

FACTORS ASSOCIATED WITH DELAY IN THE DIAGNOSIS AND TREATMENT OF ORAL
CANCER AT TWO REFERRAL CENTRES IN NAIROBI

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YEAR 2021

DECLARATION

I, Dr. Midega Augustine Awarah, do declare that this is my original work and has not been submitted by any other person to any other university for a degree or any other purpose

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DEDICATION

I dedicate this thesis to my parents Thomas Awarah and Wilfrida Awarah for teaching me the value of education and for the sacrifices they made to give me a good foundation in education. I am grateful to my wife Fiona Oduor and my daughters Kayla and Naima for the support they gave me during the entire postgraduate training. Finally, I would wish to thank my siblings for all the support they gave me and my family during my studies.

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LIST OF ABBREVIATIONS

KNH	Kenyatta National Hospital
UON	University of Nairobi
ENT	Ear, Nose and Throat
TNM	Tumor size; Nodal metastasis; Distant metastasis
NHIF	National Hospital Insurance Fund

LIST OF FIGURES

Figure 1: Different types of delay between the onset of the first symptoms and the beginning of anticancer treatment ⁷	5
Figure 2: Distribution of oral cancer based on the disease type	26
Figure 3: Distribution of oral cancer patients according to the reason given at presentation	29
Figure 4: Health facility visited by oral cancer patients upon noticing symptoms	37
Figure 5: Number of visits before Referral	38
Figure 6: Reasons for the delay in surgical or radiotherapy treatment and visits to referral facilities	43
Figure 7: Linear regression curve estimation plot model	48

LIST OF TABLES

Table 1: Distribution of socio-demographic and socio-economic characteristics distribution.	25
Table 2: Disease staging of oral cancer at presentation.	28
Table 3: Distribution of oral cancer patients based on site of lesion and the initial change or symptom.	31
Table 4: Time taken to first visit a medical facility after noticing symptoms of oral cancer based on employment status, monthly income, initial facility visited.	32
Table 5: Time taken (days) to visit hospital based on site of lesions and initial symptom noticed.	34
Table 6: Action taken by respondents upon noticing symptoms and reason for action taken.	36
Table 7: Distribution of patients' based on treatment initially received and actions taken by the initial clinician.	39
Table 8: Time taken to visit the referral centre (days) after being referred based on	40
Table 9: Time taken to visit the referral centre (days) based on site of lesions and initial symptom	42
Table 10: Treatment delay (days) based on employment status, monthly income, initial	45
Table 11: Treatment delay (days) based on site of lesions and initial symptom noticed.	46

Contents

DECLARATION	Error! Bookmark not defined.
DEDICATION	ii
ACKNOWLEDGEMENT	iii
ABSTRACT	iv
CHAPTER 1	1
1.1 Introduction	1
1.2 Literature Review	4
1.2.1 Introduction	4
1.2.2 Patient Delay	6
1.2.3 Professional Delay	8
1.2.4 Treatment delays	10
1.3 STATEMENT OF THE PROBLEM	12
1.4 JUSTIFICATION OF THE STUDY	12
1.5 OBJECTIVES	13
General	13
Specific	13
1.6 VARIABLES	14
CHAPTER 2	16
2.0 RESEARCH METHODOLOGY	16
2.1 STUDY AREA	16
2.2 STUDY DESIGN	16
2.3 INCLUSION AND EXCLUSION CRITERIA	16
2.3.1 Inclusion:	16
2.3.2 Exclusion	16
2.4 SAMPLE SIZE DETERMINATION AND SAMPLING METHOD	17
2.4.1 Sample size	17
2.4.2 Sampling method:	18
2.5 DATA COLLECTION METHOD	19

2.6 DATA ANALYSIS	19
2.7 VALIDATION AND MINIMIZATION OF ERRORS	20
2.8 QUALITY ASSURANCE PROTOCOL	21
2.9 ETHICAL CONSIDERATION	21
2.10 LIMITATIONS OF THE STUDY	22
2.11 PERCIEVED BENEFITS OF THE STUDY	22
CHAPTER 3	23
3.0 RESULTS.....	23
3.1 Socio-demographic distribution of participants	23
3.2 Status of Acquisition of Medical Cover at Time of Presentation	24
3.3 Clinical distribution of the participants based on cancer	26
3.4 Clinical Staging at presentation	27
3.5 Reason for Presentation at Time of Administration of Questionnaire	29
3.6 Site of Lesion and Clinical Presentation	30
3.7 Time taken to visit a hospital and duration of presentation of symptoms	32
3.8 Duration taken to first visit a hospital based on the site of lesion and symptoms	33
3.9 Action taken by participants upon noticing symptoms and reason for actions taken	35
3.10 Health facility visited upon noticing symptoms.....	37
3.11 Number of visits to initial facility before referral and treatment received	38
3.12 Time taken to visit the referral centre (days) after being referred.	40
3.13 Time taken to visit the referral centre (days) after being referred based on site of lesion and symptoms.....	41
3.14 Reason for delay in visiting referral facility and access to treatment	43
3.15 Treatment delay (days)	44
3.16 Treatment delay (days) based on site of lesions and initial symptom noticed.	46
3.17 Time taken to get histopathological/biopsy results	47
3.18 Duration of disease	47
CHAPTER 4	49
4.0 DISCUSSION.....	49
4.1 Socio-demographics.....	49
4.2 Oral Cancer.....	50
4.3 Delays.....	51

4.3.1 Patient Delay.....	51
4.3.2 Diagnostic Delay.....	53
4.3.3 Healthcare provider delay.....	54
4.3.4 System Factors Associated with Delay.....	55
4.4 Conclusion.....	56
4.5 Recommendations.....	57
REFERENCES.....	58
APPENDICES.....	68
APPENDIX 1:QUESTIONNAIRE.....	68
APPENDIX II: KISWAHILI QUESTIONNAIRE.....	75
APPENDIX III: PARTICIPANT INFORMATION AND CONSENT FORM.....	82
APPENDIX IV: AARHUS CHECKLIST.....	83
APPENDIX V: REVISED ANDERSEN MODEL OF PATIENT DELAY.....	83
APPENDIX VI: APPROVAL FROM KNH/UON ETHICS COMMITTEE.....	84
APPENDIX VII: TNM STAGING.....	86
APPENDIX VIII: CONSENT FORM.....	88
APPENDIX IX: KISWAHILI CONSENT FORM.....	90

ABSTRACT

Background: Most patients seen at the University of Nairobi Dental hospital and Kenyatta National hospital present with advanced stage of cancer. There is also a considerable number that visit early enough but do not get treatment in time due to either delay in diagnosis by the healthcare providers or due to system challenges. This has a negative impact on the treatment outcomes and cost. It is important to attempt to establish the cause of these delays. It is equally important to establish how long it takes to have definitive treatment of oral cancers and make a comparison with other countries. There is hardly any research that has been done in Kenya to quantify and to establish the cause of these delays.

Broad objective: To establish the duration and the factors responsible for the delay in the diagnosis and treatment of patients with oral cancer.

Study site: The study took place at the Oral and maxillofacial surgery departments at University of Nairobi dental school and Kenyatta National hospital (KNH)

Participants and Methods: This was a descriptive cross sectional study involving patients who presented with oral cancer at the two clinics. I administered questionnaires to collect data on various study variables.

Data analysis: The data was collected and entered into Microsoft excel sheets and transferred to SPSS version 25 for analysis. Categorical data are described using frequencies and percentages while continuous data using standard deviation. The Chi-square test was used to assess the bivariate relationships between categorical data of the assessed delay factors and the socio-demographic variables.

Results: Delays in diagnosis and treatment of oral cancers were caused by patient, healthcare giver and system factors. Patient delay ranged from 0-560 days with a mean of 94.15 and median of 70 days. Fifty(70.4%) participants did not immediately seek medical treatment upon noticing symptoms for various reasons. Patients presented late for treatment with 58(81.7%) and 10 (14.1%) presenting with stage IV and III of disease respectively for various reasons like self-medication and delays by healthcare givers due to delayed clinical diagnosis, inappropriate investigations or late referral. The referral delay ranged from 0-177 days with a mean of 25.83 days. Thirty six (51.7%) delayed in visiting the two referral centres mainly due to cost and distance. The two referral centres had long treatment queues that affected 59(83.1%) of the participants. Treatment delay ranged from 0-104 days with a mean delay of 11.3 days. The total duration of illness ranged from 35-840 with a mean period of 299.86 days.

Conclusions: Majority of patients(95.8%) presented late for cancer treatment. Some of the patient factors leading to delay in diagnosis and treatment include self-medication(32.4%), lack of knowledge on cancer symptoms(33.8%) and lack of finance(12.7%). Many patients delay in visiting the referral facilities upon referral for various reasons including distance and cost. Healthcare givers delay the process by not referring early enough and not initiating the relevant investigations in time. The long treatment queues at the two referral facilities further cause delay. Histopathology reports take too long(14 days) to be reported.

Recommendations: Healthcare workers should be educated on common cancer symptoms. There should be more capacity building in terms of personnel and equipment at the county and sub-county hospitals to reduce congestion at the two referral centres. Policy makers should streamline the referral system for suspected cancer patient to increase efficiency and minimize delay. Frequent screening of oral cancers should be encouraged. Histopathology reporting should be more prompt.

CHAPTER 1

Introduction and Literature Review

1.1 Introduction

Cancers of the oral cavity refer to malignancies of the lip, tongue, floor of mouth, gingiva, buccal mucosa, connective tissue and palate.¹ They arise from the skin, major and minor salivary glands, muscle, bone and mucosal surfaces of the oral cavity.² They are the seventh most common malignancies worldwide.³ Oral cancers are estimated to affect 650,000 people annually with an estimated 330,000 deaths per year worldwide.⁴

Diagnosis of oral cancer starts with either a complaint from the patient or during a routine medical or dental check-up. It is followed by a visual examination which is subjective and requires a high suspicion index from the examining practitioner to be able to identify an early lesion. It is further limited by the possibility of having dysplastic tissue that is similar in appearance to the surrounding normal epithelium or tissue. Upon encountering suspicious looking epithelium, non-invasive methods like toluidine blue or brush biopsy can be used for further investigation. Other investigative mechanisms include biopsy for histological examination, immunohistological tests to further characterize the cells and radiographic examination and other relevant imaging to establish or define the boundaries of the disease.

Staging of the disease is done based on the tumor size, nodal involvement and metastasis to distant organs. This helps to decide on the mode of management. Management of oral cancer is surgery followed by radiotherapy or chemotherapy or both. Early diagnosis and treatment of cancers lead to better outcomes, reduced morbidity and lower treatment costs. Cancer survival is poorer in developing countries due to late diagnosis and limited access to timely treatment.⁵ Many patients also present with advanced disease due to absence of early warning symptoms hence delay in seeking medical attention.⁶

The aim of this study is to identify the causes of oral cancer diagnostic and treatment delays and to quantify the delays. This information would help to guide policy formulation on cancer treatment. Patient related causes of delay will be highlighted to help create awareness on the importance of early hospital visits and to educate on early detection of cancer. Provider factors will also be highlighted to facilitate quick recognition of early disease, early diagnosis and efficient, quick and relevant referral to reduce unnecessary delays.

There are two commonly used tools used by researchers to assess delays in diagnosis of cancers by researchers namely 'The revised Andersen model of patient delay' (appendix 5) and the 'Aarhus checklist' (appendix 4)⁷.

The revised Andersen model of total patient delay is a protocol used to define the duration between detection of change in the body by the patient to diagnosis.⁸ The delay intervals described in the model are appraisal interval, help seeking interval and diagnostic interval.⁹

Appraisal interval is majorly determined by presence or absence of symptoms and the progression of the symptoms. The severity of symptoms further influences the delay in those with symptoms. In pharyngeal cancer, patients with dysphagia or neck mass are more likely to present for treatment earlier than those with sore throat.¹⁰ Patients with both pain and presence of a mass had shorter delays than those with pain only.

Aarhus checklist is a list of recommendations by researchers that seeks to provide a greater accuracy and transparency in the methodology and design in studies looking at the relationships between time interval and diagnosis of cancer.⁹ It describes events, processes, intervals and factors contributing in the trail towards diagnosis¹¹. It focuses on instruments that are available and are used to measure time intervals and points in cancer diagnosis research and creates consistent definitions and methods.⁷

1.2 Literature Review

1.2.1 Introduction

Oral squamous cell carcinoma is the most common oral cancer accounting for more than 90% of all oral cancers.¹² Early carcinomas tend to be asymptomatic and often go unnoticed.¹³ This is because early lesions tend to be subtle and rarely have clinical symptoms.^{14,15} Screening aids have not been shown to provide any advantage or superiority over visual exam.¹⁴ Screening for early detection for those exposed to risk factors would therefore decrease mortality and morbidity associated with oral cancer.^{16,15} Malignancy is preceded by dysplasia.¹³ It is possible that a potentially malignant epithelium described histo-pathologically as dysplastic could actually have a single cell crossing the basement membrane thus qualify by definition to be cancer but the cell may not be picked by hematoxylin and eosin staining.¹³ The difficulty of early diagnosis is thus compounded by absence of symptoms, lack of sensitive screening tools as well as the challenge of potential inaccuracy of histo-pathological analysis.

The severity of cancer is most often based on the TNM staging of the cancer. The TNM system is majorly a morphological description of the tumor and does not put into consideration other aspects of the tumor such as the biological behavior and symptomatic presentation. The symptomatic presentation of the tumor influences prognosis independent of the TNM staging.¹⁷

There is no consensus over a time period beyond which cancer diagnosis is considered to be delayed.¹⁸ Many researchers use the mean or median time distribution to define diagnostic delay. The median is more commonly used since it is not severely affected by extreme values and the distributions usually have wide ranges.^{19,20,21,22}

Cancer treatment outcome is influenced by the pathway taken by the patient from initial symptom to presentation and initial management by the primary healthcare giver.²³ Early treatment of small lesions lead to less invasive surgeries, minimal microscopic invasion and better long term survival of patients. Longer diagnostic intervals present with advanced oral cancers leading to poorer outcomes and more treatment related morbidity.^{24,25}

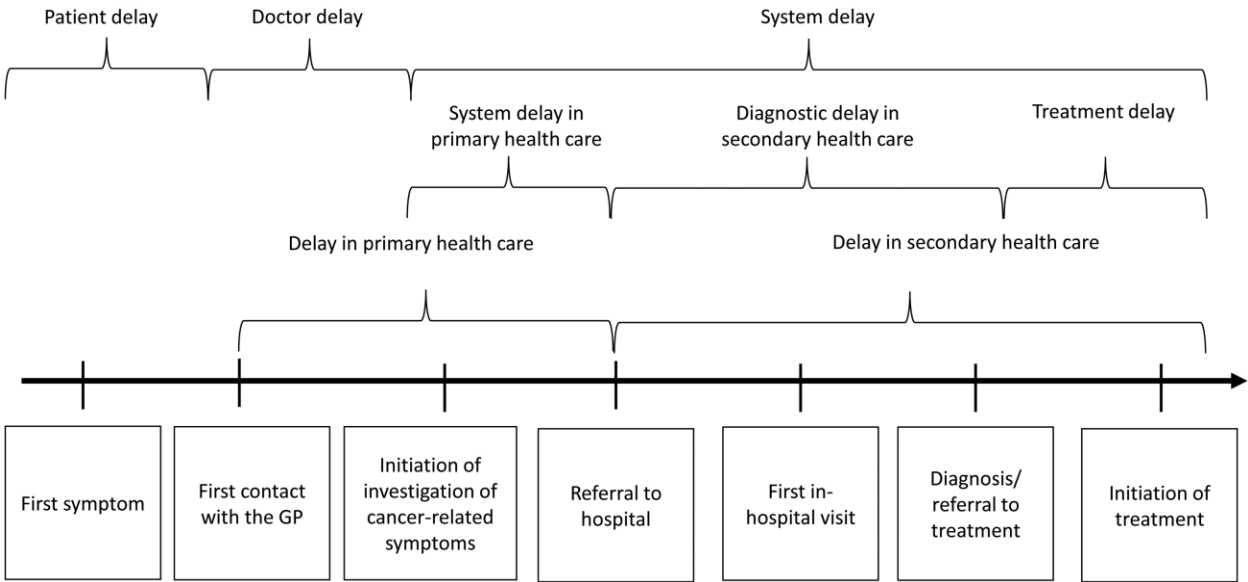


Figure 1: Different types of delay between the onset of the first symptoms and the beginning of anticancer treatment⁷

1.2.2 Patient Delay

Patient delay refers to the time period between first awareness of symptoms or notice of change and the first visit to a healthcare provider. Symptomatic presentation of oral malignancy influences health seeking habit. The presence of any ulcer, swelling, red or white lesion present for more than three weeks or unexplained loose teeth or numbness or non-healing socket should be considered to be cancerous unless proven otherwise.²⁶

Common symptoms suggestive of oral cancer include lump, lymphadenopathy, ulceration with fissuring or raised exophytic margins, pain, paresthesia or induration.¹³ Pain is the most common complaint in oral cancer constituting about 30-40% of the complaints²⁷

Swelling and/or pain were found to be the initial symptoms in a different study in Thailand with a prevalence of 52.6%.²⁸ Pain usually arises only when the lesion has grown in size hence delayed recognition of disease.²⁷ In certain locations like tongue or floor of mouth, pain can arise earlier. Carcinomas of the buccal mucosa and lip only show intense pain when at advanced stages.²⁷ Other studies have shown the main symptoms as oral cancer to be ulceration and swelling followed by pain, decreased tongue mobility, bleeding, dysphagia and paresthesia.²⁹ Oral cancer of the tongue has been reported to mainly present with pain-66.5% and lump-29%.³⁰

The stage of presentation of disease is an important prognostic factor of the disease.³¹ The 5 year survival rate of advanced disease(Stage 3 and 4) is approximately 50% or less while that of early disease(Stage 1 and 2) is 80%.³¹ Approximately forty percent of patients with oral cancer present with stage 3 and 4 of disease.^{24,32} Most of the delay is by the patients who do not seek medical attention as soon as the symptoms are felt.^{24,33,34,35}

Rogers et al did a study on reasons for delayed presentation giving a patient's perspective and it was evident that many patients were unable to pick the seriousness of common symptoms of cancer like non healing ulcer.³⁶ Many interpret such symptoms as minor, others hope the symptoms would get better while others attempt self-medication.³⁶ Lack of knowledge on oral cancers can be a cause of delay in seeking treatment.³⁶ Some studies have cited lack of access to specialist or healthcare providers as a cause of patient delay.³⁷ Patient delay can therefore be caused by patient factors or system factors. Shortening patient delay time would therefore improve survival though it seems difficult due to the non-specificity and late presentation of the symptoms.³⁸ Some studies have shown no relationship between patient delay and stage of disease.^{38,39} However, tumor aggressiveness may act as a confounding factor in the association.¹¹

Patient education and regular examination by relevant professionals for patients with a high risk of cancer is thus very important for early diagnosis. ^{39,40,41,42,43} The high risk patients include those who take tobacco in any form, alcohol users and those who have had a malignancy in any part of the body. Patients who have had previous oral carcinoma have a 9% chance of developing a second primary oral carcinoma according to Kramer et al⁴⁴ while Day and Bolt found the incidence of having a second primary malignancy at 3.7% per year.⁴⁵ Regular dental check-up has been shown to be associated with early oral cancer diagnosis.⁴⁶

1.2.3 Professional Delay

This refers to the time taken between the first point of consultation with a healthcare provider to the date of histological diagnosis.⁴⁷ Some countries have developed policies to reduce professional delay by prescribing time limits during which a suspected oral cancer should be fully investigated, tumor board discussion held and treatment options discussed with patient. In Netherlands, this should happen within 30 days. A similar patient oriented model has been proposed in the United Kingdom where a time frame of two weeks between patient's initial referral and initiation of treatment has been prescribed. To effect this, a nurse coordinator is allocated to a patient for ease of coordination.

A patient is considered to have diagnostic delay if 21 or more days elapse between the day of noticing the symptoms and the definitive diagnosis.⁴² This 21-day duration allows for 7-10 days follow-up of a symptom, a second visit and a biopsy as well as time required for a histopathological result. Delays in diagnosis could be caused by the healthcare providers who may fail to institute the relevant investigation or refer accordingly.^{38,47} Diagnostic delay can, however, be confounded by the rate of tumor growth and it has been suggested that early diagnostic is associated with improved survival. This is probably because fast growing tumors with poorer prognosis are more alarming thus faster diagnosis than indolent less aggressive tumors which are associated with longer delays in diagnosis.⁴⁸

The medical officer or dentist plays a very important role in early diagnosis as he/she is likely to have the first contact with a patient.⁴⁹ The practitioner has to have a high suspicion index to initiate the right investigation i.e. biopsy for accurate histological diagnosis. It is equally important to initiate a follow up process for patients suspected to be having

malignant lesions. Failure to adequately investigate, monitor or diagnose cancers when there is enough opportunity to do so has been considered professional misconduct in certain jurisdictions like Canada.

A local study to look at delays in diagnosis and referral of patients with head and neck cancer patients presenting at KNH by Onyango et al found a lengthy referral system as a major contributing factor to delay in treatment.⁵⁰ This is contrary in other countries like England where the maximum waiting time for referral is 2 weeks and the NHS is tasked with finding an alternative incase the primary center is not in a position to offer give an appointment within the two weeks after the referral from the medical officer or dentist.⁵¹

The diagnostic process starts with radiological investigations followed by biopsy for histology. Immunohistochemistry may be needed in certain condition. The ideal average time to process histological samples is 16-20 hours.⁵² In practice, the duration takes longer locally due to various factors. It takes about two weeks to get histopathological report in certain facilities.

Low socio-economic status has been shown to present a challenge to early diagnostic or preventive strategies like screening especially to those who have predisposing factors like smoking and alcohol intake.⁵³

1.2.4 Treatment delays

Treatment delay refers to a lengthy duration of time between the histopathological diagnosis and initiation of intervention which can either be surgery and chemotherapy or radiotherapy or both. The delay can either be because of patient or system factors. One of the patient's factors is low socio-economic status which together with illiteracy are associated with delayed treatment.⁵⁴ This may be due to high cost of medical treatment as well as reduced intellectual capacity to comprehend the urgency of treatment once a histological diagnosis has been made. Publicly funded healthcare like in Canada in comparison to privately funded healthcare like in the United States of America have been shown to have shorter treatment delays.⁵⁵ Patients with insurance cover have been shown to have shorter delays among those privately funded patients diagnosed with cancers.⁵⁶ Some patients decide to seek alternative therapy upon being diagnosed with cancer.⁵⁷ Alternative medicine refers supportive therapies used in lieu of mainstream medicine and include traditional medicine, herbs, homeopathy, acupuncture and spiritual healing.

A diagnosis of cancer is considered a death sentence by some patients due to the debilitating effect of the disease. These patients either don't see the point or urgency of treatment or go into a phase of denial thereby delaying initiation of treatment. It is recommended that counseling should be initiated as early as possible to help reduce the emotional burden both on the patients and caregivers and to allow the patients to make rational decisions devoid of emotional distress.⁵⁸ The term supportive counseling is preferred as opposed to palliative counseling so as to encourage earlier referrals of cancer patients for counseling services.⁵⁸

Long waiting time for surgery or radiotherapy increase the delay. A study done in Denmark showed shorter waiting time for patients with big tumors as compared to those with smaller tumors.⁴⁷ This is the 'waiting time paradox' as patients with smaller tumors who are more likely to survive are subjected to longer waiting time while those with bigger tumors with worse prognosis are given preference.⁵⁹ Tumor growth during this waiting period may not be accurately measured by the TNM method as a stage 4 cancer cannot progress to a higher stage

1.3 STATEMENT OF THE PROBLEM

Duration between the time a malignant disease is recognized and the time treatment is initiated is an important determinant of prognosis since the duration of the patient's treatment journey is directly related to the stage of the disease. Unfortunately many patients seen at the two referral facilities present with advanced disease which implies that there is a significant delay between the time the disease is recognized by the patient and the time they present for treatment. This leads to increased morbidity, high cost of treatment and mortality. It is conceivable that any measure that would shorten the patient's treatment journey would significantly improve treatment outcome. However, very few studies have been done in Kenya to establish causes of the delay so as to make efforts to reduce or ultimately eliminate these delays. This study aims to answer the question "what are the factors that lead to diagnostic and treatment delays in oral cancer?"

1.4 JUSTIFICATION OF THE STUDY

The study was done to establish whether the delays are caused by the patients, healthcare givers or the referral system. This would help to either improve training so as to raise the suspicion index on healthcare givers or improve on our referral system to make it more efficient. It would also help to establish the need to increase awareness among patients and to help educate patients on the early signs to look out for in oral cancers. It would also help in establishing the need for specialized treatment centres with expertise and equipment.

1.5 OBJECTIVES

General: To establish the duration of delay and factors responsible for the delay in the diagnosis and treatment of patients with oral cancer.

- Specific:**
1. To establish patient factors responsible for delay in diagnosis and treatment of oral cancer and the duration of delay.
 2. To establish professional factors that cause the delay and treatment of oral cancer and the duration of delay.
 3. To establish system factors responsible for diagnostic and treatment delays of oral cancer and the duration of delay.

1.6 VARIABLES

Demographic variables	Measure
Gender	Male/Female
Age	Years
Education Level	Primary/Secondary/Tertiary
Diagnosis	
Employment Status	Formal/Informal/Self employed/ Unemployed
Monthly Income	<Kshs10000/Kshs10000-20000/ Kshs20001-30000/Kshs30001-40000/ Kshs40001-50000/>Kshs50000
Treatment Funding, Medical Cover,	Personal funds/Insurance/Donations/ Family /Others(Specify)

Independent variables	Measure
Patient factors	Sociodemographic factors
Tumor factors	Site Symptoms
Institutional factors	Type of primary healthcare facility Caregiver factors
Etc.	

Dependent variables	Measure
Overall duration of the patients' treatment journey and the length of its individual components	Days

CHAPTER 2

2.0 RESEARCH METHODOLOGY

2.1 STUDY AREA

The study was conducted at the Oral and maxillofacial surgery departments at Kenyatta national hospital and University of Nairobi Dental Hospital in Nairobi. Kenyatta National Hospital is a level 6 teaching and referral hospital located along Ngong road with a bed capacity of 1800. The University of Nairobi Dental Hospital is a specialized institution offering both dental and maxillofacial surgical services. It is located along Argwings Kodhek road in Nairobi.

2.2 STUDY DESIGN

The study was a descriptive cross-sectional study done between February 2020 and May 2021(15 months).

2.3 INCLUSION AND EXCLUSION CRITERIA

2.3.1 Inclusion:

All patients with oral cancers who presented at the two referral facilities and consented to be participants in the study

2.3.2 Exclusion

Patients with recurrent or residual cancer.

2.4 SAMPLE SIZE DETERMINATION AND SAMPLING METHOD

2.4.1 Sample size

Considering the study design, the sample size was determined using the formula for Z test and computed as follows:

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}}\right)^2 p(1-p)}{d^2}$$

Where:

n = sample size

Z = value from the standard normal distribution for 95% confidence level = 1.96

p = prevalence of delayed diagnosis of oral cancers = 0.84⁴⁸

d = allowable error (absolute) = 0.05

Therefore:

$$\begin{aligned} n &= \frac{(1.96)^2 0.84(1-0.84)}{0.05^2} \\ &= 206.5 \sim 207 \end{aligned}$$

However, since the sample size derived is for a population > 10000 and the desired sample size is for a population < 10000, it was corrected for a sample population < 10000 using the formula:

$$nf = \frac{n}{1 + \frac{n}{N}}$$

Where:

nf = desired sample size for a sample population < 10000

n = sample size derived for a sample population > 10000

N = estimated size of the sample population with the characteristic of interest under investigation i.e. an average of 3 patients seen per week and data collected over a period of 8 months(35 weeks) = 3x35 = 105.

Therefore:

$$nf = \frac{207}{1 + \frac{207}{105}}$$
$$= 69.7 \sim 70$$

Therefore, a sample size of **71** patients was enrolled into the study.

2.4.2 Sampling method:

Convenient sampling where patients were enrolled at various stages of cancer at different dates was used to enroll them into the study. The study population was stratified by health institution i.e. University of Nairobi Dental Hospital and Kenyatta National Hospital with their respective clinic and/or ward.

The recruitment was done daily during the period of the study and all potential participants underwent a screening process to confirm whether they satisfied the inclusion criteria of the study.

2.5 DATA COLLECTION METHOD

After getting informed consent from the patients, the investigator examined them clinically, confirmed the histopathological diagnosis of cancer and staged the disease. The TNM staging was used where the nodal examination was clinical while metastasis mainly to the chest was by CT scan. The patients were interviewed with a pre-designed, pre-tested, semi-structured questionnaire. The questionnaires were administered by the investigator.

The questionnaire captured the patients demographic data like age and gender, education level, profession, presence or absence of medical cover, date of acquisition of medical cover, risk habits, date of first noticing symptoms, site of lesion, initial symptoms and action taken/initial treatment, date of first hospital visit for the condition, number of facilities visited, date of histological diagnosis and place, date of referral, date of visit to referral center, date of planned surgical treatment, date of surgical treatment, referral for radiotherapy and date of appointment for radiotherapy, worst fears, expected outcome of treatment and any counselling services. The end point was the date of initiation of treatment that was either be surgery or radiotherapy.

2.6 DATA ANALYSIS

The data collection forms were checked for completeness and accuracy prior to data entry. Data was entered onto a Microsoft Excel before being transferred to SPSS version 25 for analysis. Additionally, once data entry was done, 15% of the questionnaires were sampled for double entry to check that the entry was done accurately. The data set was checked for any logical or typographical errors.

In the first instance, data was described using frequencies and percentages for categorical data and means and standard deviations for continuous data. These results were presented in either tabular or graphical format.

Thereafter, Pearson's Chi-square test was used to assess the bivariate relationships between categorical data of the assessed delay factors and socio-demographic variables. For each predictor variable the unadjusted odds ratio, 95% confidence interval and p - value < 0.05 will be used to test the statistical significance of results. All the variables that are statistically significantly associated with delay in presentation at the bivariate stage ($p < 0.05$) were considered together using binary logistic regression. At the multivariate stage, adjusted odds ratios, 95% confidence intervals and p-values were also provided.

The final report was written and finding of the study presented in form of statements, tables and graphs.

2.7 VALIDATION AND MINIMIZATION OF ERRORS

1. Validation of the research instrument involved having research data collected being reviewed by two different parties, the person collecting the data at the health institutions (University of Nairobi Dental Hospital and Kenyatta National Hospital) and then one of the supervisors who was to ensure that there was commitment to the quality of the research.
2. Intra- examiner reliability was assessed by the principal investigator by assessing 15% of the collected data 1- 2 weeks after the data was collected and inter -

examiner reliability was assessed during the course of the research by having some repeat examinations built into the study protocol.

2.8 QUALITY ASSURANCE PROTOCOL

1. The data collection forms were checked for completeness and accuracy prior to data entry using a software.
2. Once data entry was been done, 15% of the questionnaires were sampled for double entry to check that the entry was done accurately.

2.9 ETHICAL CONSIDERATION

Patients were required to give informed consent. Those who opted out of the study midway were respectfully left out and their treatment was not affected. The proposal was submitted to the KNH/UON ethics and research committee and approval given (appendix 6). Thereafter, the head of departments where the research was to be conducted were requested for permission and the ethical approval presented. Information gathered was kept confidential and no details from the participants was given to any unauthorized personnel. The names of the participants were not recorded for purposes of confidentiality.

2.10 LIMITATIONS OF THE STUDY

1. Recall bias: Some of the dates may not be accurate due to inability to recall by participants.
2. Loss of participants: Some(5) patients were lost in the course of the study due debilitating nature of disease or death.
3. Loss to follow up on the part of the investigator.

2.11 PERCIEVED BENEFITS OF THE STUDY

1. The information collected will help identify the gaps in cancer diagnosis
2. The information gathered will add to the pool of knowledge on cancer management.
3. The findings on symptoms will help in patient education to increase awareness
4. The inefficiencies in the referral system have been identified and recommendations made to help streamline our medical referral system to minimize delays.

CHAPTER 3

3.0 RESULTS

3.1 Socio-demographic distribution of participants

A total of 71 patients were included in the study. Of these, 43 (60.6%) and 28 (39.4%) were males and females respectively (M:F=1.5:1). The sample age ranged from 14.0 – 80.0 years with a mean age of 54.83 years (± 14.36 SD), a median of 57.0 years and a mode of 57.0 years. An independent samples t test showed a non-statistically significant difference in mean age (years) between males (M = 55.19, SD = 15.85) and females (M = 54.29, SD = 11.98), $t = 0.256$, $df = 69$, $p = 0.798$.

3.2 Status of Acquisition of Medical Cover at Time of Presentation

Majority of the patients, 47 (66.2%) had NHIF medical cover at the time of presentation while 24 (33.8%) did not. Of those who had acquired a medical cover, 34 (72.3%) did before noticing the symptoms while 13 (27.7%) took a medical cover after noticing symptoms. The level of education distribution of the participants were 47 (66.2%) primary, 21 (29.6%) secondary and 3 (4.2%) tertiary level.

Table 1: Distribution of socio-demographic and socio-economic characteristics distribution.

Characteristics		Distribution	
		n	%
Education	Primary	47	66.2
	>=Secondary	24	33.8
Employment status	Unemployed	28	39.4
	Self employed	11	15.5
	Formal Employment	32	45.1
Income (Kshs)	<10000	54	76.1
	>=10000	17	23.9
Bill Payment	Personal funds	13	18.3
	Insurance	46	64.8
	Donations	8	11.3
	Family	21	29.6

3.3 Clinical distribution of the participants based on cancer

Squamous cell carcinoma was the most common lesion comprising of 57(80.2%) followed by salivary gland tumours that were 8(11.3%) and sarcomas were 6(8.5%). Of the 8(11.3%) salivary gland carcinomas, 6(8.5%)were adenoid cystic carcinomas, 1(1.4%) adenocarcinoma and 1(1.4%) mucoepidermoid carcinoma respectively

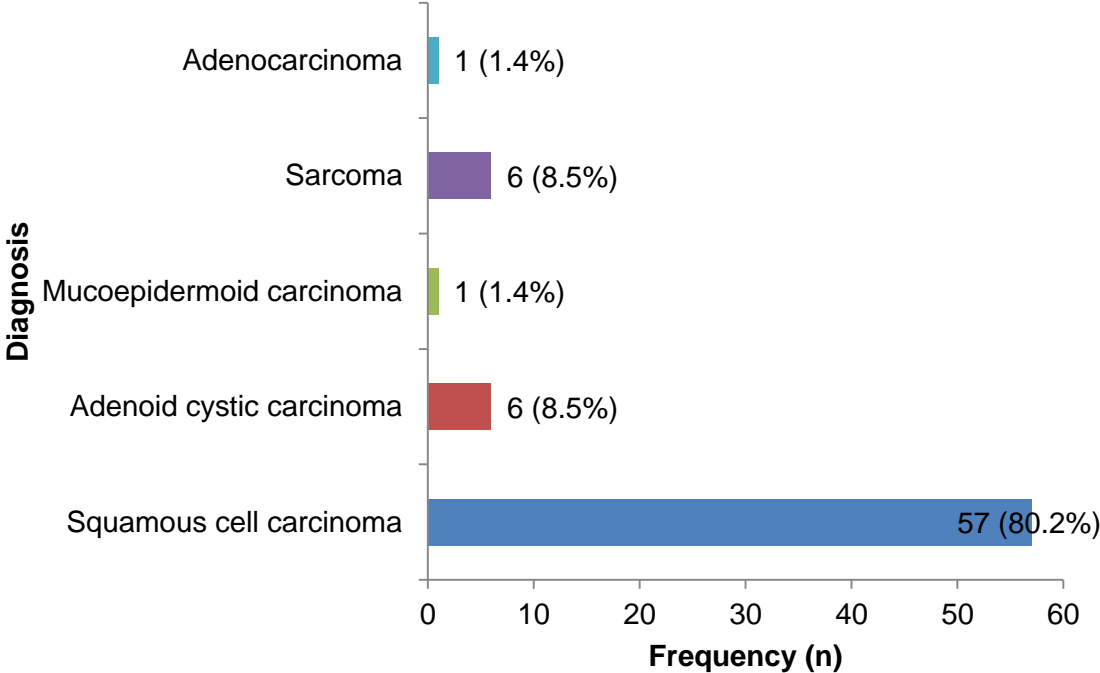


Figure 2: Distribution of oral cancer based on the disease type

3.4 Clinical Staging at presentation

Most participants, 58(81.7%) presented with stage IV. Those who presented with stage III were 10(14.1%) while those who presented with stage II were 3(4.2%). None presented with stage I.

Fifty seven (80.3%) of the participants presented with T4, 11(15.5%) had T3 tumour and 3(4.2%) who presented with T2. None of the patients presented with a tumour less than 2 cm(T1).

At the time of presentation, 57(80.3%) had clinically evident and palpable nodes of different sizes. Of these, 22(31%) had a single ipsilateral node measuring less than 3cm in its widest diameter(N1), 30(40.3%) had either multiple ipsilateral or contralateral nodes measuring 3-6cm (N2) while 5(7%) had nodes measuring more than 6 cm. The other 14(19.7%) did not have clinically palpable nodes.

Only 3(4.2%) had evidence of distant metastasis to the lungs. The other 68(95.8%) had no evidence of metastasis

Table 2: Disease staging of oral cancer at presentation.

Characteristics		Distribution	
		n	%
Staging at presentation	II	3	4.2
	III	10	14.1
	IV	58	81.7
Staging T	T2	3	4.2
	T3	11	15.5
	T4	57	80.3
Staging N	N0	14	19.7
	N1	22	31.0
	N2	30	42.3
	N3	5	7.0
Staging M	M0	68	95.8
	M1	3	4.2

n; number of cases

3.5 Reason for Presentation at Time of Administration of Questionnaire

Most of the patients, 63(88.8%), were referred to the two referral centres for various reasons. Out of this, 36(50.7%) went for a review with the specialists without histopathological reports while 27(38.1%) had histopathology reports from other facilities. Four (5.6%) patients were referred for biopsy while 2(2.8%) patients visited the facilities for the first time to be seen by a clinician. For 2(2.8%) patients, the cancers were an incidental finding during the examination.

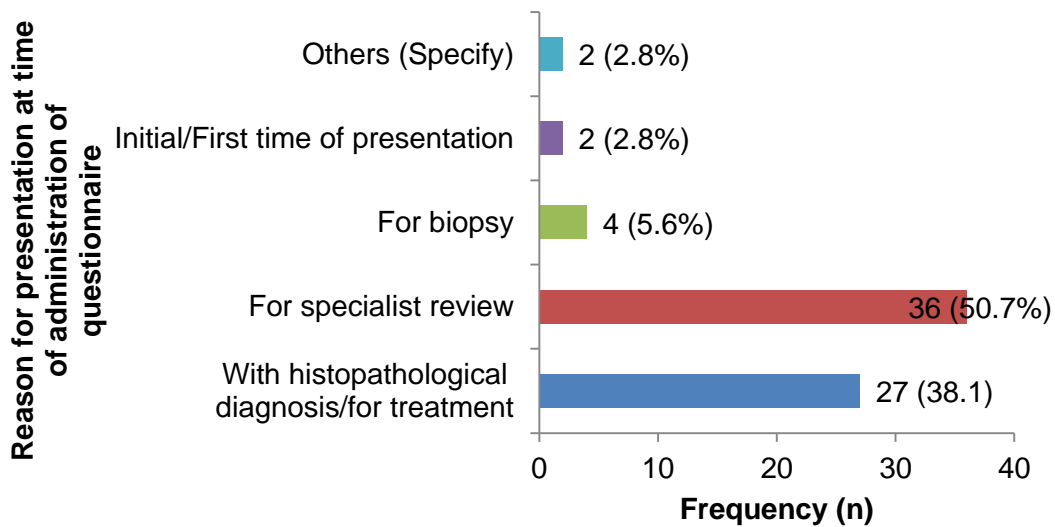


Figure 3: Distribution of oral cancer patients according to the reason given at presentation

3.6 Site of Lesion and Clinical Presentation

The most commonly affected site was the alveolar region 26(36.6%) followed by the tongue 22(31%), salivary glands 7(9.9%), floor of the mouth 6(8.5%) and oropharynx 6(8.5%).

Most lesions initially presented as swellings in 34 patients (47.9%), followed by ulceration 23(32.4%) and pain 23(32.4%). Other clinical presentations included tooth mobility 11(15.5%) and functional impairment 3(4.2%) like numbness, inability to either chew or swallow and trismus.

Table 3: Distribution of oral cancer patients based on site of lesion and the initial change or symptom.

Characteristics		Distribution	
		n	%
Site of lesion	Floor of mouth	6	8.5
	Tongue	22	31.0
	Salivary glands	7	9.9
	Alveolar region./Gums	26	36.6
	Oropharynx	6	8.5
	Lip	2	2.8
	Others (Specify)	2	2.8
Change or symptom	Pain	23	32.4
	Swelling	34	47.9
	Mobile tooth	11	15.5
	Functional impairment	3	4.2
	Ulceration	23	32.4
	Others	2	2.8

n; number of cases

3.7 Time taken to visit a hospital and duration of presentation of symptoms

The duration taken before visiting a hospital after noticing symptoms (patient delay) ranged from 0 – 560.0 days with a mean delay of 94.15 days (± 107.67 SD), a median of 70.0 days and a mode of 14.0 days.

The average time taken to first visit a medical facility by those unemployed was 79.5 days as compared with 103.7 days taken by those who were in formal employment. The time taken to visit a hospital between participants earning less than Ksh.10,000 and those earning more were 100.3 and 74.5 days respectively. Participants who first visited a private medical facility were subject to more delay (108.1 days) than those who first visited public facilities (90.1 days)

Table 4: Time taken to first visit a medical facility after noticing symptoms of oral cancer based on employment status, monthly income, initial facility visited.

		n(%)	M	SD	95% CI		Test	df	p
					Lower	Upper			
Employment status	Unemployed	28(39.4)	79.50	100.83	-76.41	28.02	t=0.924	69	0.358
	Employed	43(60.6)	103.70	112.02					
Monthly Income	<10,000	54(76.1)	100.33	116.37	-34.04	85.65	t=0.860	69	0.393
	$\geq 10,000$	17(23.9)	74.53	72.95					
Facility	Public	55(75.5)	90.11	94.38	-79.25	43.35	t=0.584	69	0.561
	Private	16(22.5)	108.06	147.54					

Independent Sample t test was used for employment, income and facility.
 CI; Confidence Interval.
 df; Degrees of freedom.
 p<0.05

3.8 Duration taken to first visit a hospital based on the site of lesion and symptoms

Patients with tongue lesions took the longest duration to visit a medical facility with a mean duration of 108.5 days compared to a mean of 107.3 days taken by those with lesions on the floor of the mouth. Participants with lesions on the salivary glands took the shortest duration (68 days) to report to hospital.

Those who initially developed tooth mobility were most prompt in visiting a medical facility with a mean duration of 42 days while those with pain and functional impairment took the longest time before visiting a hospital with mean durations of 162.1 and 88.7 days.

An Analysis of Variance (ANOVA) test elicited a statistically significant difference in means in time taken to visit a hospital after noticing symptoms based on initial symptom noticed by the patients (table x).

Table 5: Time taken (days) to visit hospital based on site of lesions and initial symptom noticed.

		n(%)	M	SD	95% CI		Test	df	p
					Lower	Upper			
Site of lesion	Floor of mouth	6(8.5)	107.33	95.95	6.65	208.04	F=0.405	6,64	0.873
	Tongue	22(31.0)	108.50	109.30	60.04	156.96			
	Salivary glands	7(9.9)	68.00	97.89	-22.54	158.54			
	Alveolar region/Gums	26(36.6)	98.81	128.16	47.04	150.57			
	Oropharynx	6(8.5)	70.00	57.89	9.25	130.76			
	Lip	2(2.8)	87.50	4.95	43.03	131.97			
	Others (Specify)	2(2.8)	7.00	0	7.00	7.00			
Symptom	Pain	19(26.8)	162.11	146.13	91.67	232.54	F=2.492*	5,65	0.040
	Swelling	25(35.2)	68.04	81.32	34.47	101.61			
	Mobile teeth	9(12.7)	42.78	67.82	-9.35	94.91			
	Functional Impairment	3(4.2)	88.67	71.84	-89.80	267.13			
	Ulceration	13(18.3)	85.08	82.62	35.15	135.00			
	Others (Specify)	2(2.8)	73.50	94.05	-771.46	918.46			

Analysis of Variance (ANOVA) test was used for all variables.

CI; Confidence Interval.

df; Degrees of freedom.

*p<0.05

3.9 Action taken by participants upon noticing symptoms and reason for actions taken

Majority did not immediately seek medical treatment upon noticing the symptoms. Of the 50 participants who did not immediately seek medical intervention, majority (29) did nothing, 23 self medicated while 3 turned to herbal medicine. Only 29 of the participants visited a medical facility for treatment.

The reasons that influenced the action taken upon noticing the symptoms were varied. Most (28) did not consider the disease serious, 20 were not in pain and therefore saw no need to visit a medical facility, 9 participants due to financial constraints while another 2 were advised by relatives not to go to hospital.

Table 6: Action taken by respondents upon noticing symptoms and reason for action taken.

Characteristics		Distribution	
		n	%
Action taken	Did nothing	24	33.8
	Self medication	23	32.4
	Visit hospital	29	40.8
	Herbal medicine	3	4.2
Reason that influenced action taken	No pain	20	28.2
	Relatives advice	2	2.8
	Lack of funds	9	12.7
	Disease not serious	28	39.4
	Others	24	33.8

n; number of cases

3.10 Health facility visited upon noticing symptoms

Majority of the patients, 55(77.5%), visited a public facility while the remaining 16(22.5%) visited a private ones. Of those who went to public facilities, majority-21 (29.6%) first went to a sub-county, 14 (19.7%) county, 3(4.2) visited a dispensary and 5(7%) visited the two referral hospitals

Of the 16 that were attended to at a private facility, majority (10) were seen in a clinic while the other 6 in a hospital

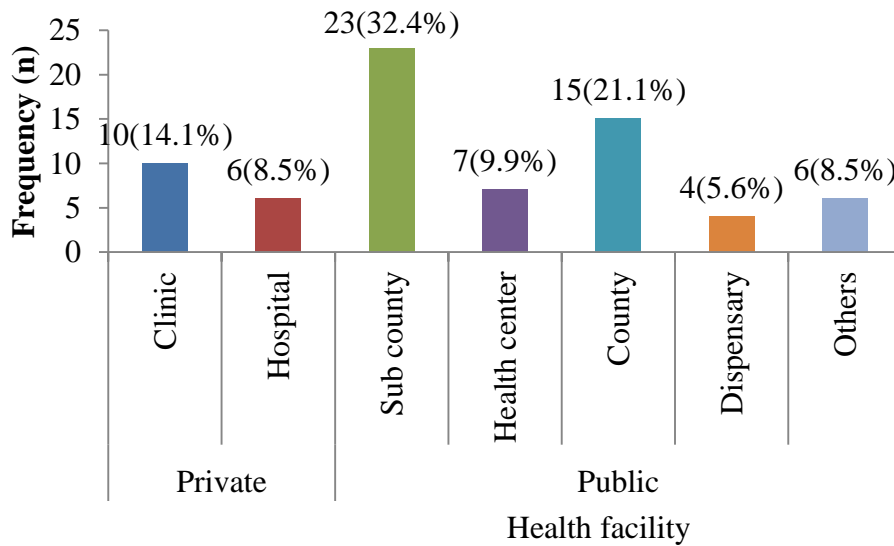


Figure 4: Health facility visited by oral cancer patients upon noticing symptoms

3.11 Number of visits to initial facility before referral and treatment received

Majority of the participants, 34, visited the initial facility at least twice before being referred or seeking treatment elsewhere. 18 only visited the initial facility once while 14 visited the initial facility more than three times for the same condition.

Almost half (35) of the patients were not aware of what they were being treated for and 34 were aware of their diagnosis while 2 could not remember. The initial treatment most commonly offered was medication. 22(31%) participants were referred while 11(15.5%) were subjected to radiographs.

Figure 5: Number of visits before Referral

Number of visits to a health facility by oral cancer patients before referral to a specialised facility

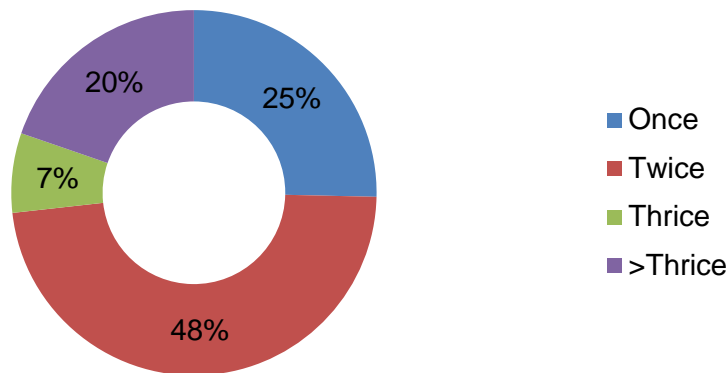


Table 7: Distribution of patients' based on treatment initially received and actions taken by the initial clinician.

Characteristics		Distribution	
		n	%
Initial treatment received	Medications	44	62.0
	X Ray	11	15.5
	Referral	22	31.0
	Others	13	18.3
Facility visits	Once	18	25.4
	Twice	34	47.9
	Thrice	5	7.0
	>Thrice	14	19.7
Informed of treatment	No	34	47.9
	Yes	35	49.3
	Can't remember	2	2.8
Facilities visited	< 3	22	31.0
	>= 3	49	69.0
Where biopsy was taken	First hospital visit	12	16.9
	Referral facility	32	45.1
	Others	27	38.0

3.12 Time taken to visit the referral centre (days) after being referred.

The delay to visit the referral hospital ranged from 0 – 177.0 days with a mean delay of 25.83 days (± 35.45 SD), a median of 14.0 days and a mode of 2.0 days.

Participants who were unemployed took longer duration to visit the referral facilities in comparison to the employed counterparts taking 32.1 days and 21.7 days respectively to visit. It took those earning less than Ksh 10,000 an average of 23.9 days to report to the referral facilities in comparison to those earning more who took 31.8 days. Those who visited public facilities took 24.5 days to visit the centres they were referred to compared to 30.4 days taken by those who initially visited private facilities

Table 8: Time taken to visit the referral centre (days) after being referred based on employment status, monthly income and initial facility visited.

		n(%)	M	SD	95% CI		Test	df	p
					Lower	Upper			
Employment	Informal Employment	28(39.4)	32.14	43.03	-6.69	27.54	t=1.215	69	0.229
	Formal Employment	43(60.6)	21.72	29.33					
Income	<10,000	54(76.1)	23.96	35.32	-27.52	11.92	t=0.789	69	0.433
	\geq 10,000	17(23.9)	31.76	36.27					
Facility visited	Public	55(75.5)	24.49	37.76	-26.13	14.23	t=0.588	69	0.599
	Private	16(22.5)	30.44	26.46					

Independent Sample t test was used for employment, income and facility.
 Analysis of Variance (ANOVA) test was used for biopsy location.
 CI; Confidence Interval.
 df; Degrees of freedom.

3.13 Time taken to visit the referral centre (days) after being referred based on site of lesion and symptoms.

It took 12.5 days for those with oropharyngeal lesions to report to the referral facilities. Those with lesions on the floor of the mouth took the longest duration(29.0 days) to report to the referral centers followed by those with tongue lesions (28.8 days)

Based on the symptoms, participants with functional impairment were the fastest to report to the referral facilities after an average of 7 days while those with ulcerations took the longest duration to report (34.8 days). Participants with pain equally took long to report to the referral facility with a mean duration of 34 days.

Table 9: Time taken to visit the referral centre (days) based on site of lesions and initial symptom.

		n(%)	M	SD	95% CI		Test	df	p
					Lower	Upper			
Site of lesion	Floor of mouth	6(8.5)	29.00	39.77	-12.74	70.74	F=0.371	6,64	0.895
	Tongue	22(31.0)	28.73	34.12	13.60	43.85			
	Salivary glands	7(9.9)	20.86	24.07	-1.40	43.11			
	Alveolar region/Gums	26(36.6)	27.85	42.92	10.51	45.18			
	Oropharynx	6(8.5)	12.50	19.55	-8.02	33.02			
	Lip	2(2.8)	38.50	34.65	-272.80	349.80			
	Others (Specify)	2(2.8)	3.00	1.41	-9.71	15.71			
Symptom	Pain	19(26.8)	34.00	45.57	12.04	55.96	F=1.122	5,65	0.357
	Swelling	25(35.2)	14.60	17.36	7.43	21.77			
	Mobile teeth	9(12.7)	32.89	59.78	-13.06	78.84			
	Functional Impairment	3(4.2)	7.00	6.93	-10.21	24.21			
	Ulceration	13(18.3)	34.85	25.06	19.70	49.99			
	Others (Specify)	2(2.8)	26.50	12.02	-81.50	134.50			

Analysis of Variance (ANOVA) test was used for all variables.

CI; Confidence Interval.

df; Degrees of freedom.

3.14 Reason for delay in visiting referral facility and access to treatment

Thirt five patients(49.3%) promptly visited the referral facilities that they were referred to while 36(51.7%) did not for various reasons. Most participants delayed due to lack of funds for logistical costs or for treatment. The other major cause of delay was the long distance to the referral facility and therefore the participants took a bit of time to organize themselves. Other reasons for delay in visiting the referral facility was because some had lost hope, a few others did not have time while others decided to seek a second opinion

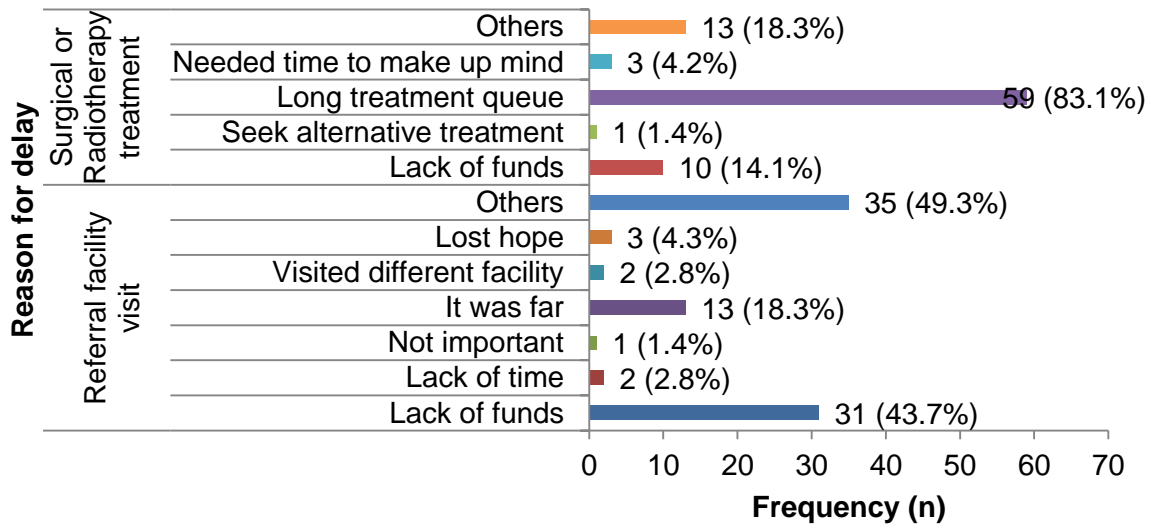


Figure 6: Reasons for the delay in surgical or radiotherapy treatment and visits to referral facilities

3.15 Treatment delay (days)

Treatment delay was attributed to long waiting time as a result of lengthy treatment queues. This affected 59(83.1%) of the participants. Other causes of delay included lack of funds, some needed to think about the treatment protocols while a few others decided to seek alternative treatment first.

The treatment delay ranged from 0 – 104.0 days with a mean delay of 11.30 days (± 22.56 SD), a median of 0 days and a mode of 0 days.

Participants who were unemployed were subjected to a mean delay of 8.0 days as opposed to 13.4 days by those in formal employment. Based on the first hospital visited, participants who first visited public facilities were subjected to less delay (6.3 days) in comparison to those who first visited private facilities (28.6 days)

Treatment delay based on where the biopsy was taken was shortest when the biopsy was taken at the two referral centres (5.9 days) and longest when the biopsy was taken at the initial facility visited.

An Independent Samples t test elicited a statistically significant difference in means in treatment delay between initial facilities visited by patients.

Table 10: Treatment delay (days) based on employment status, monthly income, initial facility visited and where the biopsy was taken.

		n(%)	M	SD	95% CI		Test	df	p
					Lower	Upper			
Employment	Unemployed	28(39.4)	8.04	12.32	-16.31	5.55	t=0.982	69	0.329
	Employed	43(60.6)	13.42	27.18					
Income	<10,000	54(76.1)	10.48	20.05	-15.98	9.18	t=0.539	69	0.591
	>=10,000	17(23.9)	13.88	29.76					
Facility	Public	55(75.5)	6.27	14.69	-34.00	-10.6	t=3.798*	69	<0.022
	Private	16(22.5)	28.56	34.45					
Where Biopsy was taken	First hospital visited	12(16.9)	16.25	26.19	-0.39	32.89	F=1.721	2,68	0.187
	Referral facility	32(45.1)	5.89	10.07	2.24	9.51			
	Others (Specify)	27(38.0)	15.52	29.88	3.70	27.34			

Independent Sample t test was used for employment, income and facility.

Analysis of Variance (ANOVA) test was used for biopsy location.

CI; Confidence Interval.

df; Degrees of freedom.

p<0.05

3.16 Treatment delay (days) based on site of lesions and initial symptom noticed.

Oropharyngeal lesions were subject to the shortest treatment delays (2.33 days) while alveolar lesions had the longest (18.3 days). Other anatomical sites subjected to long delays were lip (10.5 days), floor of mouth (9.7 days) and tongue (8.6 days)

Various symptoms were subject to different durations of delays. Functional impairments were subject to the shortest (2.3 days) while swellings were subjected to the longest (15.3 days). Pain and ulcerations were subjected to 10.5 and 8.5 days delay respectively

Table 11: Treatment delay (days) based on site of lesions and initial symptom noticed.

		n(%)	M	SD	95% CI		Test	df	p
					Lower	Upper			
Site of lesion	Floor of mouth	6(8.5)	9.67	13.72	-4.73	24.07	F=0.748	6,64	0.614
	Tongue	22(31.0)	8.59	20.28	-0.40	17.58			
	Salivary glands	7(9.9)	4.00	10.58	-5.79	13.79			
	Alveolar region/Gums	26(36.6)	18.31	30.12	6.14	30.47			
	Oropharnyx	6(8.5)	2.33	3.61	-1.46	6.13			
	Lip	2(2.8)	10.50	14.85	-122.92	143.92			
	Others (Specify)	2(2.8)	8.00	8.49	-68.24	84.24			
Symptom	Pain	19(26.8)	10.47	24.59	-1.38	22.34	F=0.326	5,65	0.895
	Swelling	25(35.2)	15.36	29.50	3.18	27.54			
	Mobile teeth	9(12.7)	10.33	11.24	1.70	18.97			
	Functional Impairment	3(4.2)	2.33	4.04	-7.71	12.37			
	Ulceration	13(18.3)	8.46	12.55	0.88	16.05			
	Others (Specify)	2(2.8)	4.50	6.36	-52.68	61.68			

Analysis of Variance (ANOVA) test was used for all variables.

CI; Confidence Interval.

df; Degrees of freedom.

3.17 Time taken to get histopathological/biopsy results

While all the patients, 71 (100%) had their histopathological report, the time taken for the patients to get their histopathological report after biopsy was taken ranged from 2.0 – 31.0 days with a mean period of 15.03 days (± 5.36 SD), a median of 14.0 days and a mode of 14.0 days.

3.18 Duration of disease

The duration (days) the patient suffered from the disease ranged from 35.0 – 840.0 with a mean period of 299.86 (± 164.06 SD), a median of 282.0 and a mode of 280.0.

A Pearson Correlation Coefficient (r) test of association elicited a statistically significant, strong, positive association between the patients' duration (weeks) for the first visit to the hospital after noticing symptoms and the duration (weeks) of having the lesion ($n=71$, $r=0.705^{***}$, $p<0.001$).

A Linear Regression (Curve Estimation) model elicited a statistically significant association between the patients' duration (weeks) for the first visit to the hospital after noticing symptoms and the duration (weeks) of having the lesion as the predictor variable ($n=71$, $R^2=0.560^{***}$, $B=0.748$, $F=87.732$, $df=1$, $p<0.001$).

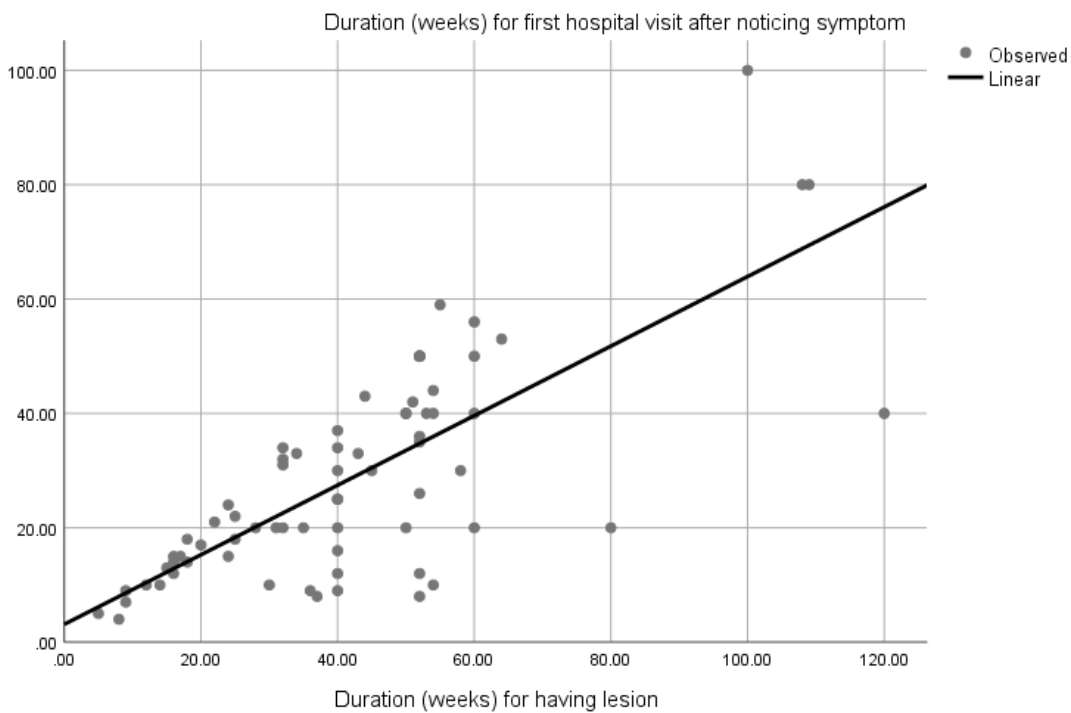


Figure 7: Linear regression curve estimation plot model

CHAPTER 4

4.0 DISCUSSION

4.1 Socio-demographics

There were more males (60.6%) than females (39.4%) who presented with oral cancers in this study. This is in line with global trends where oral cancer is higher in males than females.⁶⁰ The same was reported in a previous local study.^{61,62} The gender disparity could be as a result of societal practices where women are less exposed to the risk habits like alcohol intake and tobacco smoking. This study did not capture the exposure to the risk factors by the patients.

Majority of the patients had National Health Insurance cover which facilitated them in getting treatment. None of the patients was covered by a private insurance. There could be a possibility that those with private insurance covers sought treatment from the private sector since none of the two centres are contracted to see patients with private insurance. Those without insurance were financially assisted by friends and relatives. This demonstrated the significance of having a medical cover.

4.2 Oral Cancer

Oral squamous cell carcinoma was found to be the most common oral malignancy just like a local audit report by Dimba et al.⁶¹ However, in this study, the prevalence was higher compared to the audit. This could be an indicator of more exposure to the risk factors of oral squamous carcinoma. More studies should be done to investigate this rise. The commonest site of occurrence was the gingiva followed by the tongue. Previous local study found the opposite with the tongue being the commonest site of occurrence followed by the gingiva.⁶² Healthcare workers should have a high index of suspicion when dealing with symptoms like tooth mobility and tongue swellings or ulcers as these are the commonest presentation and should not be confused with other oral conditions that present in the same manner

4.3 Delays

4.3.1 Patient Delay

Most patients presented with stage III and IV disease. Patient delay is the most significant contributor to delay spectrum.^{55,33} This is evident in other studies done in Pakistan.⁶³ In this study, the median period before seeking treatment was 70 days. Other studies done elsewhere had lower median of 21 days in United Kingdom⁶⁴ and Denmark⁶⁵. Unlike the UK study where only 30% of the patients were victims of patient delay, this study found all the patients to have a delay. Some of the reasons advanced for delay in seeking medical treatment include self-medication and lack of knowledge on cancer symptoms.⁶⁴ Other reasons include inability to perceive lesion as cancer in a British study³⁶, low education status in a study done in Karachi⁶⁶ and fear of cancer, its investigation and treatment.⁶⁷ Some of these factors were also contributory in this local study such as self-medication and lack of knowledge on severity of condition and symptoms of cancers. Self-medication tends to lengthen the patient delay as it tends to manage the symptom as opposed to disease. This could be the reason why patients in pain had the longest delay as they could easily access analgesics to control the initial pain and only sought medical treatment when they were overwhelmed during which the disease had progressed. It is worth noting that absence of pain in the initial stage significantly increased the delay in seeking medical attention. Some studies report pain as an initial symptom only in 20% of cases and mainly in stage III and IV cancer.⁶⁹

Fear of cancer where the condition is viewed as a death sentence calls for early counselling in these patients to give them hope. This study did not look at the impact of counselling on the health seeking habit and therefore the impact of fear of cancer was not looked at but other studies can do so.

Referral delay is the time taken to visit the facility to which they were referred. Few studies have looked at this delay with others reporting very minimal time taken by patients to visit the referral centres. This is sometimes further reduced by the referring doctor making arrangements by contacting the specialized centres prior to referring the patients. Studies have found indirect referral and lengthy referral procedures as causes of referral delay.^{40,50} In this study, they lengthy referral system did not play a significant role as the reasons given were mainly financial constraint, lack of knowledge on the seriousness of the symptoms and distant referral centres. In the United States, this delay has been significantly reduced by designating a 'patient navigator' whose role is to ensure that the patient established contact with the relevant specialist within 1 or 2 days of referral and to ensure a treatment plan is established within two weeks of referral⁷⁰. This if applied locally can significantly reduce the delay

Employment status was looked at in this study. Those who were employed took the longest time to report to hospitals followed by unemployed and the least time taken by self employed. This difference was not statistically significant. Those in self employment could have taken the shortest time probably due to financial stability and lack of control by bosses as opposed to those who are employed who probably took time to organize for leave from work. Employers must be sensitized to allow their employees time to seek medical attention as early as possible as this could be a possible reason for the long delay by those who were employed.

4.3.2 Diagnostic Delay

All patients were subjected to diagnostic delay. It takes about 14 days to get a histopathological diagnosis after biopsy. This causes further delay. This is longer than 16-20 hours recommended by some studies.⁵² This was mainly due to the organization of consultant clinics which are once weekly and with each day of the week having a specific consultant. This could also be compounded by the crowding of these patients at the two referral facilities thereby stretching the resources available in the laboratory. Our laboratories must however make effort to reduce the turn-around time and give out results within a shorter duration. Private laboratories could also be encouraged to help reduce the backlog. A study could be done to identify the challenges faced locally by the pathologists and recommendations made to make the process more efficient and comparable to other countries. We were not able to accurately capture the diagnostic delay because some patients came with the histopathology results from other centres, others came for biopsy reports and were thereafter treated in the tertiary facilities and the questionnaire did not accurately capture the first contact of the participants with a medical practitioner.

4.3.3 Healthcare provider delay

Most patients were medicated upon presentation and had multiple visits to the initial medical facility before being referred to specialists or having relevant investigations like biopsy.

Healthcare workers must know when to refer and do so at the earliest opportunity. Other patients had extractions done due to mobility of teeth without the cause of mobility being investigated. Basic investigations like panoramic x-rays can be used to identify suspicious lesions. This study did not identify the level of training of the first medical practitioner who came in contact with the patients and the treatment aids at their disposal. Future studies should look at this. Studies elsewhere have found lack of knowledge⁷¹ and inexperience²² among healthcare providers as a cause of delay in referring cancer patients. Cost was not a major influencing factor as only 12.7% attributed the delay to seeking treatment to lack of funds. Research has concluded that the standard time interval for a cancer patient to be referred to a specialist should range between 2 days⁷² and 2 weeks⁷³

Site of lesion has been associated with delay in diagnosis⁷⁴. In this study, delay based on site was most prevalent in the tongue followed by floor of mouth and alveolar regions. Other studies have found an almost similar pattern of tumours of the floor of mouth, retromolar trigone and gingivae being more advanced at time of diagnosis⁷⁵. The reason why this sites are vulnerable to delay was not investigated in this study but dentists should be sensitized on the need to routinely examine these sites when doing intra-oral exam and initiate basic radiographic investigations like panoramic x-rays. Some of the alveolar tumours could be

originating from the maxillary antrum which is an enclosed anatomical region hence difficult to examine clinically leading to delay in diagnosis

More participants visited public facilities as opposed to private facilities. This is an indication of how wide the public facilities serve and thus the need to adequately equipping the public facilities with both equipment and personnel. It could also be due to the low financial status of our participants since cost of treatment is lower in public compared to private hospitals.

Many patients who were referred to the two referral centres visited soon after referral since they had an idea of the need to urgently seek treatment. This elaborates the importance of cancer awareness especially of symptoms as it was evident in the promptness in visiting the referral centres. A good number of patients were not informed what they were initially being treated for. This shows the lack of information on the seriousness of the conditions either due to lack of knowledge of the healthcare workers or the patients or both.

4.3.4 System Factors Associated with Delay

Treatment delay was mainly due to lengthy waiting time probably due to lack of personnel to offer treatment at the referring facilities. Participants who had biopsies taken at the lower level facilities were still referred to the two referral centres. They were thus further subjected to delay due to the convergence at the two referral centres leading to long treatment queues. There is need to have a more structured referral system where patients can be followed up by both the referring doctor and that to whom patient is referred. This would help in reducing referral delays.

4.4 Conclusion

Majority of patients (95.8%) present late for cancer treatment. Patient delay was mainly caused by lack of knowledge of the early symptoms of cancer, self medication and lack of finance by the patients. Some healthcare workers further worsened the delay by either not referring the patients in time or initiating appropriate investigations. Some patients were started on wrong treatments like medications and extraction of mobile teeth. Some of the patients who were referred to the two referral facilities did not report immediately. During the referral, some patients had no idea of the need to urgently visit the referral facilities and the importance of early treatment. Many patients are referred to the referral centres leading congestion and further delaying treatment due to the long queues. Few patients go for screening hence very few cancers are detected in the initial stages. Histopathology reports take too long to be generated.

In this study, none of the factors tested was shown to be statistically significant apart from the initial facility visited. This could be in indication that the sample size was too small to be projected to the general population. A study on a larger sample should be done to get a more accurate association. The impact of the delay on the tumor progression was also not accurately investigated in this study. This is because the tumors were picked at different stages with majority being in stage IV which is the worst. Describing tumor progression beyond stage IV was not possible and this could be a weakness of the TNM staging system.

In our view, 35 days is a reasonable duration to define delay upon patients reporting to a medical facility. This includes 14 days to follow up a non-healing ulcer or swelling before doing a biopsy, 7 days to get a histopathology report and another 14 days to initiate treatment.

4.5 Recommendations

1. There is need to educate both the caregivers and the community on the common symptoms of cancer so as to increase the index of suspicion
2. More capacity building in terms of personnel and equipment at the county and sub-county hospitals to reduce the waiting time for treatment.
3. Our referral system should be restructured to reduce referral delays and patients followed up more closely upon referral.
4. There should be clear guidelines on how to handle suspected or confirmed cancer patients by primary healthcare workers.

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APPENDICES

APPENDIX 1:QUESTIONNAIRE

1. Gender
2. Age
3. Education level
 - a. Primary
 - b. Secondary
 - c. Tertiary
4. Diagnosis
5. Employment status
 - a. Formal
 - b. Informal
 - c. Self employed
 - d. Unemployed
6. Monthly income
 - a. <Kshs10000
 - b. Kshs10000-20000
 - c. Kshs20001-30000
 - d. Kshs30001-40000
 - e. Kshs40001-50000
 - f. >Kshs50000

7. How do you plan to meet the expenses associated with the treatment of the disease

- a. Personal funds
- b. Insurance
- c. Donations
- d. Family
- e. Others(Specify)

8. Staging at presentation

- a. T
- b. N
- c. M

9. Reason for presentation at time of administration of questionnaire

- a. Initial/First time of presentation
- b. For specialist review
- c. For biopsy
- d. With histopathological diagnosis/for treatment
- e. Others(specify)

10. Do you have a medical cover

- a. Yes
- b. No

11. If yes, when did you acquire it?

- a. After noticing the symptoms
- b. Before noticing the symptoms

12. Site of lesion

- a. Lip
- b. Tongue
- c. Salivary glands
- d. Alveolar region/Gums
- e. Floor of mouth
- f. Oropharynx
- g. Others(specify)

13. How long have you had the lesion(in weeks)

14. What was the initial change/symptom that you noticed

- a. Pain
- b. Swelling
- c. Mobile tooth
- d. Functional impairment
- e. Ulceration
- f. Others(specify)

15. What action did you take when you first noticed the change/symptoms

- a. Did nothing
- b. Self-medication
- c. Visit to a nearby hospital
- d. Traditional medicine
- e. Others(specify)

16. What made you make the decision above

- a. There was no pain
- b. Advice from relatives/guardian
- c. Lack of funds
- d. Did not consider disease to be serious
- e. Others(specify)

17. How long ago (in weeks) did you first visit a hospital for the symptoms?

18. What was the initial facility that you visited

- a. Private (Go to Q19)
- b. Public (Go to Q20)

19. If private,

- a. Clinic
- b. Hospital

20. If public

- a. Dispensary
- b. Health center
- c. Sub county
- d. County
- e. Others(specify)

21. Initial treatment received

- a. Medications
- b. X ray
- c. Immediate referral
- d. Others(specify)

22. How many visits did you make to the initial facility

- a. 1
- b. 2
- c. 3
- d. >3
- e. Can't remember

23. Were you told what you were being treated for?

- a. Yes
- b. No
- c. Can't remember

24. How many health care facilities have you visited for the same condition

25. Do you have a histopathological report

a. Yes

b. No

26. If yes, when was the biopsy taken?

27. Where was the biopsy taken?

a. First visited hospital

b. Referral facility

c. Others(specify)

28. How many days after biopsy did you get the histopathology results

29. Date of first referral

30. Date of visit to the referral center

31. What was the reason for the delay

a. Lack of funds

b. Lack of time

c. I didn't see the importance

d. It was far

e. Visited a different facility to seek a second opinion

f. I lost hope

g. Others(specify)

32. Date of planned surgical/radiotherapy treatment

33. Date of actual surgical/radiotherapy treatment

34. What was the reason for the delay

- a. Lack of funds
- b. To seek a second opinion
- c. To seek alternative treatment
- d. Long treatment queue
- e. I needed time to make up my mind
- f. I had other commitments
- g. Others(specify)

35. Stage of lesion at time of treatment

- a. T
- b. N
- c. M

APPENDIX II: KISWAHILI QUESTIONNAIRE

HOJAJI

1. Jinsia
2. Umri
3. Kiwango cha elimu
 - a. Shule ya msingi
 - b. Shule ya upili
 - c. Chuo cha ufundi
4. Matokeo ya upimaji wa ugonjwa

5. Ajira
 - a. Kazi ya rasmi
 - b. Kazi isiyo ya rasmi
 - c. Kujiari
 - d. Sijaajiriwa
6. Mshahara wa kila mwezi
 - a. <Kshs10000
 - b. Kshs10000-20000
 - c. Kshs20001-30000
 - d. Kshs30001-40000
 - e. Kshs40001-50000
 - f. >Kshs50000

7. Utalipaje gharama ya matibabu ya ugonjwa huu?
- Pesa zangu binafsi
 - Malipo ya bima
 - Usaidizi kutoka kwa wafadhili
 - Familia
 - Zingine(elezea)
8. Ugonjwa wako ulikuwa katika kiwango gani
- T
 - N
 - M
9. Sababu za kujiwaslisha wakati wa uwasilishaji wa hojaji hii ni ipi?
- Nilikuwa nimekuja hospitalini kwa mara ya kwanza.
 - Nimetumwa kwa daktari wa upasuaji
 - Niko hapa ili sampuli ya uvimbe ichukuliwe
 - Niko na ripoti ya sampuli ya uvimbe/natafuta matibabu
 - Mengine(elezea)
10. Kuna bima yeyote inakusimamia?
- Ndio
 - La
11. Iwapo jibu lako ni ndio, uliipata lini?
- Baada ya kuona dalili
 - Kabla ya kuona dalili

12. Umeugua wapi haswa

- a. Mdomo
- b. Ulimi
- c. Tezi ya mate
- d. Ufizi
- e. Upande wa chini wa kinywa
- f. Koo
- g. Mengine(elezea)

13. Umeugua kwa wiki ngapi?

14. Dalili ya kwanza uliyoiona ni gani

- a. Uchungu
- b. Uvimbe
- c. Kutingika kwa jino/meno
- d. Kushindwa kufanya kazi
- e. Kidonda
- f. Zingine(elezea)

15. Ulichukua hatua gani baada ya kuona dalili

- a. Sikufanya lolote
- b. Nilijinunulia madawa kwenye duka la dawa
- c. Nilitembelea hospitali iliyopo karibu
- d. Nilitumia dawa za kienyeji

e. Zingine(elezea)

16. Nini kilichokufanya ufanye uamuzi huo?

a. Sikuwa nahisi uchungu

b. Nilipata mawaidha kutoka kwa jamaa yangu

c. Ukosefu wa pesa

d. Sikuona kana kwamba ugonjwa huo una madhara yoyote?

e. Mengine(elezea)

17. Baada ya kuona zile dalili, ulitembelea hospitali yako ya kwanza baada ya wiki ngapi?

18. Kituo cha kwanza cha afya uliyotembelea ni ipi?

a. Ya kibinafsi (Nenda kwa swali la 19)

b. Ya umma (Nenda kwa swali la 20)

19. Iwapo ni ya kibinafsi ilikuwa:

a. Klinki

b. Hospitali

20. Iwapo ni ya umma ilikuwa:

a. Zahanati

b. Kituo kidogo cha afya

c. Hospitali ya kaunti ndogo

d. Hospitali ya kaunti

e. Zingine(elezea)

21. Ulipata matibu yapi hapo awali?

- a. Nilipewa dawa
- b. Nilifanyiwa eksirei
- c. Nilitumwa katika hospitali nyingine papo hapo
- d. Mengine(elezea)

22. Ulitembelea hospitali yako ya kwanza yapata mara ngapi?

- a. 1
- b. 2
- c. 3
- d. >3
- e. Sikumbuki

23. Uliarifiwa unatibiwa ugonjwa upi?

- a. Ndio
- b. La
- c. Sikumbuki

24. Umetembelea hospitali ngapi ukitafta matibabu ya ugonjwa huu?

25. Je, una ripoti ya kukatwa uvimbe?

26. Iwapo jibu lako ni ndio, sampuli zilichukuliwa lini?

27. Sampuli hizo zilichukuliwa wapi?

- a. Katika hospitali ya kwanza niliyotembelea
- b. Katika hospitali niliyotumwa
- c. Mengine(elezea)

28. Baada ya sampuli zako kuchukuliwa, ulingoja kwa muda gani ili kupata matokeo?

29. Siku ya kwanza kutumwa hospitali nyingine kwa uchunguzi zaidi ni lini?

30. Siku maalum ya kuitembelea hospitalini niliko tumwa

31. Kwa nini matokeo yako yalikawia?

- a. Ukosefu wa pesa
- b. Kukosa wakati
- c. Sikuona umuhimu wake
- d. Ilikuwa mbali
- e. Nilitembelea hospitali nyingine kutafuta njia nyingine ya matibabu
- f. Nilipoteza matumaini
- g. Mengine(elezea)

32. Ulipangiwa kufanyiwa upasuaji lini?

33. Upasuaji ulifanyika lini haswa?

34. Sababu ya kukawia ilikuwa ipi?

- a. Ukosefu wa pesa
- b. Kutafuta mawaidha zaidi
- c. Kutafuta njia tofauti ya matibabu
- d. Kulikuweco na laini ndefu ya wagonjwa waliohitaji kutibiwa
- e. Nilihitaji muda zaidi kufanya uamuzi wangu
- f. Nilikuwa na mahitaji mengine
- g. Mengine(elezea)

35. Ugonjwa wako ulikuwa umefikia kiwango gani wakati ulipata matibabu?

- a. T
- b. N
- c. M

APPENDIX III: PARTICIPANT INFORMATION AND CONSENT FORM

Title of study: Factors responsible for delay in the diagnosis and treatment of oral cancers at two referral centers in Nairobi

Principal investigator: Dr Midega Augustine, a postgraduate student in Oral and maxillofacial surgery at The University of Nairobi

Study purpose: The study seeks to establish the causes of delay in presentation, diagnosis and treatment of patients with oral cancer. Most patients present to the two referral facilities with advanced disease. Advanced disease has poor prognosis hence poor surgical outcomes in comparison to early disease.

Study procedure: The information will be acquired by administration of a questionnaire. The principal investigator will ask questions and record your response. The questions will cover the entire duration from when you first discovered a change related to the cancer, when you first sought medical attention and the kind of attention that was given. The principal investigator will follow you up until beginning of treatment without interfering with the process of getting treatment.

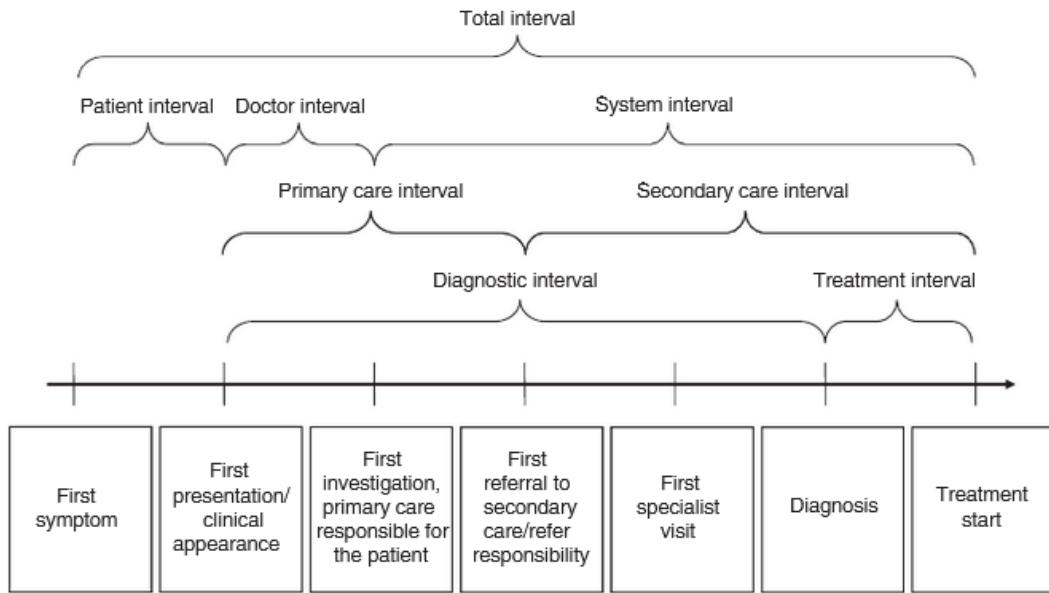
Voluntariness of the participation: Participation is voluntary and one is at the liberty to decline to participate or withdraw at any stage without loss of any benefits.

Confidentiality: The information obtained will be treated with utmost confidentiality. No personal details like name will be taken.

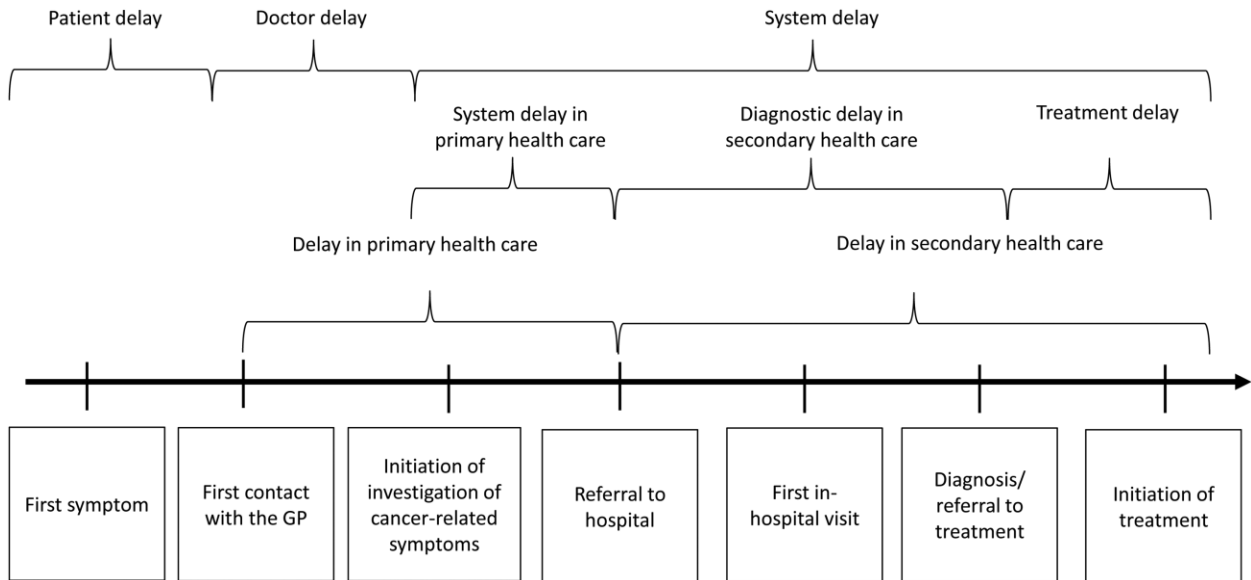
Benefits of participation: This study will help to understand better some of the challenges patients face when seeking treatment for oral. This feedback will be used to make a contribution in making cancer diagnosis and treatment more efficient.

Risks of participation in the study: There is no expected risk of psychological or bodily harm to the participants.

APPENDIX IV: AARHUS CHECKLIST




APPENDIX V: REVISED ANDERSEN MODEL OF PATIENT DELAY




APPENDIX VI: APPROVAL FROM KNH/UON ETHICS COMMITTEE



UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19678 Code 00202
Telegrams: varsity
Tel: (254-020) 2726300 Ext 44355




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



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

Ref: KNH-ERC/A/206

10th July 2020



Dr. Augustine Awarah Midega
Reg. No. V60/87602/2016
Dept. of Oral and Maxillofacial Surgery
School of Dental Sciences
College of Health Sciences
University of Nairobi

Dear Dr. Midega

RESEARCH PROPOSAL- FACTORS ASSOCIATED WITH DELAY IN THE DIAGNOSIS AND TREATMENT OF ORAL CANCER AT TWO REFERRAL CENTRES IN NAIROBI (P215/03/2020)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 10th July 2020 – 9th July 2021.

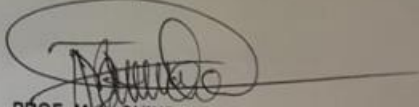
This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- 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.
- Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
- 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*).
- 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.

Protect to discover

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

Yours sincerely,



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

- c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Dental Sciences, UoN
The Chair, Dept. of Oral and Maxillofacial Surgery, UoN
Supervisors: Prof. J. F. Onyango, Dept. of Oral and Maxillofacial Surgery, UoN
Dr. M. R. Akama, Dept. of Oral and Maxillofacial Surgery, UoN
Dr. Fawzia Butt, Dept. of Oral and Maxillofacial Surgery, UoN

APPENDIX VII: TNM STAGING

T — Primary tumour ^{1,2}

TX	Primary tumour cannot be assessed
T0	No evidence of primary tumour
Tis	Carcinoma in situ
T1	Tumour 2 cm or less in greatest dimension
T2	Tumour more than 2 cm but not more than 4 cm in greatest dimension
T3	Tumour more than 4 cm in greatest dimension
T4a (lip)	Tumour invades through cortical bone, inferior alveolar nerve, floor of mouth, or skin (chin or nose)
T4a (oral cavity)	Tumour invades through cortical bone, into deep/extrinsic muscle of tongue (genioglossus, hyoglossus, palatoglossus, and styloglossus), maxillary sinus, or skin of face
T4b (lip and oral cavity)	Tumour invades masticator space, pterygoid plates, or skull base; or encases internal carotid artery

N - Regional Lymph Nodes^{##}

NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in a single ipsilateral lymph node, 3 cm or less in greatest dimension
N2	Metastasis as specified in N2a, 2b, 2c below
N2a	Metastasis in a single ipsilateral lymph node, more than 3 cm but not more than 6 cm in greatest dimension
N2b	Metastasis in multiple ipsilateral lymph nodes, none more than 6 cm in greatest dimension
N2c	Metastasis in bilateral or contralateral lymph nodes, none more than 6 cm in greatest dimension
N3	Metastasis in a lymph node more than 6 cm in greatest dimension

M - Distant metastasis

M0	No distant metastasis
M1	Distant metastasis

Stage grouping

Stage 0	Tis	N0	M0
Stage I	T1	N0	M0
Stage II	T2	N0	M0
Stage III	T1, T2	N1	M0
	T3	N0, N1	M0
Stage IVA	T1, T2, T3	N2	M0
	T4a	N0, N1, N2	M0
Stage IVB	Any T	N3	M0
	T4b	Any N	M0
Stage IVC	Any T	Any N	M1

APPENDIX VIII: CONSENT FORM

Participant's statement

I, (initials), have read this consent form or had the information read to me. My questions have been answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

Participant signature / Fingerprint Date

Researcher's statement

I, Dr. Midega Augustine, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Signature..... Date.....

In case of any clarifications or concerns regarding the study you may contact the investigator, the lead supervisor or secretary KNH/UON ethics , research and standards committee using the following contacts:

1. Dr. Midega Augustine (principal investigator)

Tel 0723353634; austine62003@gmail.com

2. Prof. J.F. Onyango

Tel 0722766701; dr.jfonyango@gmail.com

3. Prof A Guantai

Tel 2726300 Ext. 44102; uonknherc@uonbi.ac.ke

APPENDIX IX: KISWAHILI CONSENT FORM

KIAMBATISHO 2: FOMU YA RIDHAA NA MAELEZO YA MSHIRIKI

Mada ya utafiti: Mambo yanayochangia kuchelewa kwa uchunguzi na matibabu ya ugonjwa wa saratani ya kichwa na shingo katika hospitali mbili kuu za saratani zilizoko jijini Nairobi

Mtafiti mkuu: Daktari Midega Augustine, mwanafunzi wa uzamili chuo kikuu cha Nairobi anayesomea masomo ya upasuaji wa uso, kinywa shingo na kichwa.

Lengo la utafiti: Utafiti huu unakusudia kutambua sababu za kukawia kwa wagonjwa kujifikisha hospitalini, kufanyiwa uchunguzi na kupata matibabu ya saratani ya kichwa na shingo. Wagonjwa wengi huenda katika hospitali hizo mbili kuu wakati wameugua kwa kiwango kikubwa. Ugonjwa ambao umesambaa mwilini kwa kiwango kikubwa aghalabu huwa hautibiki na hivyo basi hata juhudi za upasuaji hazifui dafu ikilinganishwa na ugonjwa ambao haujasambaa mwilini.

Mpangilio wa utafiti: Maelezo yatapatikana kwa kuuliza maswali. Mtafiti mkuu atakuuliza maswali na kurekodi majibu yako. Utaulizwa maswali kuhusiana na ni lini ulianza kuona dalili za saratani, ulienda hospitali gani na ulipewa matibabu gani. Mtafiti mkuu atafuatilia kuanzia ni lini ulianza matibabu bila kuhitilafiana na jinsi matibabu yalivyotekelezwa.

Kujitolea kwa mshiriki: Mshiriki anashiriki katika utafiti huu kwa hiari na ana uhuru wa kujiondoa pasipo na hasara yoyote.

Siri: Maelezo yatakoyopeanwa na mshiriki yatakuwa ya siri. Jina lake litabanwa.

Manufaa ya kushiriki: Utafiti huu utatusaidia kujua changamoto ambazo wagonjwa hupitia wakati wanatafuta matibabu ya saratani ya shingo na kichwa. Majibu tutakayopata hapa yatusaidia kuboresha matibabu ya ugonjwa wa saratani na pia yatasaidia kuugundua ugonjwa wa saratani mapema.

Kuna madhara yoyote ya kushiriki katika utafiti huu: Hamna madhara yoyote yanayotarajiwa kuwapata watakaoshiriki

FOMU YA RIDHAA

Kauli ya mshiriki,

Mimi,..... (Majina), Nimeisoma fomu hii ya ridhaa au nimesomewa ujumbe ulipo kwenye fomu hii. Nilipata fursa ya kujadiliana kuhusu utafiti huu na mtafiti. Maswali yangu yamejibiwa kwa lugha ambayo naielewa. Nimeelezwa manufaa na hatari zilizopo. Naelewa kwamba ushiriki wangu katika utafiti huu ni wa hiari na naweza kujiondoa wakati wowote. Nimekubali kwa hiari kushiriki katika utafiti huu. Naelewa kuwa habari zangu za kibinafsi zitahifadhiwa vyema.

Kwa kutia sahihi fomu hiiya ridhaa,sijatupilia mbali haki zangu zxa kisheria kama mshiriki katika utafiti huu.

Sahihi ya mshiriki / Alama ya kidole Tarehe

Kauli ya mtafiti

Mimi daktari Midega Augustine, nimetoa maelezo kamilifu kuhusiana na utafiti huu kwa mshiriki ambaye ametajwa katika utafiti huu na naamini kwamba mshiriki ameelewa na akatoa ridhaa yake kwa hiari.

Sahihi..... Tarehe.....

Iwapo utahitaji ufafanuzi zaidi kuhusu utafiti huu zungumza na mkuu wa uchunguzi, msimamizi mkuu au katibu wa kamati ya maadili na utafiti ya KNH/UON kupitia kwa nambari zifuatazo:

1. Dr. Midega Augustine (mkuu wa uchunguzi)

Tel 0723353634; austine62003@gmail.com

2. Prof. J.F. Onyango

Tel 0722766701; dr.jfonyango@gmail.com

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