TOBACCO SMOKING, ALCOHOL CONSUMPTION AND KHAT CHEWING PRACTICES AMONG PATIENTS DIAGNOSED WITH ORAL CANCER AT THE UNIVERSITY OF NAIROBI DENTAL HOSPITAL.

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V28/23742/08

A RESEARCH PROJECT PROPOSAL SUBMITTED IN PARTIAL FULFILLMENT OF THE BACHELOR OF DENTAL SURGERY (BDS) OF THE UNIVERSITY OF NAIROBI.

2012
DECLARATION
I Carolyne Bosibori Moturi declare that this proposal is my original work and has not been submitted for the award of a degree at this or any other university.

Signature: ___________________________  Date: ____________

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School of

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Signature:

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APPROVAL

I, Carolyne Bosibori Moturi, wish to submit this proposal in partial fulfillment to the UON/KNH Research, Ethics and Standard Committee for approval.

Signature: _______________ Date: _______________

This proposal has been submitted with the approval of my supervisors.

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SIGNATURE: _______________ Date: 09.11.12
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ABBREVIATIONS

UNDH-University of Nairobi Dental Hospital

TNM-Tumor Nodal Metastases

OSCC- Oral Squamous Cell Carcinoma

IARC- International Agency for Research on Cancer

DNA- Deoxyribonucleic acid

HIV/AIDS- Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
ABSTRACT

BACKGROUND:

There is very little information on the etiological factors that are associated with oral cancer in Kenya this prompted me to base my project on this topic. The knowledge gained from this study will be instrumental in the design of oral cancer preventative programs and effective management.

OBJECTIVE:

To describe cigarette smoking, alcohol consumption and khat chewing practices in patients diagnosed with oral cancer at University of Nairobi Dental Hospital and Kenyatta National Hospital.

STUDY DESIGN:

The study will be a retrospective study based on records review.

STUDY SETTING:

The study will be carried out at the University of Nairobi Dental Hospital (UNDH) Nairobi, Kenya.

STUDY POPULATION:

Patients who have been diagnosed with oral cancer and treated at the University of Nairobi Dental Hospital and Kenyatta National Hospital between 1st January 2006 to 31st December 2011.

MATERIALS AND METHODS:

Records of patients diagnosed with oral cancer from 1st January 2006 to 31st December 2011 at the two referral hospitals in Nairobi, Kenya will be retrieved and examined for the following variables mainly: age of the patient, sex, site of the lesion, diagnosis, absence or presence of smoking cigarettes, alcohol consumption or chewing of khat. This data will be recorded in a special designed data collection form. Data obtained will be analyzed using Statistical Package for Social Science software (SPSS) version 17.0. The data will be represented in the form of pie charts, bar graphs and tables.

The results obtained will benefit the health profession in the fight against oral cancer particularly in the design of preventative strategies and effective management of the cancer.
CHAPTER 1:

INTRODUCTION

Oral cancer is a subtype of head and neck cancer that is associated with tissue growth located in the oral cavity. It is a lesion that may arise as a primary lesion originating in any of the oral tissues by metastasis from a distant site of origin or by extension from a neighbouring anatomic structure such as nasal cavity or the oral cancers may originate in any of the tissues of the mouth, and may be of varied histological types: teratoma, adenocarcinoma derived from a major or minor salivary gland, lymphoma from a tonsillar or other lymphoid tissue or melanoma from pigment producing cells of the oral mucosa (1). There are numerous types of oral cancer but the most common type of oral cancer is oral squamous cell carcinoma. This type of oral cancer occurs both intra and extra orally. The most common area of occurrence is on the lower lip and the posterior lateral and ventral aspect of the tongue (2). It also found at the floor of the mouth the reason being due to pooling of carcinogens at the floor of the mouth, anterior tonsillar and lingual aspect of the retromolar pillar (3).

Over 90% of malignant neoplasm in the oral cavity is squamous cell carcinoma (4). In areas such as north of France and East Europe especially Hungary and parts of South America and South East Asia have a high incidence (2). In United Kingdom and United States of America the rate of incidence of 2% but in areas such as India and Sri Lanka, the incidence is 40%. Oral cancer is an age related disease and 98% of the patients being over the age of 40 years. There is a sharp linear increase of occurrence of oral cancer with age as seen with other carcinomas (4). The age of occurrence this disease in East, West and Southern Africa is reported to be between 50-60 years of age (6). This is a condition that is thought to occur in developing countries commonly affecting males of over 45 years of age (shown to be 90%) who have been exposed to certain risk factors (3). The lip cancer has been noted to occur in individuals who suffer repeated or prolonged exposure to sunlight, while the tongue cancer has been linked to alcohol consumption, cigarette smoking and chewing of khat. Oral cancer has been shown to have a wide variety of causes these being: smoking cigarette, alcohol consumption, chewing khat, viruses, betel, oral hygiene and certain host factors, nutrition, fungal infection, free radical exposure, radiation damage (1).

The objectives of this study are to describe the tobacco cigarette smoking, alcohol consumption and khat chewing practices among patients diagnosed with oral cancer. Khat chewing is widely practiced in Kenya and is suspected to increase the risk of oral
cancer occurrence but this has yet to be proven. This study will either confirm or disqualify it as a risk factor.
CHAPTER TWO

LITERATURE REVIEW

Oral cancer is a condition that is highly on the rise in this day and age. According to the WHO it is defined as a subtype of head and neck cancer in any cancer tissue growth located in the oral cavity. The lesion that may arise as a primary lesion originating in any of the oral tissues by metastasis from a distant site of origin or by extension from a neighbouring anatomic structure such as nasal cavity or the oral cancers may originate in any of the tissues of the mouth, and may be of varied histological types: teratoma, adenocarcinoma derived from a major or minor salivary gland, lymphoma from a tonsillar or other lymphoid tissue or melanoma from pigment producing cells of the oral mucosa (1). The most common type of oral cancer is oral squamous cell carcinoma and accounts for 90% of all malignant tumors of the oral cavity and orofacial region (2). In Kenya the frequency of occurrence of oral cancer as determined in a study carried out in KNH from 1978-1997 was reported to be 2-3% (3). The cancer rates were expected to increase from ten million in 2000 cases globally to fifteen million in 2020 (4). The survival rate has not improved from 35-50% in the past three decades even with the enhancements in the diagnosis and treatment of the disease (5). This is mainly due to the change in the presenting age, gender predisposition and the site of occurrence and this has been attributed mainly due to change in lifestyle and the discovery of other risk factors (6).

Areas mostly affected with OSCC are the lip, palate, tongue floor of the mouth (5). Lip cancer is a form of oral cancer that occurs at the junction between the oral cavity and the skin specifically at the vermilion boarder commonly referred to as the ‘lipstick zone’ which is basically the area between the labial mucosa and the skin of the lip (6). The incidence rate is more in males than in females and has a peak occurrence in the sixth and seventh generations of life and is more common in the lower lip. It is more common in white males than in black males and this has been attributed to the fact that blacks have more of the melanin pigment hence providing protection from the harmful ultraviolet rays (6). The geographical distribution of this condition is mostly in parts of Indian subcontinent, parts of Europe especially France. There has been a noted rising incidence and mortality particularly from younger adults in United States, many parts of Europe and Japan. This is mostly due to the early exposure to the risk factors and binge drinking (6).

Other sites for intra oral cancer to occur is at the tongue-ventral and lateral surfaces, the floor of the mouth reason being due to pooling of carcinogens at the floor of the mouth, anterior tonsillar and lingual aspect of the retromolar pillar (5). As mentioned
earlier the most common form of tongue cancer is oral squamous cell carcinoma accounting for over 95% of the reported tongue cancer incidences (3,5 et al).

The age of occurrence of oral cancer has been described to be between the sixth and seventh decade of life. In the East, West and Southern Africa, the peak age is in the fifth and six decades of life. These are the same figures for the age of occurrence of OSCC in North eastern Nigeria (7), in Zimbabwe it’s the 4th – 6th (8, 9 et al) and in Ghana (10). A study done in Kenya showed that the mean age of occurrence for OSCC in males was 41.4 +/- years and for the females it was 51.0 +/- 20.2 years (11). Another study showed that most of the cancers occurred in the age groups above 40 years though there is a wide age range with occurrence being cited as early as the first decade of life(3).

In relation to gender there is a higher rate of occurrence of oral cancer in men than women with the ratio being dependent on the geographical location and anatomical site (12). The incidence for women is thought to be increasing more than males in high prevalence areas such as South East Asia and Turkey (13). Study done in KNH, Kenya that looked at 793 cases revealed 507 of the patients were males and 286 were females giving a male female ratio of 2:1 which coincides with other studies worldwide (14).

Recent studies have shown that oral health plays a role in development of head, neck and esophageal cancer. Persons who had received dental treatment show a reduced risk of developing oral cancer. Periodontal disease and tooth loss have implicated with development of OSCC where each millimeter of alveolar bone resorption being associated with a 5.25 fold increase in the risk of development of tongue cancer. The likely explanation is that due to the interaction between microbial in supragingival plaque having mutagenic interaction with saliva and both oral Streptococci and Neisseria synthesizing acetaldehyde from alcohol which is a known carcinogen (6).

Tobacco is considered to be the main risk factor for oral cancer whether it is smoked or smokeless. Smokeless forms include; betel, snuff and smoked forms include cigarettes, bidis (hand rolled) and cigars. Tobacco generates a tobacco specific nitrosamines TSNAs [N'-nitrosonornicotine, 4-(methylnitrosamino)-1-(-3-pyridyl)-1-butanone] as well as free radicals that cause alterations in the antioxidant enzymes of glutathione-s-transferase, glutathione reductase, superoxide dismutase, catalase as well as lipid peroxidation and total thiol. Studies have shown that there is a 20 fold increase risk of developing oral squamous cell carcinoma in heavy smokers and a strong dose-response relationship, and the risk increases with the number of cigarettes smoked per day and the duration of smoking (6). Pan (betel) chewing increases the rate of oral cancer occurrence in both genders while bidi smoking increased the rate of occurrence of oral cancer in men (6).
Alcohol has also been associated with the development of oral cancer. It is broken down by oxidation to acetaldehyde which is a known carcinogen. Acetaldehyde is then broken down by acetaldehyde dehydrogenase to acetate which is non carcinogenic (6). There is a multiplicative risk for oral squamous cell carcinoma in patients who smoke tobacco and drink alcohol as smoking tobacco increases acetaldehyde load after alcohol consumption and alcohol drinking in tobacco smokers increases the activation of pro carcinogens in tobacco cigarettes due to increased metabolic activation of induced cytochrome p450 2E1- dependent microsomal biotransformation system in the mucosa and liver (6).

A damaged host defense system has been shown to be a risk factor in the development of OSCC. This leads to an undermined host defense against carcinogens, repair or defense mechanisms. Such conditions that may lead to an undermined host defense include: organ transplant, Fanconi Syndrome, Dyskeratosis congenita, Diabetes and Scleroderma. Other factors include HIV/AIDS and an inherited cancer syndrome called Li-Fraumeni Syndrome (6).

Nutrition has also been shown to have an effect on oral cancer. Most consistent dietary findings in many societies are of high fruit and high vegetable content especially yellow/orange variety. Especially folate is very protective whilst mild iron deficiencies and low glutathione levels increase the oxidative stress thereby increasing the risk of occurrence of OSCC (6). Dietary antioxidants from fruits and vegetables such as carotene, carotenoids, flavonoids, flavanones, vitamin A, C and K tend to decrease risk rate of OSCC. Preserved vegetables are a risk factor. Even in the presence of high alcohol consumption and tobacco use, a high intake of fruits and vegetables reduce the occurrence of SCC of the head and neck by a quarter and possibly one half of OSCC (6).

Viruses have also been associated with the development of oral cancer. These viruses include; Epstein Barr Virus, Human Papilloma Virus, Cytomegalovirus's, Herpes Simplex Viruses (8). This has been thought to be the cause of oral cancer in patients that do not smoke cigarettes or drink alcohol (8). It is thought to increase the occurrence of OSCC in women with cervical cancer caused by HPV and also increases its occurrence in their spouses (6). Human papilloma virus causes development of OSCC affecting the palate and base of the tongue (9). A study done in Boston reported a couple diagnosed with OSCC who tested positive for the viral genomes of HPV 16 showing that there was transmission between the couple (9).

Betel plant also referred to as areca nut was established as a carcinogen by the IARC but is still being used by 20% of the world’s population (6). It contains tobacco, areca nut and slaked lime wrapped in betel leaf (15). It contains arecoline an alkaloid that, it is
thought as a hypermethylation agent that alters gene expression, blocks tumor suppressor genes; p14, p15, p16 and p53, it represses DNA repair and triggers DNA damages response in responses in human epithelial tissues. Gene expression is also altered (6). The lime is thought to reduce the pH and accelerate the release of alkaloids the betel and tobacco (15).

Khat is also known as miraa (in Kenya) or Catha edulis. Cultivation of khat is carried out mainly in East Africa and Middle East where it contribute to the economic development of the communities (16). It has been found to be genotoxic to the cells of the oral mucosa and is associated with histopathologic changes such as hyperkeratosis, epithelial hyperplasia and mild dysplasia (17). A study done in Norway showed normal cells exposed to low levels khat in vitro showed had an increased expression of p53, p21, p16 proteins and a subsequent cell cycle arrest at the G1 phase. The author carried out another study that showed that the likely mechanism by which khat causes cell death is by oxidative stress (18).

OSCC has wide a wide variety of presentations. Early diagnosis is detrimental for treatment of the patients. Doctor on the floor should have a high index of suspicion if a patient present with an ulcer that persists for more than two weeks and is not responsive to any forms of treatment. The earliest signs of lip cancer are ulceration, encrustation and soreness. The advanced form of lip cancer presents as an extensive ulcerative or invasive. The rate of growth of this cancer is slow. Metastasis into the surrounding lymph nodes occurs in the later course of this disease (6). The best treatment modality is surgical excision of the lesion (6). It has up to 95% five year survival rate that is mostly related to early clinical diagnosis of the lesion (3).

The prognosis of this tumor depends on the area of occurrence, stage of the tumor and the patient compliance on the mode of treatment.

Diagnosis of this condition is condition is done through; clinical diagnosis, obtaining samples via fine needle aspiration (FNA) and tumor biopsy and carrying out specific tests such as histochemical, cytopathology and immunoflourecence test. The diagnosis of this condition is done by an oral pathologist.

The etiological factors associated with the development of oral cancer in Kenya have not been well described. Further studies are also needed to determine whether Khat which is grown and chewed in Kenya has a role to play in the aetiology of oral cancer.
CHAPTER 3

STATEMENT OF PROBLEM AND JUSTIFICATION

3.1 STATEMENT OF THE PROBLEM
Oral cancer is a major neoplasm accounting for 90% of all the malignant tumors of the orofacial region (17). With increasing prevalence of alcohol consumption, tobacco smoking and khat chewing in Kenyan adults the incidence and prevalence of oral cancer is likely to rise with time. Lack of understanding of the aetiological factors is likely to hinder proper management of oral cancer.

3.2 STUDY JUSTIFICATION
Oral cancer being the eighth leading cancers in the world is a major concern and any research on this topic will greatly lead to better management of patients with this condition and help prevent further cases from arising.

Aetiological factors associated with oral cancer have yet to be well studied in Kenya. Understanding such aetiological factors will be useful in designing of oral cancer preventative programs and in the management of the afflicted persons.

3.3 OBJECTIVES

3.3.1 General:
To cigarette smoking, alcohol consumption and khat chewing practices amongst patients diagnosed with oral cancer at University of Nairobi Dental Hospital.

3.3.2 Specific:
1. To describe the demographic characteristics of the patients.
2. To describe the cigarette smoking practices among the patients.
3. To describe the alcohol consumption practices among the patients.
4. To describe the khat chewing practices among the patients.

3.4 HYPOTHESIS
65% of the patients diagnosed with oral cancer smoke cigarettes.
25% of the patients diagnosed with oral cancer drink alcohol.
10% of the patients diagnosed with oral cancer chew Khat.
3.5 VARIABLES AND MEASUREMENTS

3.5.1 Socio-demographic variables
-Age: the number of years.

-sex: whether male or female.

3.5.2 Independent
-Smoking
  • Current smokers or previous smokers
  • Type of cigarettes: bidi, cigars, conventional cigarettes
  • Number of cigarettes smoked per day
  • Duration of smoking

-Alcohol consumption
  • Current alcohol consumers or previous consumers
  • For current:
    - Type of alcohol consumed
    - Amount of alcohol consumed
    - Duration of alcohol consumption

-Chewing khat
  • Current chewers or ex-chewers
  • For current chewers:
    - Duration of khat chewing practices.

3.5.3 Dependent Variables
- Type of cancer lesion
- Site of the lesion
- Stage of the tumor (TMN classification)
- Duration of symptoms
4.0: METHODOLOGY

4.1 Study area
The study will be carried out at University of Nairobi Dental Hospital in Nairobi, Kenya. University of Nairobi Dental surgery is located three kilometers from Nairobi Central Business District of the capital opposite Nairobi Hospital. It is a teaching hospital providing training for the various courses in the school of Dental Science for both undergraduate and postgraduate students. It has an oral histopathology laboratory as the centre for diagnosis in the hospital, a major and minor operating theatres and one surgical ward capable of holding a capacity of nine patients and other clinics such as: pediatric, orthodontics, Periodontology and prosthetic. It is currently one of the highest referral and training dental hospitals in Kenya. It has a variety of qualified personnel ranging from general practitioners, specialized dentists to technicians.

4.2 Study population
The study will include clinical records of all the patients diagnosed with oral cancer at UNDH between 1st January 2006 and 31st December 2011. This will constitute a period of five years.

4.3 Study design
This is a descriptive cross-sectional study (retrospective study) conducted by reviewing records of patients diagnose with oral cancer.

4.4 Sample size determination
All the records of the patient diagnosed with oral cancer and managed at UNDH between 1st January 2006 and 31st December 2011 will be studied.

4.5 Sampling methods
The sampling method chosen for this study is convenient sampling. Records of all the patients diagnosed with oral cancer at UNDH oral and maxillofacial department will be traced from the respective registry and pathology laboratories where the diagnosis was confirmed using the patients file numbers. The patient files and histopathology records will be examined for suitability and those suitable will be included in the study.

4.6 Inclusion criteria
All the patients diagnosed with oral cancer in the period of five years.

Patients with complete records.

4.7 Exclusion
Patients diagnosed before 1st January 2006 and after 31st December 2011.
Patients with a diagnosis other than oral cancer.

Patients with an unclear diagnosis,

Incomplete records

4.8 Data collection instruments and methods
The patients’ files and their histopathology reports will be retrieved by me the researcher and examined for the aforementioned variables. The data obtained will be recorded in a data collection form by the researcher. To ensure that the reports are not tampered with and do not get lost I will ensure that they are kept in a safe place and only used when they are required.

4.9 Data analysis and presentation
The data will be analyzed using MS-Excel and MS-Statistical program for Social Studies. Data will then be represented in the form of tables, pie charts and graphs.

4.10 Ethical consideration
Approval from the University of Nairobi/KNH Research, Ethics and Standard Committee shall be obtained before commencement of the study. Permission from the Dean of the University of Nairobi Dental Hospital for access to the patients’ records will be sought.

All the information derived from this study will be regarded as confidential and used for the purpose of this study and shall not be divulged to anyone for whatever reason. The records shall be kept in a closed locker with a key whereby only the researcher shall have access to the locker.

Patients who are still currently in the wards will be asked to sign consent forms so that their records will be made available to the researcher.

4.11 Study benefits
The findings of this study will establish the frequency of cigarette smoking, alcohol consumption and khat chewing practices among the persons with oral cancer. This will help extrapolate the possible association between these practices and oral cancer in Kenya.

Both the proposal and the final report will be submitted in partial fulfillment for the degree of Bachelor of Dental Surgery.
### 7.0: BUDGET

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**Contingency (15% of total)** 726.50  
**Sum Total** 7991.5

### 6.0 SCHEDULE OF ACTIVITIES

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<td>3. Development of research project proposal</td>
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<td>4. Submission of proposal to KNH/UoN Research, Ethics and Standards Committee</td>
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<td>5. Data collection and analysis</td>
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<td>6. Research project findings writing</td>
<td>September- October 2012</td>
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Sponsorship: SELFSPONSERED
7.0 : REFERENCES


6. Scully S.C. and Bagan J.V. Review article on oral squamous cell carcinoma; overview on the current understanding on aetiopathogenesis and clinical implications.


16. Moore S.R., Johnson N.W., Pierce A.M, Wilson D.F. The epidemiology of lip cancer: a review of global incidence and aetiology. -School of dentistry, The University of Adelaide, Australia 5005;2-Division of Oral Medicine, Microbiology, Pathology and Immunology, Guy’s, King’s and St Thomas’ School of dentistry, King’s Dental Institute, London SE 9RW, UK.


8.0: APPENDIX 1

Staging of malignant neoplasm (TNM system)

T (primary tumor)

T1 - lesion with greatest diameter not greater than 2cm.

T2 - lesion with greater diameter than 2cm but less than 4cm.

T3 - lesion with greatest diameter than 4cm.

T4 - massive lesion greater than 4cm in diameter and involves adjacent structures.

N (cervical lymph nodes)

N0 - no clinically positive nodes

N1 - single clinically positive homolateral/ipsilateral nodes

N2 - single clinically positive homolateral(<6cm) or multiple clinically positive homolateral nodes(<6cm)

N3 - massive homolateral node(s)

M (distant metastasis)

M0 - no known distant metastasis

M1 - distant metastasis presents, specify site
APPENDIX 2

TOBACCO SMOKING, ALCOHOL CONSUMPTION AND KHAT CHEWING PRACTICES AMONG PATIENTS DIAGNOSED WITH ORAL CANCER AT THE UNIVERSITY OF NAIROBI DENTAL HOSPITAL.

Consent form

I Carolyne Bosibori Moturi am a level three student of Bachelor of Dental Surgery, University of Nairobi. I am conducting a study on the cigarette smoking, alcohol consumption and khat chewing practices in patients diagnosed with oral cancer.

Purpose of the study

The study will be used to provide information on the frequency of these habits in patients diagnosed with oral cancer. This will help extrapolate the association between these practices and oral cancer in order to design preventative programs. It will also be used in the partial fulfillment of my degree course in the bachelor of Dental Surgery.

This study will involve letting me get access to your records in order to acquire information on your smoking, drinking and khat chewing practices. Participation is voluntarily, no risk is anticipated for participating in the study. The information given to the researcher will be kept in strict confidence. No information by which the identity of the respondent will be released or published.

I would therefore appreciate your consent by signing here.

I do hereby give my full consent to participate in the study

Sign: ___________________ Date: ___________________
APPENDIX 3

DATE

TOBACCO SMOKING, ALCOHOL CONSUMPTION AND KHAT CHEWING PRACTISES AMONG PATIENTS DIAGNOSED WITH ORAL CANCER IN UNIVERSITY OF NAIROBI DENTAL HOSPITAL FROM 1ST JANUARY 2006 TO 31ST DECEMBER 2011.

Patient's no: ___________________________ hospital: ___________________________
Age: ___________________________ Sex: ___________________________
Type of lesion: ___________________________
Site of lesion ___________________________

Tobacco smoking at the first time of history taking;
Currently smoking: ( ) or Ex-smokers ( )
If currently smoking:
Type of cigarette; Bidi( ) cigars( ) conventional cigarettes ( ) Kiraiku ( )
Number consumed per day: ___________________________
Duration of smoking: ___________________________

Alcohol consumption at the first time of history taking;
Currently drinking( ) Ex-consumer ( ) Never consumed alcohol ( )
If currently drinking:
Type of alcohol consumed: ___________________________ Amount consumed per day: ___________________________
Duration of alcohol consumption: ___________________________

Khat chewing at the first time of history taking:
currently chews khat ( ) ex-chewers ( ) never chewed khat ( )
If currently chewing khat;

Duration of khat chewing practices: