlango wa uzazi ili kufanya ukaguzi wa kuona iwapo kuna uwepo wa celi za saratani
    b) Ni ugonjwa
    c) Sijui
    d) Mengine (tafadhali yataje).....

38. Je, saratani ya mlango wa uzazi ni ugonjwa wa kuambukizwa?

    Ndio ( ) La ( ) Sijui ( )

39. Je, kutangatanga kunaweza kuwa kisababishi cha saratani ya mlango wa uzazi?

    Ndio ( ) La ( ) Sijui ( )

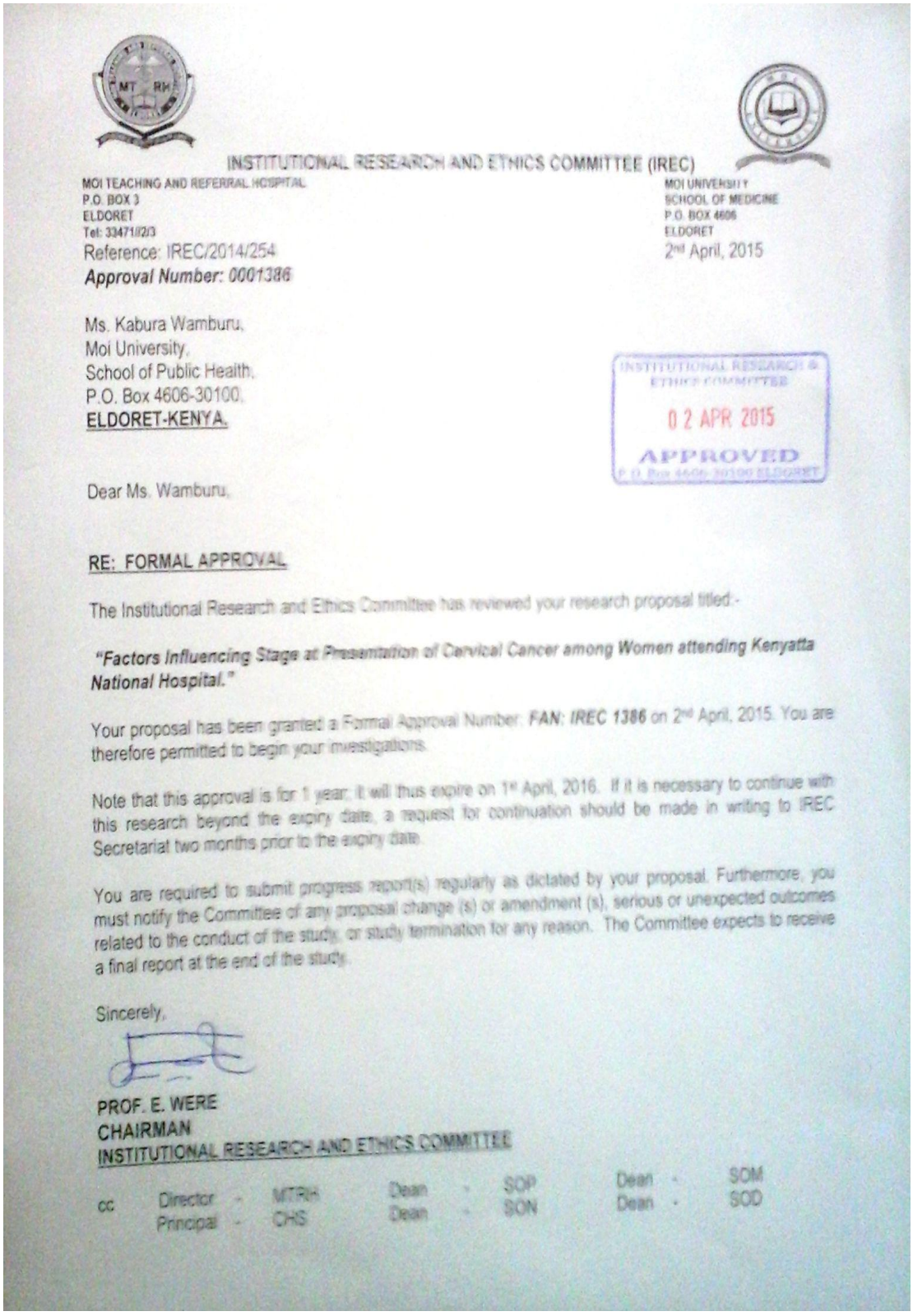
40. Unatumia vidonge vya kupanga uzazi vya homoni?

    Ndio ( ) La ( ) Sijui ( )

41. Iwapo jibu la swali la 39 ni ndio, umevitumia vidongo hivi kwa muda gani? Miaka.....

Kansa ambayo haijasambaa	Hatua 1	Hatua 2	Hatua 3	Hatua 4	Haijulikani

Appendix 5: MUCHS-IREC Approval Letter



INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

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

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2014/254
Approval Number: 0001386

2nd April, 2015

Ms. Kabura Wamburu,
Moi University,
School of Public Health,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
02 APR 2015
APPROVED
P.O. Box 4606-30100 ELDORET

Dear Ms. Wamburu,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Factors Influencing Stage at Presentation of Cervical Cancer among Women attending Kenyatta National Hospital."

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1386*** on 2nd April, 2015. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 1st April, 2016. 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.

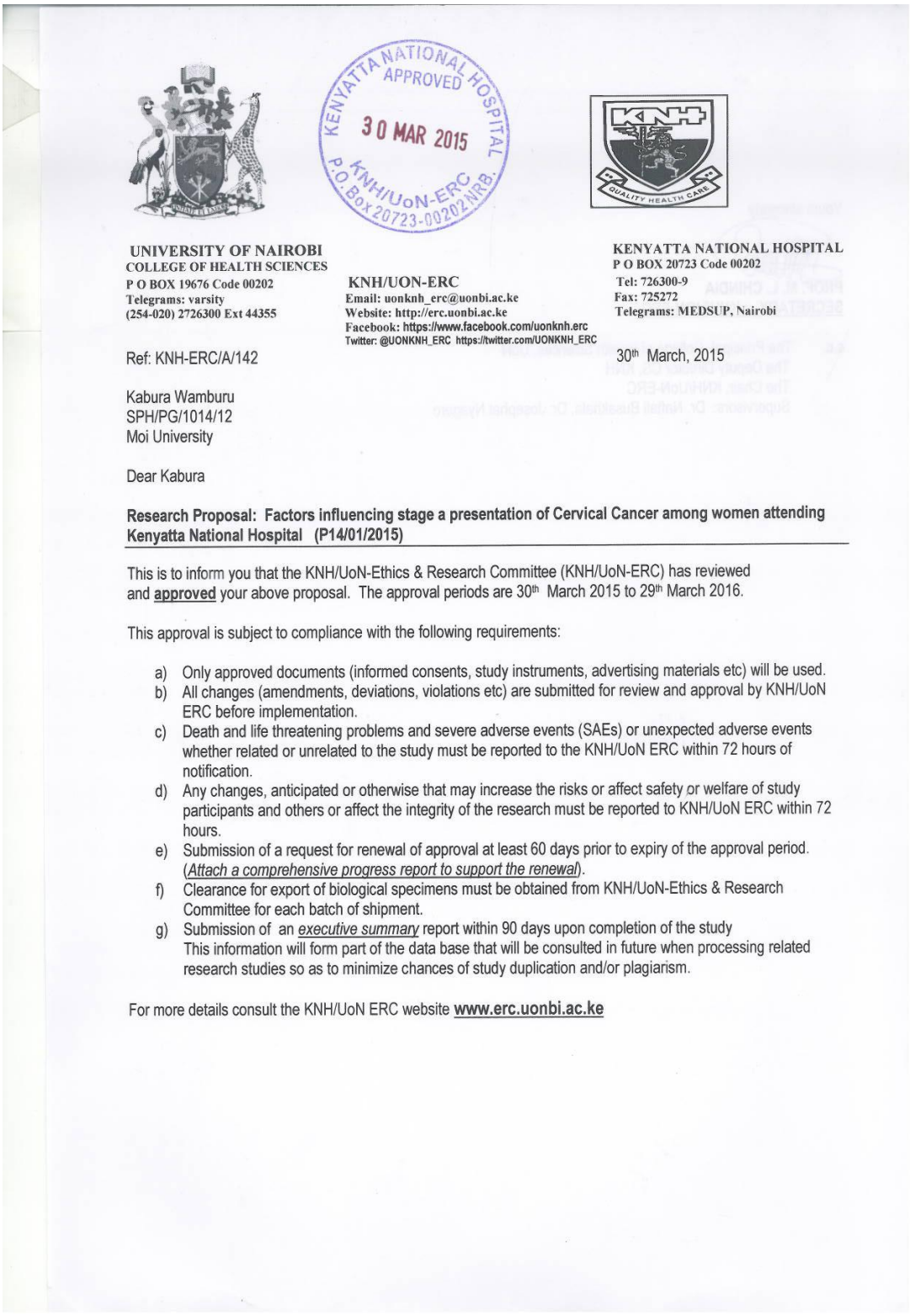
You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects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

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc Director - MTRH, Dean - SOP, Dean - SOM
Principal - CHS, Dean - SON, Dean - SOD

Appendix 6: KNH/UON-ERC Approval Letter



KENYATTA NATIONAL HOSPITAL APPROVED 30 MAR 2015 KNH/UoN-ERC P.O. Box 20723-00202 NRB.

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

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://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/142

30th March, 2015

Kabura Wamburu
SPH/PG/1014/12
Moi University

Dear Kabura

Research Proposal: Factors influencing stage a presentation of Cervical Cancer among women attending Kenyatta National Hospital (P14/01/2015)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 30th March 2015 to 29th March 2016.

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 severe 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 72 hours.
e) 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*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
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 research studies so as to minimize chances of study duplication and/or plagiarism.

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