# PREVALENCE AND MANAGEMENT OF CANCER PAIN IN AMBULATORY PATIENTS AT KENYATTA NATIONAL HOSPITAL

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**MBChB**

**A DISSERTATION SUBMITTED AS PART OF FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE IN INTERNAL MEDICINE, UNIVERSITY OF NAIROBI.**

## DECLARATION

This dissertation is my original work and has not been presented for a degree at any other university or previously published

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**ACKNOWLEDGEMENTS**

I would like to express my sincere and heartfelt gratitude to the following;

The Almighty God for bringing me this far.

My supervisors;

Professor Othieno Abinya, for his guidance in preparation of this thesis. He has been a great advisor.

Professor Erastus Amayo, for his expert and wise guidance right from proposal preparation until the completion of this thesis. He has been a wonderful advisor.

Dr Esther Munyoro for her positive criticism and valuable contribution in preparing this thesis.

I would also like to thank Mr. Kenneth Mutai, my statistician for effectively and efficiently analyzing my data.

I am also grateful to my research assistants Prudence and Edith for their assistance during data collection.

I would also like to thank Kenyatta National Hospital for providing the financial grant to carry out this study.

Finally I would like to thank my family Flo, Elsie and Faith for their patience and support.

**TABLE OF CONTENTS**

**ABBREVIATIONS.**

| | | |
|---|---|---|
| AMPA | - | Alpha amino hydroxyl methyl isoxazole propionic acid |
| ATP | - | Adenine triphosphate |
| BPI | - | Brief Pain Inventory |
| COX | - | Cyclooxygenase |
| ECOG | - | Eastern Co-operative Oncology Group |
| EFIC | - | European Federation of IASP Chapters |
| EPIC | - | European Pain In Cancer |
| GABA | - | Gamma amino butyric acid |
| HIV | - | Human Immunodeficiency Virus |
| IASP | - | International Association for the Study of Pain |
| KEMRI | - | Kenya Medical Research Institute |
| KNH | - | Kenyatta National Hospital |
| NEJM | - | New England Journal of Medicine |
| NMDA | - | N- methyl D Aspartate |
| NRS | - | Numerical Rating Scale |
| PAG | - | Periaqueductal gray |
| PMI | - | Pain Management Index |
| RVM | - | Rostral ventral medulla |
| VAS | - | Visual Analogue Scale |
| VRS | - | Verbal Rating Scale |
| WHO | - | World Health Organization |
| 5HT3 | - | 5-hydroxytryptamine 3 |

## ABSTRACT.

**Background:** Cancer is a leading cause of death worldwide and an important cause of morbidity and mortality in Kenya. Pain is one of the most common and distressing symptoms in cancer patients. Pain is an important determinant of a cancer patient's quality of life. Adequate management of cancer pain is required to improve the quality of life in cancer patients. The current prevalence of cancer pain and its management in Kenya is unknown. This study aimed to determine the prevalence and management of cancer pain in patients and correlate this with patient characteristics.

**Objective:** To determine the prevalence and management of cancer pain in ambulatory cancer patients attending the Kenyatta National Hospital oncology clinics.

**Methods:** The study was carried out in the hemato-oncology and radio-oncology clinics of Kenyatta National Hospital. Ambulatory cancer patients were consecutively recruited in this cross sectional survey to a sample size of 520 patients. We recruited patients who had a pathological diagnosis of cancer, were aware of their diagnosis, were 18 years and older and gave written consent. We excluded patients with severe cognitive or mental illness or in remission for cancer. Each patient was interviewed using the BPI questionnaire for assessing presence of cancer pain, cancer pain severity and management. Information on cancer type, treatment information and currently prescribed analgesics was obtained. The adequacy of pain management was calculated using the PMI, which compares the potency of analgesic used with the severity of pain experienced by the patient.

**Results:** The population was middle aged (mean age 50 years). Majority (74%) of the sample population was female. The commonest cancers were breast (31.2%) and cervix (24.2%). Prevalence of cancer pain was found to be 38.5%. Metastatic cancer was associated with increased likelihood of having cancer pain (P=0.044, OR, 1.9). A poorer functional status (P<0.001, OR, 4.4) and a longer duration since diagnosis (P=0.011, OR, 0.986) were associated with more likelihood of presence of cancer pain. Pain was sub optimally managed in 65% of cancer patients. Forty seven percent of the cancer patients with pain were on non opioid drugs, while 13% were on no analgesics. Only 10% were on a strong opioid. Presence of metastatic disease was associated with less likelihood of inadequate pain management (OR 0.5, P=0.045).

**Conclusion**s: Cancer pain is common in patients at Kenyatta National Hospital and its management is insufficient. Action should be taken to include cancer pain screening in management of cancer patients. Cancer symptom management guidelines tailored around the WHO cancer pain relief guidelines should be developed. Increasing awareness among clinicians on pain management should be undertaken.

## 1.0 DEFINITION OF PAIN

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage[1]. It is a state of discomfort (sensory component) and distress (affective component) and corresponds poorly to the degree of tissue destruction. Intensity is not proportional to extent and type of tissue damage.

It is a subjective multidimensional experience unique to the individual[2]. It has physical, psychological, social and spiritual dimensions. It consists of a multi-dimensional phenomenon having sensory discriminative, cognitive evaluative and affective motivational components[3].

Pain may be characterized as acute or chronic, nociceptive or neuropathic. Acute pain is protective and physiological. It is the normal pain that alerts an individual of tissue damage. It is nociceptive. It usually resolves with healing. Chronic pain is always pathological. It is usually neuropathic though it may be both neuropathic and nociceptive. It may be malignant or non malignant. Nociceptive pain may be somatic or visceral.

## 1.1 PAIN PATHOPHYSIOLOGY

Experience of pain is complex[4]. Tissues are usually damaged by mechanical, thermal or chemical stimuli. These stimuli induce release of chemical substances such as prostaglandins, bradykinin, serotonin, histamine and substance P. These neurotransmitters stimulate peripheral nociceptive receptors. Pain is then transmitted through the nerve endings (nociceptors) to the spinal cord via the Aδ and C fibers[5].

## 1.2 ASSESSMENT OF PAIN

No objective measure for pain exists [6]. It is a symptom which when present, is a subjective indicator perceptible only to the patient. The patient's self report of pain is thus the gold standard of pain assessment. There is no universally accepted tool for assessment of cancer pain[6]. Many different assessment tools are used throughout the world.

European Association of Palliative Care recommends use of standardized pain assessment tools in research and clinical practice [7]. These include unidimensional scales; visual analogue scales (VAS), numerical rating scales (NRS), and verbal rating scales (VRS) especially in the cognitively impaired, very elderly or patients in the dying phase. They measure one dimension of the pain experience, for example, intensity. They are accurate, simple, and easy to use and understand. They are commonly used for acute pain assessment like post operative pain assessment.

The multidimensional pain assessment tools provide information about the qualitative and quantitative aspects of pain. They are more useful in chronic and neuropathic pain. They require the patient to have good verbal skills and sustained concentration as they take longer to complete. These include Brief pain inventory, McGill pain questionnaire, multi-dimensional pain

inventory, pain disability index and Memorial pain assessment scale. The Brief Pain Inventory is a multidimensional pain assessment questionnaire incorporating the NRS and VRS and has been validated in different cultures.

## 1.3 BRIEF PAIN INVENTORY QUESTIONNAIRE

The Brief Pain Inventory (BPI) questionnaire is a multidimensional pain assessment tool. It has demonstrated reliability and validity in different cultures and languages. It has been adopted in different countries for clinical pain assessment, epidemiological studies and in studies of the effectiveness of pain treatment[40]. The Brief Pain Inventory questionnaire is a two part questionnaire with the first part addressing the presence or absence of cancer pain, and the second part the pain severity, its effect on the patient's general wellbeing and its management.

The prevalence of cancer pain is determined by dividing number of patients who respond affirmatively to the screening questions for the presence of pain by the number of patients screened. The questionnaire then asks the patients to attribute their pain to either their primary disease, the effects of its treatment or another medical condition

An answer in the affirmative then leads to the second part of the questionnaire, which determines the site of the pain, the severity of the pain at its worst, least for the last 1 week and on average using a numerical rating scale of 1 to 10.

Pain at the time of interview is also rated. Aggravating and relieving factors are also determined.

Pain medication being used is determined and the level of relief it provides to the patient. Cancer pain effect on the patient's general activity, mood, sleep, walking ability, normal work, relations with other people and enjoyment of life is also assessed using a numerical scale of 1 to 10.

## 2.0 LITERATURE REVIEW

### 2.1 CANCER EPIDEMIOLOGY

Cancer is a leading cause of death worldwide with 7.6 million deaths occurring annually, constituting 13% of all deaths[8]. 70% of cancer deaths in 2008 occurred in low and middle income countries. The deaths are projected to rise to 13.1million by 2030[9].

Estimated cancer incidence in Kenya was 129.4/100,000 in 2008. There were 12,647 reported cases [9]. This could be an underestimate due to under-diagnosis and under-reporting. The five most common types of cancer globally are of the lung, breast, colorectal, stomach and prostate[9]. Breast cancer and prostate cancer are the most common in females and males respectively[9]. There is currently no national cancer registry in Kenya. The Nairobi cancer registry located at KEMRI captures data from Nairobi and its environs, while the Eldoret cancer registry, located at the Moi Teaching and Referral Hospital captures data from the North Rift and Western provinces of Kenya.

According to the Nairobi cancer registry[10] in 2002, 3310 cancers were detected between the years 2000 and 2002. 54.3% were females and 45.6% were males. The most common cancers in males were cancer of the esophagus, cancer of the prostate, stomach cancer, kaposi's sarcoma and liver cancer. For females, cancer of the breast, cancer of the uterine cervix, esophageal cancer and stomach cancer were reported as the most common.

Tenge et al[11] analyzed data from the Eldoret cancer register from 1999 to 2006. Estimated incidence of cancer was 671 cases per year with a male to female ratio of 1:1. Solid tumors accounted for 79% of the cases, with the commonest being of esophageal origin. Cancer of the cervix was the most common in females while prostate cancer was the most common in males.

### 2.2 PAIN IN CANCER

Throughout their clinical course, cancer patients suffer from various symptoms, including pain, fatigue and dyspnea that impair bodily functions and quality of life[12]. Anneli et al[12] studied a cohort of patients with advanced cancer and found that pain is the most common symptom in advanced cancer. Management of these symptoms has been recognized as crucial in improving cancer patients' quality of life[12].

Pain is a common symptom experienced by cancer patients[13]. Cleary et al[13] reported pain, fatigue, dyspnoea and psychological symptoms to be the commonest symptoms in advanced cancer. Pain prevalence and severity increases with progression of the disease, increasing to 74%

in metastatic disease[13]. He also stated that symptom management should extend from the initial care in seeking a cure to the final hours of a patient's life. Mwanda et al[15] et al studied the quality of life in 42 male cancer patients at Kenyatta National Hospital. He found pain to be one of the chief complaints by the patients. It was present in 21% of them and it negatively affected their quality of life.

Pain is also a major determinant of the quality of life in cancer patients[16.] In a study done by Di Deng et al[16], presence of moderate to severe pain had significantly impaired quality of life. It significantly correlated with mood, appetite, sleep and fatigue.

In Thailand, Thienthong et al[17] studied the effect of better pain management on the health related quality of life. Seventy six percent of patients had pain in 2 sites with an average quality of life score of 58.6%. He found that a decrease in pain scores of at least three points had a significant impact on the patients' quality of life by raising the quality of life to 61%.

There is a strong relationship between psychological factors and chronic cancer pain. It is strongly associated with psychological distress and moderately affected by social support[18].

Pain can kill[19]. Liebeskind[19] et al demonstrated that pain repressed the body's immune system and could indirectly promote tumor growth. Cancer pain is usually chronic i.e. persistent and prolonged. It may also involve breakthrough pain i.e. transient exacerbation of pain that occurs either spontaneously or in relation to a specific predictable or unpredictable trigger, despite relatively stable and adequately controlled background pain[20].

Pain in cancer may be distressing and incapacitating if not well controlled. Cancer pain results from mixed mechanisms, since it rarely presents as a pure neuropathic, somatic or somatic pain syndrome, but as a complex one with inflammatory, neuropathic and or ischemic components, often at multiple sites. [14,21,22.]

Causes of cancer pain may include;

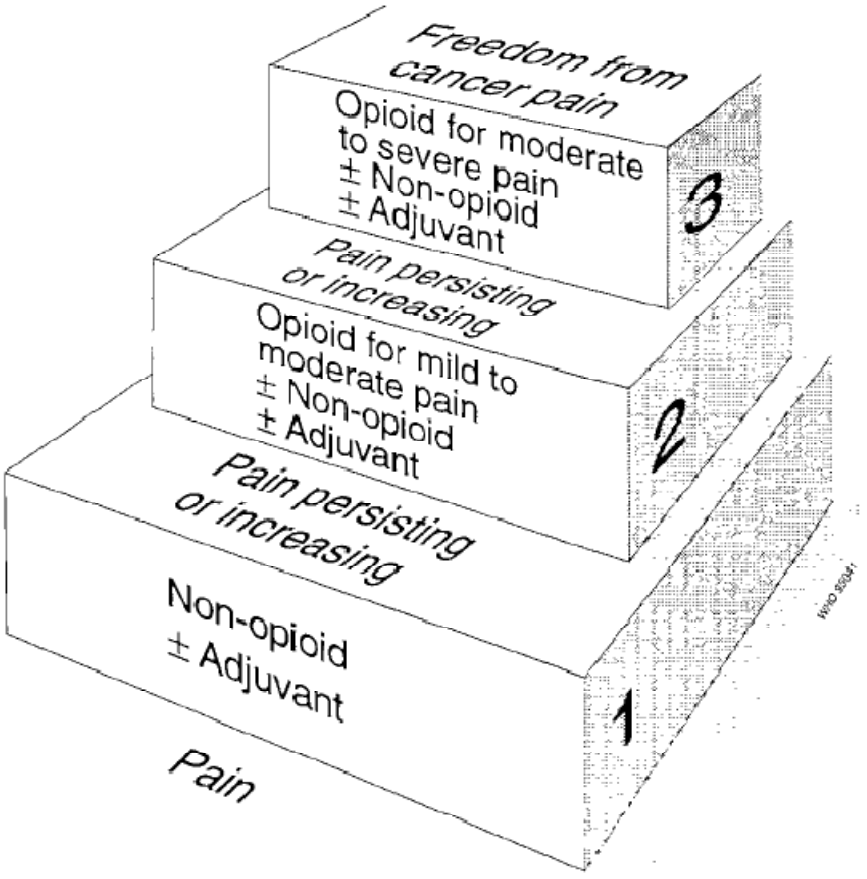
- Tumor causing nerve or spinal cord compression; neuropathic pain,
- Tissue inflammation and damage; nociceptive pain,
- Obstruction of blood vessels, lymph vessels or part of gastrointestinal system,
- Surgery, radiotherapy or chemotherapy induced tissue damage.
- Direct tumor involvement is the most common cause of pain, present in 67% of patients with pain from metastatic cancer[12]. This is from bone invasion by tumor (50%), nerve compression or infiltration, or involvement of the gastrointestinal tract or soft tissue (50%). Up to 25% of patients have pain related to their therapy.

## 2.3 CANCER PAIN MANAGEMENT

Access to pain management is a fundamental human right[23]. The WHO, IASP and EFIC on October 11 2004 declared the treatment of pain a human right in what is referred to as the declaration of Montreal. Several guidelines for cancer pain management have been published[5, 24, 25, and 26].

In the European Association for Palliative Care guidelines by Hanks et al[25], morphine is the drug of choice for moderate to severe cancer pain. Jacox [26] indicated that drug therapy is the cornerstone in management of pain in cancer.

The WHO cancer pain relief guidelines[24] which were released in 1986 are simple and easy to follow. They emphasize administration of analgesics orally and at fixed time intervals using the WHO analgesic ladder illustrated below.




WHO ANALGESIC LADDER (Adapted from WHO cancer relief Guidelines 1986)

Cancer pain can be relieved in 70-90% of patients using an opioid based analgesic regime and WHO analgesic guidelines regime[27, 28, 29].

Zech et al[27] found that the WHO cancer pain relief guidelines achieved pain control in 88% of cancer patients in a 10 year prospective study. Ventafridda et al[28] found that the WHO analgesic ladder was efficacious in 71% of cancer pain patients.

Mercadante et al[29] reported adequate pain control in 70-90% of patients with cancer pain, using the WHO analgesic ladder.

Adequacy of pain management can be assessed by the Pain Management Index and the morphine consumption data. Both are based on WHO guidelines for cancer pain.

## 2.4 PREVALENCE OF CANCER PAIN STUDIES

Beck et al[30] studied the prevalence and management of cancer pain in South Africa. She used the BPI questionnaire from the Pain Research Group, Department of Neurology; University of Wisconsin-Madison. She found 35.7% of cancer patients had cancer related pain. She also found 30.5% of the patients with cancer pain had a negative score on the Pain Management Index, a comparison of the most potent analgesic used by a patient relative to their worst pain.

In the EPIC study, a pan-European survey of prevalence, treatment and patient attitudes on cancer-related pain conducted by Breivik et al[31], involving 5084 adults, the overall pain prevalence was found to be 72%, with 56% patients experiencing moderate to severe pain. In 69% of patients, pain affected their everyday activities despite treatment. Thirty two percent of patients reported the pain was so bad they wanted to die.

Cleeland et al[32] studied treatment of pain in 1308 outpatients with metastatic cancer from 54 treatment locations affiliated with the Eastern Cooperative Oncology Group. Sixty seven percent of patients reported pain and 42% had inadequate analgesia using the pain management index. Inadequate pain management was commoner in those aged 70 years or older, females and minorities.

Larue et al[33] studied cancer pain and its treatment in France among 605 patients in a multicentre study. Cancer pain prevalence was 57% and was commoner in metastatic disease. Fifty one percent of patients had a negative PMI. Inadequate treatment of pain was significantly associated with younger patients, patient without metastatic disease and those with better performance status.

Liu et al[34] found a cancer pain prevalence of 61% in a national survey in China. Majority (85%) of pain was caused by advanced cancer, while the main reasons for poor management were over-concern on opioid analgesic addiction and reluctance to report pain.

A meta-analysis of 52 studies on prevalence of cancer pain, a systemic review of the past 40 years, done by Marieke et al[35] showed greater than 50% prevalence of pain in patients with cancer. Patients on curative anti-cancer treatment had higher risk of not being treated adequately for their pain than patients on palliative anti-cancer treatment. Patients with low education levels were also at greater risk of receiving inadequate pain treatment than patients with high education levels.

Deandrea et al[36] assessed prevalence of under-treatment of cancer pain using the pain management index via a meta-analysis of studies on medline. Twenty six studies were included in the analysis. Forty three percent of patients had a negative PMI indicating inadequate treatment. Patients who were rated less ill, with better performance status and at an early stage of the disease were more likely to receive inadequate analgesia.
Okuyama et al[37] studied the adequacy of pain management in a Japanese cancer Hospital. He studied 138 ambulatory cancer patients with pain. Physicians undertreated pain in 70% of patients. Patients with better ECOG performance status and those without metastasis were undertreated more frequently than other patients in the study.

Demographics have been shown to play a role in influencing adequacy of analgesia. Cleeland et al[32] found that minorities, were three times more likely to have a negative PMI score. Women, patients who were 70years or older and patients rated as less ill were more likely to have inadequate analgesia.
The more advanced the cancer, the more prevalent and more common is the cancer pain.

## 3.0 JUSTIFICATION

Cancer is common and on the increase in our population as a non communicable disease. Pain is a common symptom in cancer patients which negatively affects their quality of life. There is currently no national or KNH policy on cancer pain relief.

Following the enactment of the cancer prevention and control act in June 2012, the results of this study will form baseline information for the Cancer Prevention and Control Institute on the state of cancer pain management. In advanced disease as most of our patients in Kenya present, establishing the prevalence and treatment of pain is important for policy makers in deciding approach to its treatment in cancer patients.

There is paucity of data pertaining to prevalence and management of cancer pain locally. The findings of this study are intended to contribute to the healthcare information database.

## 4.0 RESEARCH QUESTION

What is the prevalence and the management of cancer pain in ambulatory patients at Kenyatta National Hospital?

## 5.0 OBJECTIVES

### 5.1 PRIMARY OBJECTIVES

The primary objectives were:

- To determine the prevalence of pain in ambulatory cancer patients attending the oncology clinics in Kenyatta National Hospital.
- To document the pain treatment that ambulatory cancer patients are getting in KNH oncology clinics.
- To determine the adequacy of pain management in ambulatory cancer patients at KNH oncology clinics.

### 5.2 SECONDARY OBJECTIVE

The secondary objective was to correlate the prevalence of cancer pain and adequacy of pain management with;

a) age,
b) gender,
c) performance status
d) Stage of disease of the patients.

## 6.0 METHODOLOGY

### 6.1 STUDY DESIGN

The study was a cross sectional descriptive study

### 6.2 STUDY SITES

Hemato-oncology and radio-oncology clinics in Kenyatta National Hospital.

### 6.3 STUDY PERIOD

The study was carried out over a three month period between December 2012 and February 2013.

### 6.4 STUDY POPULATION

These were cancer patients receiving treatment at oncology clinics in Kenyatta National Hospital.

#### 6.4.1 Inclusion criteria

The study included patients who;

1. Were aged above 18 years of age
2. Gave written informed consent
3. Had a pathological diagnosis of cancer
4. Had been informed of their diagnosis of cancer
5. Had ongoing treatment for cancer

#### 6.4.2 Exclusion criteria

The study excluded;

1. Patients suffering from severe cognitive or mental disorder
2. Patients in documented remission for cancer.

### 6.5 SAMPLE SIZE

The following formula was used

$$n = \frac{Z^2 * P\,(1-P)}{d^2}$$

n= sample size
t=1.96 (95% confidence interval)
p=estimated prevalence (Beck et al 2001)
m= margin of error at 7%

Beck et al found a prevalence of pain in cancer patients of 35.7% and the proportion with inadequate pain management was 30.5%.

By substituting into the formula, a minimum sample of 466 patients was required to estimate the prevalence of pain in cancer patients.
The estimated prevalence value used had been obtained from the prevalence study done by Beck et al in South Africa.
Using the South African prevalence of 35.7%, 155 patients would be assessed for adequacy of pain management.

| Objective | Prevalence | n | With pain |
|---|---|---|---|
| Prevalence of pain in cancer patients | 35.7% | 180 | 55 |
| Proportion of patients with inadequate pain management. | 30.5% | 466 | 166 |

## 6.6 SAMPLING METHOD

The method used was stratified random sampling from the oncology clinics. There are two main oncology clinics in which 93% of cancer patients are followed up. Stratification was based on the number of patients seen in each of the two clinics per week. Sixty percent of patients were derived from the radio-oncology clinic while the remaining forty percent were recruited in the hemato-oncology clinic.

| Clinic | Numbers per week | Ratio | Sample |
|---|---|---|---|
| Hemato-oncology | 100 | 0.4 | 180 |
| Radio-oncology | 150 | 0.6 | 286 |
| Total | 250 | 1 | 466 |

## 6.7 SCREENING, RECRUITMENT AND CLINICAL METHODS

The files of oncology patients presenting to the relevant clinic were screened for eligibility. Patients found to be eligible were informed about the study and consent was sought. Those willing to participate signed an informed consent form (see appendix 2). Patients who gave consent were recruited into the study.

The pathological diagnosis of the cancer, history of cancer specific treatment modalities, intention of treatment i.e. whether cure or palliative was all obtained from the file. Socio-demographic data was obtained from the patient by direct questioning. An ECOG score as an objective functional assessment was recorded.

The Brief Pain Questionnaire (see Appendix 4) was administered by the principal investigator or his two trained research assistants (clinical officers). The assistants were trained for two days and a pilot study done to ensure standardization of their work. For patients who could not understand English a translator was used. A Swahili version of the Brief Pain Questionnaire was also available (see Appendix 5).

The time spent with each patient was approximately 30 minutes.

For ease of administration locally, especially to the illiterate participants, the numerical rating scale and visual analogue scale were combined for quantifying the severity of pain. a translator was also used. A Swahili version of the BPI was also available.

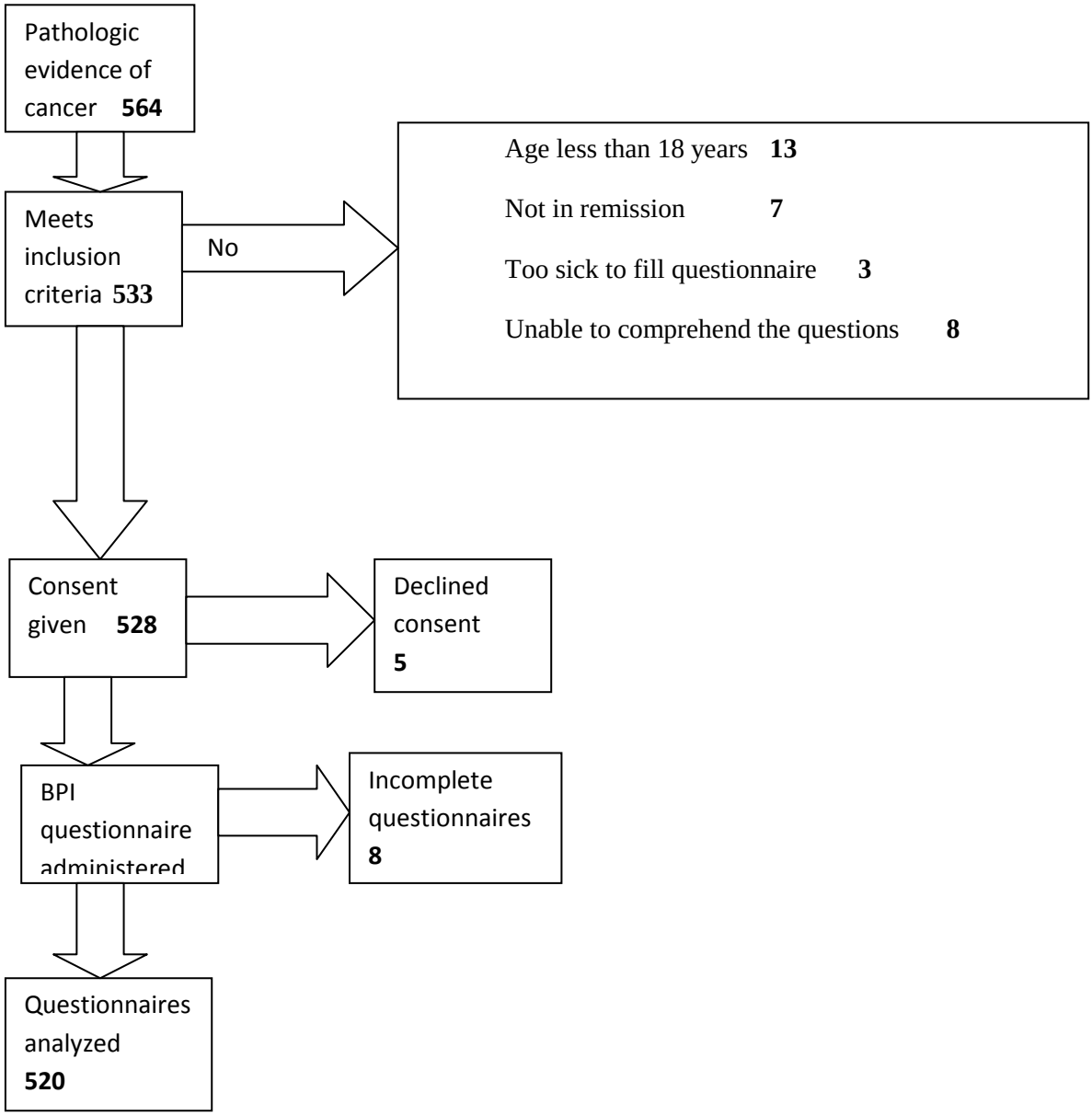
## 6.8 PAIN MANAGEMENT INDEX

The Pain Management Index was used to determine the adequacy of pain management. It was calculated as follows: The most potent analgesic prescribed was classified at one of four levels: 0= no analgesics, 1= non opioid analgesics, 2= weak opioid, 3= strong opioid.

Patients' self-reports on pain on the BPI was classified into three groups based on its severity. 0= no pain, 1 = mild pain (ratings 1-3), 2= moderate pain (ratings 4-7), 3= severe pain (ratings 8-10).

The PMI, calculated by subtracting the pain level from the analgesic level can thus range from -3 to 3, with the lower value representing greater under treatment. Negative PMIs are considered to be an indicator of under treatment regarding analgesics, and scores of zero or more are considered to be conservative indicators of acceptable treatment.
The patients were interviewed after being reviewed by the doctor so that any adjustment to the patient's analgesic therapy could be made when filling the Brief Pain Inventory questionnaire.

## 6.9 Flow chart



## 6.10 DATA MANAGEMENT AND ANALYSIS

All data forms were stored in a secure cabinet accessible only to the principal investigator and statistician. Data was cleaned, verified and entered into a password protected computer program.

Analysis was carried out using the Statistical Package for Social Scientists version 17.0

Means, modes, medians and standard deviations, were used to describe continuous data, while proportions were used to describe categorical data.

Pearson's correlation was used to analyze associations between continuous variables and severity of pain, while associations with categorical data were analyzed using Chi square and Mann-U-Whitney test. The p value was set at 0.05.

## 7.0 ETHICS

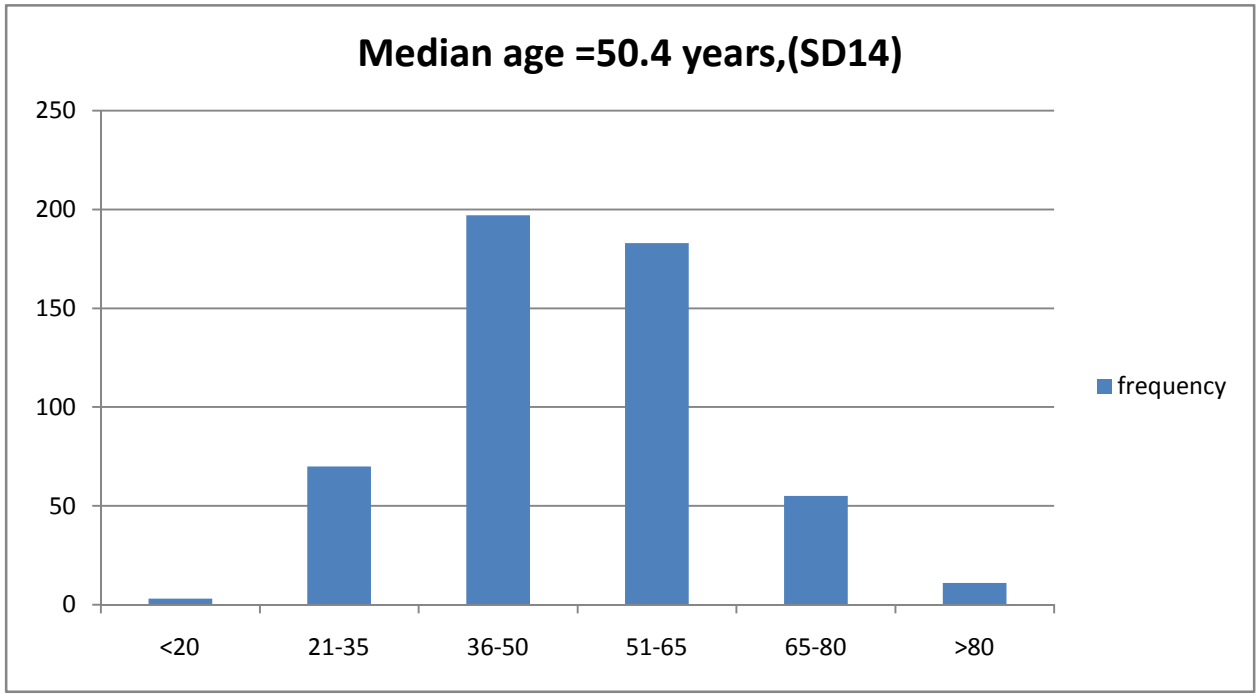
Before commencing, permission to carry out this study was sought from the Ethics and Research Committee of Kenyatta National Hospital/University of Nairobi after presentation and clearance from the Department of Clinical Medicine and Therapeutics, University of Nairobi. Only patients who gave informed consent were recruited into the study. No patient was coerced into participating. There was no discrimination against any patient who declined to participate.

All information collected was treated as confidential. Any information that was important for the management of the patient was communicated to the primary health care provider without delay.

## 8.0 RESULTS

The study was carried out between December 2012 and February 2013. A pool of 564 patients was identified for the study. We recruited 338 patients from the radio-oncology clinic while 226 patients were recruited from the hemato-oncology clinic. However, 13 patients were excluded due to being underage, 5 declined consent, 7 were in remission, 3 were too sick to fill in the questionnaire and 8 were unable to comprehend the questions since they could not understand English or Swahili. In addition, 8 questionnaires were incomplete and could not be used to meet the study objectives. Thus, 92% of the population screened during the designated time frame was included. The age ranged from 19 to 95 with a mean age of 50 years. This is illustrated in the figure 1 below.

**Figure 1: Age distribution of the cancer patients (n=520)**




Majority (74%, n=385) of patients were female. Majority of the patients were married at 62.7%, while 16% were either single or widowed. Approximately 90% of the patients had some form of schooling, with 13.5% having attended a tertiary institution. More than 40% of the patients were working either full time or part time. The social demographic and clinical characteristics of the cancer patients are shown in the table 1 below.

**Table1: Social demographic characteristics of the cancer patients. n=520**

| Variable | Frequency (%), n=520 |
|---|---|
| Mean **age** (SD) | 50.4(SD,14.0) |
| Min – Max | 19.0 - 95.0 |
| **Age** | |
| <20 years | 3 (0.6) |
| 21-35 years | 70 (13.5) |
| 36-50 years | 197 (37.9) |
| 51-65 years | 183 (35.2) |
| 66-80 years | 55 (10.6) |
| >80 years | 11 (2.1) |
| Missing | 1 (0.2) |
| **Sex** | |
| Male | 135 (26) |
| Female | 385 (74) |
| **Marital status** | |
| Single | 85 (16.3) |
| Married | 326 (62.7) |
| Widowed | 87 (16.7) |
| Separated/divorced | 22 (4.2) |
| **Education** | |
| None | 54 (10.4) |
| Primary | 213 (41.0) |
| Secondary | 183 (35.2) |
| Tertiary | 70 (13.5) |
| **Job status** | |
| Working outside the home,fulltime | 147 (28.3) |
| Working outside the home,part-time | 67 (12.9) |
| Homemaker | 148 (28.5) |
| Retired | 65 (12.5) |
| Unemployed | 87 (16.7) |
| Self employed | 6 (1.2) |

## The cancer descriptions

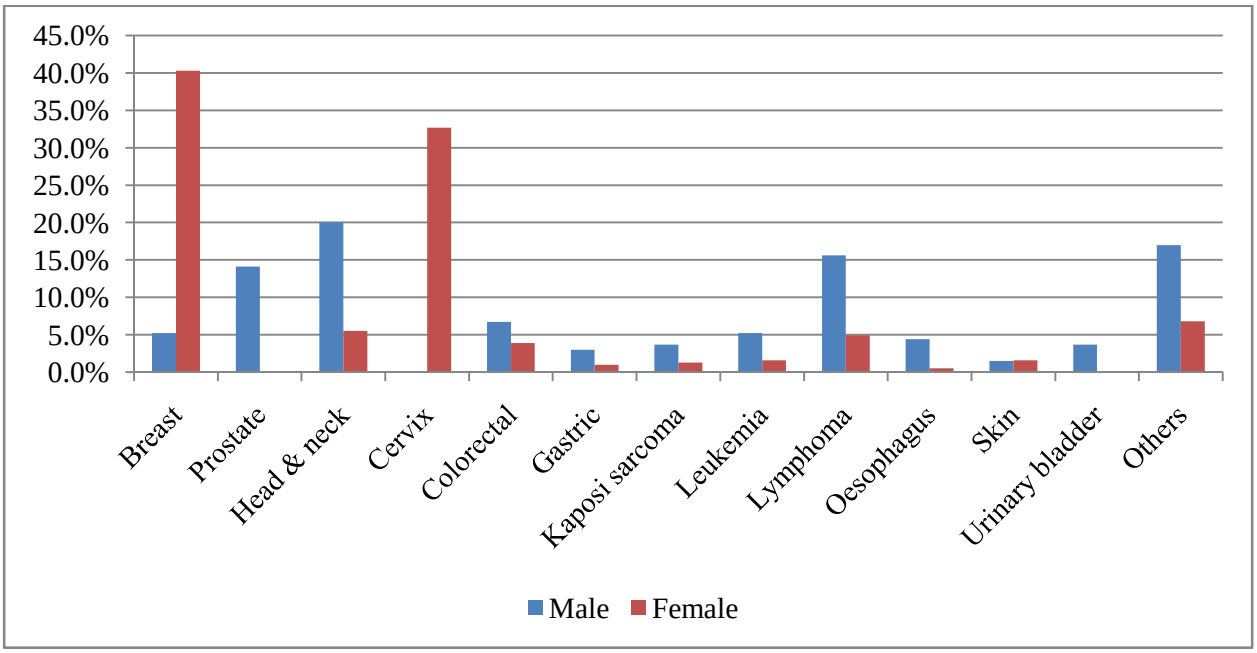
Table 2 below summarizes the predominant sites of cancer for both men and women. Breast cancer and cancer of the cervix were the most predominant cancers representing 55.4% of the total sample so these cancers are over represented in the sample. These two cancers were the commonest cancers in females. The commonest cancers in males were head and neck, lymphoma and prostate cancer. These accounted for almost half of all male cancers. These findings are illustrated in figure 2 below. Only 15% of patients had metastatic disease, while 18% were in a poor

functional state at an ECOG status of 2 or more. In almost half of the patients, the cancer diagnosis had been made within the preceding year.

**Table 2: The distribution of the different cancers in our study population.**

| Variable | Frequency (%,) (n=520) |
|---|---|
| **Cancer diagnosis** | |
| Breast | 162 (31.2) |
| Cervix | 126 (24.2) |
| Head & neck | 48 (9.2) |
| Lymphoma | 40(7.7) |
| Colorectal | 24 (4.6) |
| Prostate | 19(3.7) |
| Leukemia | 13 (2.5) |
| Multiple myeloma | 13 (2.5) |
| Kaposi's sarcoma | 10 (1.9) |
| Gastric | 8 (1.5) |
| Skin | 8 (1.5) |
| Oesophagus | 8 (1.5) |
| Urinary bladder | 5 (1.0) |
| Others | 36 ( 6.9) |

**Figure 2: Gender distribution of cancers in study population. (n=385, 135)**



Additional patient characteristics are shown in the table 3 below.

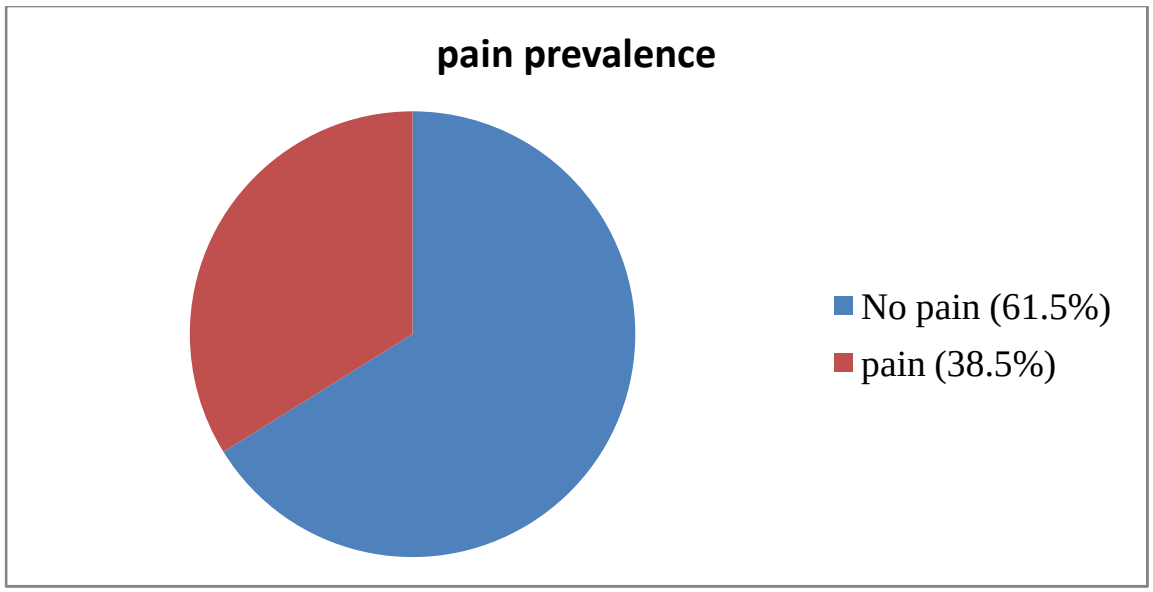
**Table 3: Additional cancer patient characteristics.**

| Variable | Frequency(%)n=520 |
|---|---|
| **Cancer description** | |
| Metastatic | 77 (14.8) |
| Non-metastatic | 443 (85.2) |
| **ECOG status** | |
| 0 | 189 (36.3) |
| 1 | 239 (46) |
| 2 | 71 (13.7) |
| 3 | 16 (3.1) |
| 4 | 5 (1) |
| **Duration of illness (months)** | |
| Median (IQR) | 12 (6 - 24) |
| Range | <1-300 |
| **Duration since diagnosis( months)** | |
| <12 | 254 (48.8) |
| 12-60 months | 234 (45.0) |
| >60 months | 29 (5.6) |
| Missing | 3 (0.6) |

## Cancer pain

A total of 200 patients (38.5%) reported having experienced pain or taken pain medication in the last one week. (95% CI; 34.6, 42.7) This is illustrated in figure 3 below.

**Figure 3: prevalence of cancer pain in the study population**




A total of 149 patients had pain attributable to the primary disease (cancer) while 24 attributed it to its treatment. Pain attributable to other medical conditions unrelated to their cancer diagnosis was present in 27 patients. Thus a total of 173 patients had pain attributable to their diagnosis of cancer.

There were 13 patients who had undergone surgery in the preceding month. These patients were excluded due to the possibility they may have had post surgical rather than disease related pain. The prevalence of pain attributable to cancer was thus determined to be 30.8%. We used all the patients with pain to assess pain management and calculate the Pain Management Index (adequacy of pain management). This was a point prevalence of pain.

Cancer pain was highest in cancers of the esophagus, skin and urinary bladder and lowest in Kaposi's sarcoma, leukemia and lymphoma. The table 4 below illustrates the prevalence of cancer pain in different cancers.

**Table 4: Prevalence of cancer pain by cancer type**

| | n=520 | Frequency (n=200) | (%) Percentage |
|---|---|---|---|
| **Type of cancer** | | | |
| Esophagus | 8 | 7 | 87.5 |
| Skin | 8 | 7 | 87.5 |
| Urinary bladder | 5 | 4 | 80.0 |
| Head and neck | 48 | 26 | 54.2 |
| Multiple myeloma | 13 | 7 | 53.8 |
| Prostate | 19 | 9 | 47.4 |
| Cervix | 128 | 49 | 38.9 |
| Gastric | 8 | 3 | 37.5 |
| Breast | 162 | 48 | 29.6 |
| Colorectal | 22 | 7 | 29.2 |
| Lymphoma | 40 | 11 | 27.5 |
| Leukemia | 13 | 3 | 23.1 |
| Kaposi sarcoma | 10 | 2 | 20.0 |
| Others | 36 | 17 | 47.2 |

## Pain intensity and management.

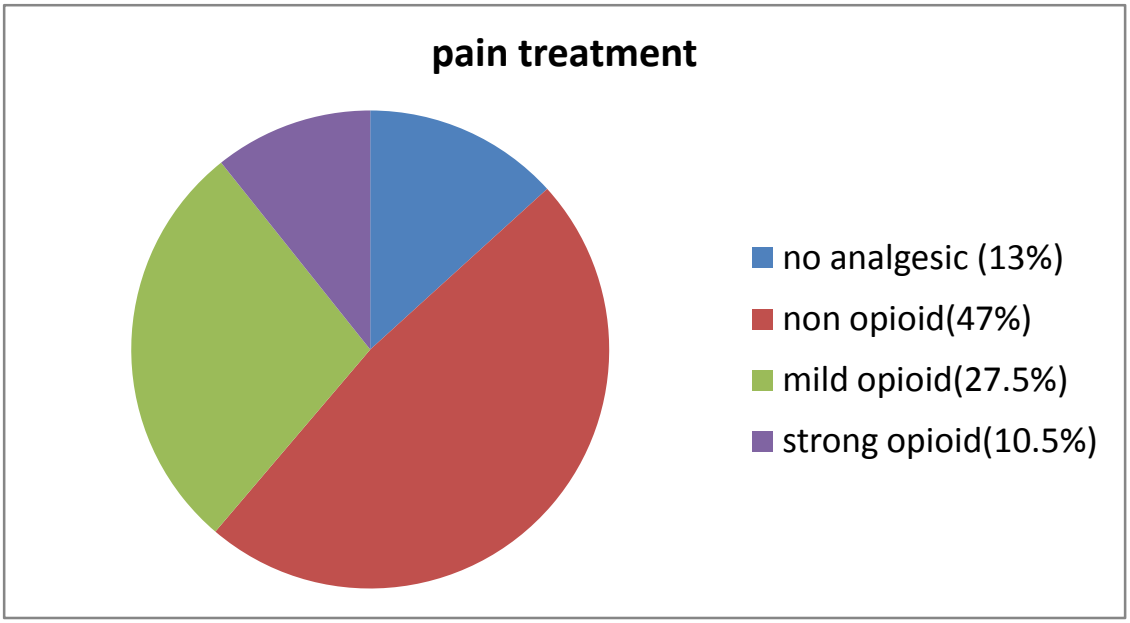
We evaluated the 200 patients found to have pain for its management. Among the patients with pain, 40% reported the pain as substantial at the time of filling the questionnaire (a score of 4 or higher). A total of 85% of patients reported their worst pain to be moderate or severe. Pain relief was attributed to medication in 70 %( 138) of patients, while18% were relieved by resting. Walking aggravated the pain in 26% of the patients.

Pain treatment was documented as the treatment prescribed by the doctor. A significant proportion of patients were not on analgesics prescribed by a doctor (13%, n=26) while only 10% were on strong opioids i.e. morphine. The majority (47%) were on non opioid analgesics i.e. paracetamol and non steroidal analgesics.

A majority of patients (59%) reported 100% relief after taking analgesics. However, 34% reported the pain recurred within 4 hours of analgesic therapy. Most (56.5%) preferred taking pain medications on a regular basis. A significant number of patients (44.5%) felt they needed a stronger type of medication while 30.5% of them felt they needed to take more of the pain medication than the doctor had prescribed.

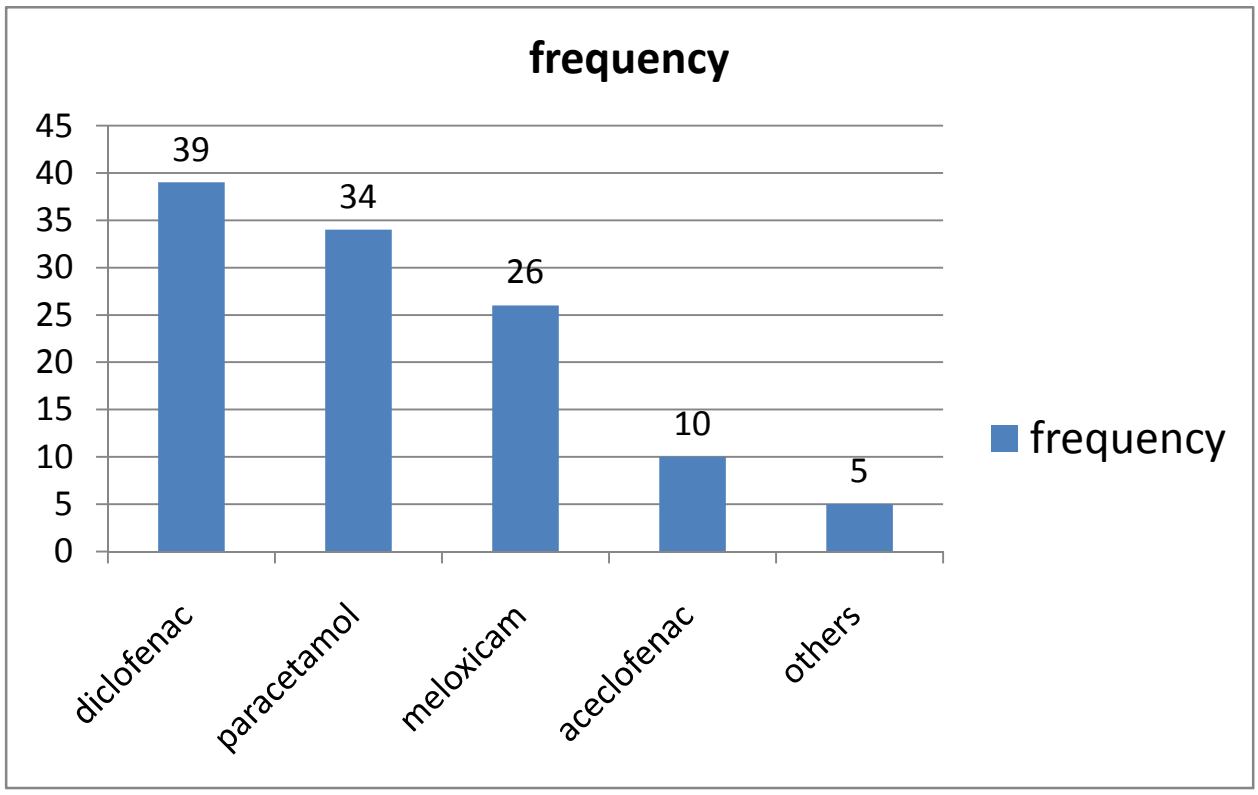
The frequency of the type of analgesic used is shown in the figure 4 below.

**Figure 4: Pain treatment in the study population (n=200)**



The non opioids commonly used are shown in the figure 5 below

**Figure 5: the most commonly used non opioid analgesics in our study population.**



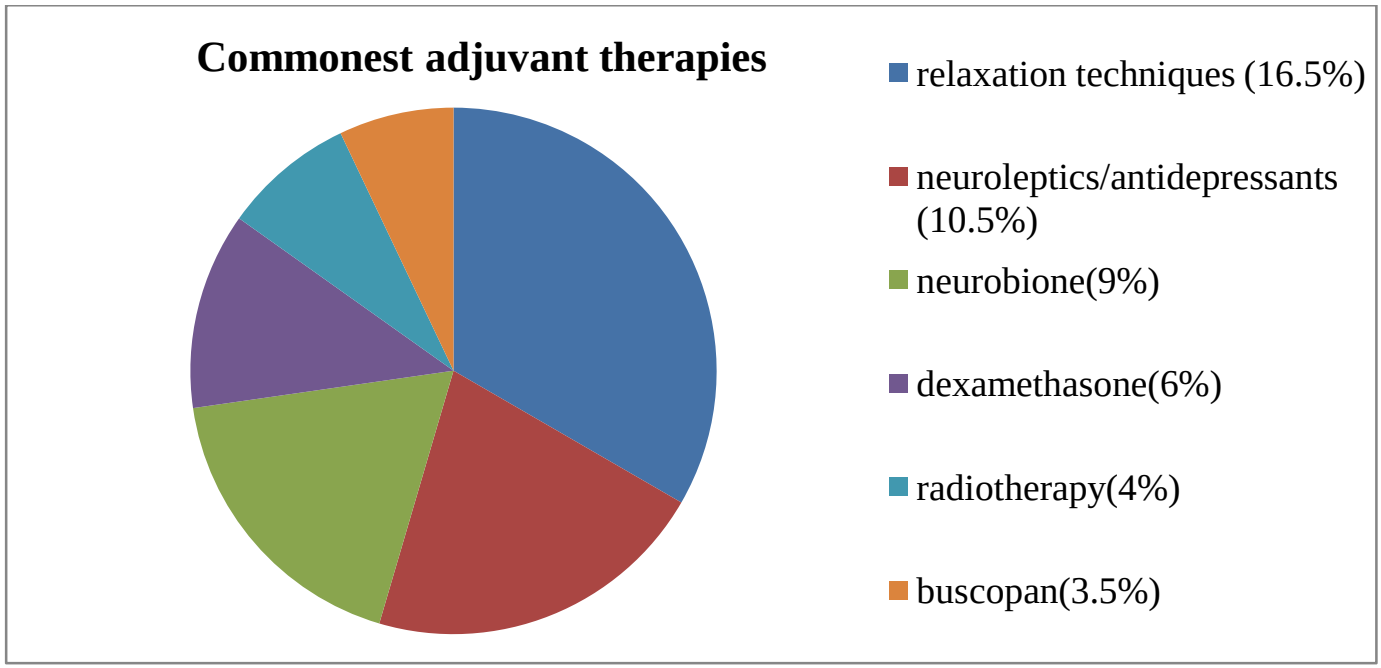

The most common used opioid and opioid-like analgesics are indicated in table 5 below

**Table 5: Most common opioid analgesics used in our cancer population**

| Drug | Frequency | Percentage |
|---|---|---|
| Dihydrocodeine | 41 | 20.5 |
| Morphine | 21 | 10.5 |
| Tramadol | 14 | 7 |
| Codeine | 6 | 3 |

The patients were on adjuvant medications and treatment as shown figure 6 below.

**Figure 6: The most common adjuvant therapies used by our cancer patients n=105**




A substantial number (34%) of the patients with cancer pain were on pain medications not prescribed by the doctor. These results are shown in the table 6 below

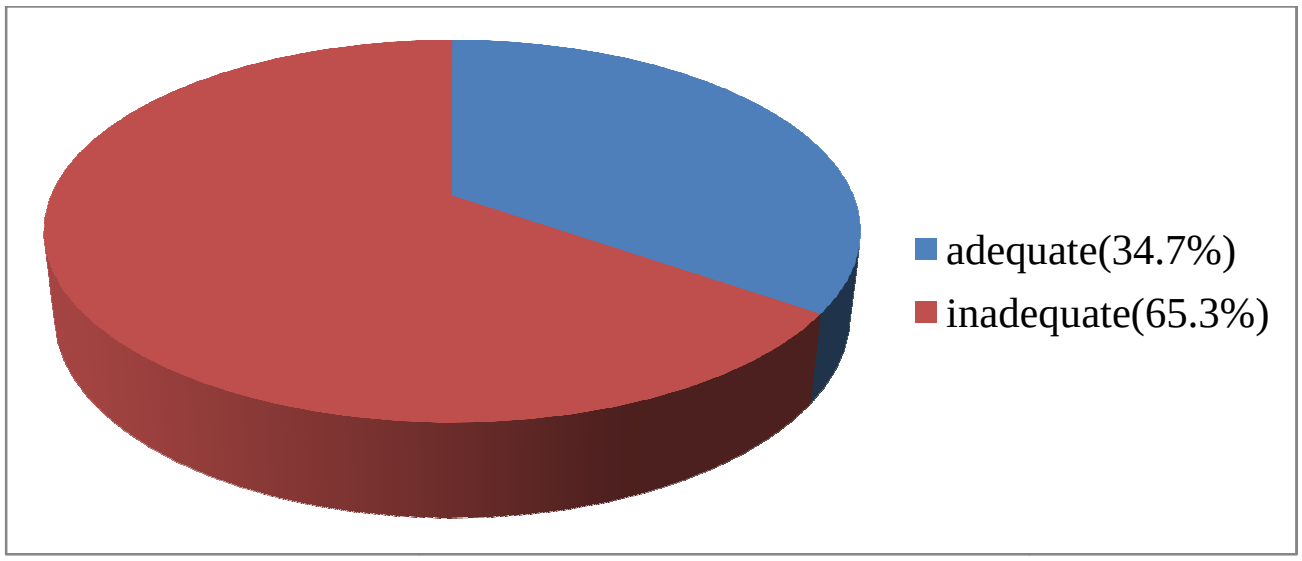
**Table 6: Most commonly used self pain medication**

| Drug | Frequency | Percentage |
|---|---|---|
| Paracetamol | 27 | 13.7 |
| Ibuprofen | 14 | 7.1 |
| Diclofenac | 12 | 6.1 |
| Pain gels | 2 | 1 |

The adequacy of pharmacological management was calculated using the Pain Management Index. This is a comparison of the most potent analgesic used as compared to the worst pain a patient is experiencing. The level of pain was scored as 1 for mild pain, 2 for moderate pain and 3 for severe pain. The level of analgesic was graded as 0 for no analgesic, 1 for non opioid analgesic, 2 for mild opioid and 3 for strong opioid. The Pain Management Index (PMI) was calculated for all patients

with pain. 65.3% of the patients with pain had a negative Pain Management index. Mean -0.84(SD 0.94). The negative Pain Management Index indicates inadequate pain management. This is illustrated in figure 7 below.

**Figure 7: Adequacy of pain management.**




**ASSOCIATION OF VARIABLES**

Bivariate analysis was done to explore the association of presence of cancer pain with age, gender, presence of metastasis and ECOG performance status. All the variables reached statistical significance.

Prevalence of cancer associations on bivariate analysis are summarized in table 7 below.

**Table 7: Correlations of pain with patient characteristics**

| Variable | Prevalence of cancer pain | | OR (95% CI) | P value |
|---|---|---|---|---|
| | Pain | No pain | | |
| **Age** | 53.5 (12.2) | 48.5 (14.8) | - | **<0.001** |
| **Sex** | | | | |
| Male | 66 (33.0%) | 69 (21.6%) | 1.8 (1.2-2.7) | **0.004** |
| Female | 134 (67.0%) | 251 (78.4%) | 1.0 | |
| **Cancer description** | | | | |
| Metastatic | 47 (23.5%) | 30 (9.4%) | 3.0 (1.8-4.9) | **<0.001** |
| Non-metastatic | 153 (76.5%) | 290 (90.6%) | 1.0 | |
| **ECOG status** | | | | |
| 0 | 27 (13.5%) | 162 (50.6%) | 1.0 | |
| 1 | 106 (53.0%) | 133 (41.6%) | 4.8 (3.0-7.7) | **<0.001** |
| 2 | 48 (24.0%) | 23 (7.2%) | 12.5 (6.6-23.8) | **<0.001** |
| 3 | 16 (8.0%) | 0 (0.0%) | - | 0.998 |
| 4 | 3 (1.5%) | 2 (0.6%) | 9.0 (1.4-56.4) | **0.019** |

The patients with pain were generally older (mean age of 53.5 years) compared to those without pain. (Mean age of 48.5 years); this difference was statistically significant (p<0.001). Patients with pain were more likely to be male (OR=1.8) with 95% CI (1.2-2.7) p=0.004. Pain was more common in those with metastatic disease. OR=3, CI 1.8-4.9, p=0.001.

## FACTORS INDEPENDENTLY ASSOCIATED WITH CANCER PAIN

Logistic regression on multivariate analysis identified presence of metastatic disease and a poor performance status to be independently associated with cancer pain. This is illustrated in table 8 below

**Table 8: Factors independently associated with cancer pain (logistic regression analysis)**

| Variable | OR (95% CI) | P value |
|---|---|---|
| **Age** | 1.01 (0.10-1.030) | 0.174 |
| **Male sex** | 1.2 (0.7-1.9) | 0.530 |
| **Metastatic cancer** | 1.9 (1.0-3.5) | **0.044** |
| **ECOG** | | |
| 0 | 1.0 | |
| 1 | 4.4 (2.6-7.3) | **<0.001** |
| 2 | 10.3 (5.1-20.5) | **<0.001** |
| >=3 | 44.9 (9.5-212.7) | **<0.001** |

### Factors independently associated with inadequate pain management

Age, gender and ECOG performance status were not significantly associated with a negative PMI score. The percentage of patients with a negative PMI score was higher in those with non metastatic disease and this was statistically significant. (OR 0.5, p=0.045). These are shown in the table 9 below.

**Table 9: Independent associations with inadequate pain management**

| Variable | Negative PMI | Good PMI | OR (95% CI) | P value |
|---|---|---|---|---|
| Mean age (SD) | 52.2 (11.7) | 55.4 (12.9) | - | 0.077 |
| Sex | | | | |
| Male | 45 (35.2%) | 17 (25.0%) | 1.6 (0.8-3.1) | 0.146 |
| Female | 83 (64.8%) | 51 (75.0%) | 1.0 | |
| **ECOG status** | | | | |
| 0 | 17 (13.3%) | 9 (13.2%) | 1.0 | |
| 1 | 70 (54.7%) | 33 (48.5%) | 1.1 (0.5-2.8) | 0.802 |
| 2 | 29 (22.7%) | 19 (27.9%) | 0.8 (0.3-2.2) | 0.674 |
| 3 | 11 (8.6%) | 5 (7.4%) | 1.2 (0.3-4.4) | 0.822 |
| 4 | 1 (0.8%) | 2 (2.9%) | 0.3 (0.0-3.3) | 0.304 |
| **Cancer description** | | | | |
| Metastatic | 25 (19.5%) | 22 (32.4%) | 0.5 (0.3-0.99) | **0.045** |
| Non-metastatic | 103 (80.5%) | 46 (67.6%) | 1.0 | |

## 9.0 DISCUSSION

There is paucity of data on the prevalence and management of cancer pain in (ambulatory) cancer patients in Kenya. Information on cancer pain and management has been extrapolated from other studies done worldwide. We report the findings of our study that set out to determine the magnitude of cancer pain and its management in cancer patients attending oncology clinics in a single national referral centre in Kenya, the Kenyatta National Hospital.

The population in our study was middle aged (median age 50 years), mostly female (74%) with majority having formal education. Majority had non metastatic disease and an ECOG status of 0 or 1 indicating good functional status. Breast cancer and cancer of the cervix formed the bulk of disease contributing more than 55% of the total sample. These are over represented in our sample. The predominance of these cancers also led to the over-representation of females in our sample population.

Our sample population was predominantly female which explains why the two commonest cancers were breast and cervix. This could be due to the type of cancers

commonly followed up in the two clinics. They are mainly breast and cervical cancer.

The prevalence of pain in ambulatory cancer patients at Kenyatta National hospital was found to be 38.5%. The presence of metastasis and a poor performance status were predictive of cancer pain. Patients with metastatic disease were two (1.9) times more likely to have pain than those without metastasis. Two thirds of our sample population with pain was inadequately managed. Absence of metastatic disease was associated with higher likelihood of inadequate pain management.

Our sample population was selected from two oncology clinics which handle more than 80% of the outpatient oncology patients in Kenyatta National Hospital. We included all types and all stages of cancer. We however note that terminal patients in hospice palliative care were not included. Patients with early prostate and gynecologic cancers may have been on follow up in surgical and gynecological clinics. Thus, the study result is not a representation of the prevalence of cancer in Kenyatta National Hospital. Majority of our patients had non metastatic disease and were in good functional status. This could have contributed to the lower prevalence of pain than reported in other studies[32, 33]. This prevalence is consistent with studies elsewhere [30].

Our cancer pain prevalence of 38.5% is comparable to other studies. It is similar to that of Beck et al[30] who did a cross sectional study of cancer pain prevalence in both inpatient and outpatient setting in two health care facilities, found a prevalence of 35.7% (n=263) in South Africa. Another similar study by Cleeland et al[32] found a prevalence of 62% (n=1308) in patients with metastatic cancer attending outpatient oncology clinics. The lower percentage of patients with pain in our study may be due to a lower frequency of metastatic disease in our study population. Pain prevalence in cancer has been shown to increase with progression of the disease, increasing to 74% in metastatic disease[13]. In a multicentre study of cancer pain and its treatment in France, Larue et al[33] found cancer pain prevalence to be 57%. This was much higher than what we found in this study. It is notable however, that a big proportion (52%) of his study population had metastatic disease unlike in our study population (14.8%). This may explain the discrepancy in the pain prevalence between the two populations. It is also notable that our study population was recruited in the outpatient set up and thus this may explain the lesser incidence of pain. Patients who have more severe disease and thus more pain would be inpatients.

In our study, patients were more likely to have pain if they had metastatic disease, were older, male, had a poor functional status (worse ECOG performance status) and had a longer duration from diagnosis. All these associations reached statistical significance. However, when subjected to multivariate analysis with logistic regression, only presence of metastatic disease and poor performance status were shown to be predictive of pain in cancer patients. Cleeland et al[32] found patients were more likely to have pain if they were older, male, had metastatic disease and were rated to be sicker (worse ECOG performance status). This is consistent with the findings in other studies[32, 33.]

Women are at a significantly higher risk of many clinical pain conditions[39]. Post operative and post procedural pain is also more severe in women compared to men[39]. This was not evident in our study. However, the cancers associated with higher frequency of pain were commoner in males. These were esophagus, skin and urinary bladder. Moreover, the commonest cancers in females (breast and cervix) were associated with low prevalence of pain and most were non metastatic. However, gender was not demonstrated to affect pain perception. Other studies have found mixed findings [35, 44, 45]. Male gender was found to be predictive of pain by Fatma et al[44] in Turkey. This has not been replicated in other studies. Poor performance status is associated with more advanced disease. These patients are more likely to have pain, a finding also found in other studies[32, 41.]

Blacks were found to experience pain at almost twice the rate of whites by Beck et al[30] in South Africa. Our population was however almost purely a black population. The perception of pain by patients and reporting to health workers differs between different cultures and ethnic communities[43]. This may lead to poorer pain assessment and inferior management[43].

Most (86%) of the patients with pain rated their worst pain as significant (a score of 4 and above. However, almost half of the patients (47%) on analgesics were on non opioid analgesics, which is step 1 of the WHO analgesic ladder. Thirty four percent of patients with pain were on pain medications not prescribed by the doctor.

Two thirds of patients in pain were receiving inadequate analgesia. This rate is double that found by Beck et al[30] and higher than Cleeland et al[32] who found 42% of patients receiving inadequate analgesia. However it is similar to several studies [38,41,45,46.] It is important to note that only few of our study population (14.8%) consisted of patients with metastatic disease. Beck et al[30] had 40% of her study population with advanced cancer.

It has been found that absence of metastatic disease is predictive of inadequate pain relief[33, 38]. This may partially be due to more vigilance by clinicians in managing patients with metastatic disease since management is primarily palliative. Patients whose cancer management is directed towards cure may have their pain overlooked as part of management. The patients may also be reluctant to report pain for fear of distracting the physician from treatment of the underlying disease or, fear that pain may mean a worse disease[14]. Patients' reluctance to report pain and use analgesics has been reported as a major barrier to management of cancer pain[36]. Fear of addiction, notion that 'good' patients do not complain about pain and concerns about side effects have been found to be major barriers to treatment of cancer pain[36].

Our results are similar to the 70% level of inadequate treatment found by Okuyama et al[38] in Japan (n=138). The only factor found to be predictive of inadequate analgesia was absence of metastatic disease. This is like other studies, where less advanced cancer is associated with inadequate analgesia as shown by Okuyama et al[38] and Cleeland et al[32]. This may be because of the physician under assessing the patients' pain.

Another factor that may contribute to the high level of inadequate pain management may be the lack of use of opioid analgesics. Almost half (47%) of our patients were on step 1 of the WHO analgesic ladder, with 27.5% being on mild opioids and only 10% on morphine. In South Africa, Beck et al[30] found 30.5% of patients had inadequate pain management, 40% of them were on mild opioids and 36% were on morphine. However, a big proportion (52.5%) of our patients were on adjuvant therapy for pain.

A significant number (34%) were also on self medication with analgesics. This may reflect inadequate prescription of analgesics or prescription of less potent analgesics. It may also be due to unavailability of the more potent medications despite being prescribed. These medications are usually more expensive than the over the counter analgesics.

The large percentage of patients with inadequate analgesia as indicated by a negative PMI may be due to a lack of specific education in pain management for physicians who have not specialized in oncology or palliative care. It may also be due to physician attitude, where they may fear prescribing opioids due to risk of patient addiction. Physicians may also be reluctant to prescribe opioids for cancer pain. Yun et al[42], in a study to assess the predictors of prescription of morphine for severe cancer pain by physicians in Korea, found that only 16.5% of physicians

would prescribe morphine for severe cancer pain. Fear of patient addiction on using opioids by physicians was the main reason cited. This may also be the case in our set up.

Integration of oncology and palliative services would also greatly improve the cancer pain management of these patients. This would be by setting up a comprehensive cancer centre involving medical, radiation, surgical oncologists and supportive cancer care services as is the practice in various countries. This would incorporate pain clinics in the oncology units.

There were some limitations in our study. The evaluation of pain management using the PMI does not take into account other aspects of cancer pain management like patient compliance to therapy, the dosage and route of administration of the most potent analgesic prescribed, potential interactions with further analgesics, adjuvant drugs and with other non pharmacological therapies. A patient could have been under medicated because they were not taking the analgesics prescribed. The analgesic prescribed may have been of the right potency but inadequate dosage. The PMI does not take in to account adjuvant analgesic drugs (i.e. antidepressants, steroids and anticonvulsants) and other non pharmacological therapies (acupuncture, biofeedback).

## CONCLUSION

This study documents a high prevalence of cancer pain. There is also a high proportion of cancer patients getting inadequate pain management. This study reflects the management of cancer pain in the public health system since Kenyatta National Hospital is one of the only two public hospitals in the country offering oncology services. It provides a baseline from which improvement can be measured over time.

## 10. RECOMMENDATIONS

Firstly we recommend that the WHO cancer pain relief guidelines be implemented in management of cancer pain. Secondly, further studies are needed to identify the factors contributing to such a high rate of inadequate pain management in our cancer patients. Interventional studies can then be carried out to determine efficacy of interventions aimed at improving cancer pain management. The role of adjuvant therapies in cancer pain management should be further explored. Finally, a similar study among inpatients would provide further information on cancer pain management.

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**APPENDIX 1: PATIENT INFORMATION FORM**

My name is Dr. Wanjuki. I am a post-graduate student of Internal Medicine at the University of Nairobi. The purpose of this statement is to inform you about a research study that am carrying out.

## What is the study about?

I am carrying out a research study on the prevalence and management of pain in cancer patients attending Kenyatta National Hospital. We do not have enough information on how common and how well pain in cancer is managed. The aim of this study is to find out how common pain is in cancer patients and how well it is being managed from their perspective. Recommendations can then be made to health care providers on interventions that can improve pain management in our patients.

## What does the study involve?

You have been chosen because you have cancer.

Participation in this study is voluntary. Should you accept to participate, the following is a summary of what the study involves:

1. Obtaining socio-demographic information such as age gender, and residence from the patient.
   NOTE: your name and hospital identification number shall not be included in this information for your privacy.
2. Administering a questionnaire to assess the presence and severity of pain.

This will require about half an hour of your time.
Please note that your identity shall not be recorded nor revealed to any other persons.
All information will be treated as confidential.
Your primary health physician shall be informed of any findings relevant to your medical care.
A consent form shall be supplied to you to sign if you agree to participate.
If you do not agree to participate, there will be NO consequences. Your medical care will continue as usual.
Even if you agree to participate, you are free to withdraw from the study at any time with no consequences at all.
If you have any questions, please do not hesitate to ask.

**Are there any dangers involved?**

There are no dangers involved. There will be no invasive procedures.

**Will** I **benefit from the study?**
Yes. After analyzing the study results we will be able to know whether you have pain related to your cancer and how well we are managing it.
The study will also provide information on how common pain is in cancer patients and how well it is managed. This will be used to develop guidelines for better pain management in cancer patients.

Clarifications may also be addressed to any of the following:

Dr. Wanjuki J.N
P.O. Box 19676
Nairobi
0721-352981

Prof. N. A. O. Abinya
Department of Clinical Medicine and Therapeutics
University of Nairobi
P.O. Box 19676
Nairobi

Prof. E. O. Amayo
Department of clinical medicine and therapeutics
University of Nairobi
P.O. Box 19676
Nairobi

Dr. E.C. Munyoro
Palliative care Unit
Kenyatta National Hospital
P.O. Box 20723
Nairobi

## APPENDIX 2: CONSENT FORM

I…… ……consent to take part in this research study on the prevalence and management in cancer pain.

The nature of this study has been explained to me by Dr. Wanjuki J.N.

I have been assured that participation in this study is voluntary and will not negatively affect my medical care, and that any information obtained will be treated as confidential.

Signed/ thumbprint ……

On this day and date……

**Investigator's statement**

I, the investigator have provided an explanation on the purpose and implications of the above research study to the participant.

Signed ……Date …….

**APPENDIX 3: ADDITIONAL QUESTIONNAIRE.**

**CANCER DIAGNOSIS** ----------

**CANCER DESCRIPTION** METASTATIC ☐

NON METASTATIC ☐

**ECOG STATUS**

0 ☐ Fully active, no performance restriction

1 ☐ Strenuous physical activity restricted. Fully ambulatory and able to carry out light work

2 ☐ Capable of all self-care but unable to carry out any work activity. Up and about >50% of waking hours

3 ☐ capable of only limited self-care; confined to bed or chair > 50% of waking hours.

4 ☐ Completely disabled; cannot carry out any self-care; totally confined to bed or chair.