PATIENT AND DIAGNOSTIC INTERVALS IN ORAL CANCER: A SEQUENTIAL EXPLANATORY STUDY

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Ph.D. THESIS

2021

SREE CHITRA TIRUNAL INSTITUTE FOR
MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram

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A THESIS PRESENTED BY

PHINSE M PHILIP

TO

THE SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM

Thiruvananthapuram

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF

DOCTOR OF PHILOSOPHY

2021

DECLARATION BY THE STUDENT

I, Phinse M Philip hereby certify that I had personally carried out the work depicted in the thesis entitled, "Patient and Diagnostic Intervals in Oral Cancer: A Sequential Explanatory Study".

No part of the thesis has been submitted for the award of any other degree or diploma prior to this date.

Date : 10.06.2021

Phinse M Philip

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This is to certify that **Phinse M Philip** in the AchuthaMenon Centre for Health Science Studies of this institute has fulfilled the requirements prescribed for the Ph.D degree of the SreeChitraTirunal Institute for Medical Sciences and Technology, Trivandrum. The thesis entitled, "Patient and Diagnostic Intervals in Oral Cancer: A Sequential Explanatory Study" was carried out under my direct supervision. No part of the thesis was submitted for the award of any degree or diploma prior to this date. Clearance was obtained from the Institutional Ethics Committee for carrying out the study.

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Date: 10.06.2021

APPROVAL OF THESIS

The thesis entitled

PATIENT AND DIAGNOSTIC INTERVALS IN ORAL CANCER: A SEQUENTIAL EXPLANATORY STUDY

Submitted by

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for the degree of

Doctor of Philosophy

Of

THE SREE CHITRA TIRUNAL INSTITUTE
FOR
MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
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Acknowledgment

There are many people whose help, support, guidance, and effort have contributed significantly to this research work. Let me record my gratitude and feelings for all those who have accompanied me on this journey.

First and foremost I am extremely grateful to **Dr. Srinivasan Kannan,** Professor, AMCHSS, for guiding and mentoring me all these years with patience and affection. He helped me in his various capacities as a guide, academician, and public health expert throughout my research study. His immense and in-depth knowledge was a source of reference that improvised my research. He stood by me as an endless source of inspiration and without his support, this research would have never materialized. I am indebted to you Sir.

I express my sincere thanks to **Dr.Satheesan Balasubramanian,** Director, MCC for introducing me to the world of public health and offered the opportunity to embark on the research journey. His wisdom and pragmatism were vital and I gratefully acknowledge his unrelenting support in all my efforts.

I would like to thank my Doctoral Advisory Committee members **Dr.SankaraSarma**, Head of Department, AMCHSS, **Dr.Jayakrishnan R**, Associate professor, Community Oncology Department, Regional Cancer Centre, and **Dr.Jissa VT**, Scientist C, AMCHSS for their insightful comments, constructive criticisms, and critical evaluation at different stages of the research.

I would like to thank my teachers at **AMCHSS Dr.K.R.Thankappan, Dr.V.RamanKutty, Dr. Mala Ramanathan, Dr.BijuSoman, Dr.Manju Nair,Dr.Ravi Prasad Varma, and Dr.Jeemon** for their wonderful classes during my Ph.D. coursework. I remember with gratitude the helps they had extended to me despite the busy schedule of teaching and research activities.

I take this opportunity to express my gratitude to **Dr.Neethu AP, Dr.Geetha M, Dr.Sajith Babu,** for their support for my Ph.D. research. Their contribution was substantial in this arduous journey.

I would like to thank **Dr.Dimla Denny C** for her unwavering support and encouragement during my Ph.D. research.

I take this opportunity to thank **Dr.Moni Kuriakose, Dr. Gigi Thomas, Dr.Sudha S, Dr.Haris PS, Dr.Mehul R Mahesh, Dr.PramodSankar, Dr.Divya K.D, Dr. Iris Valsan, Dr.Babu C Eden, Dr. Rahul K and Dr.AnjuAnu Jose** for their valuable suggestions. I have been infinitely benefitted by the intellectual interactions with you all.

I gratefully acknowledge the assistance received from the Community Oncology, Radiation Oncology, and Surgical Oncology Department staff of Malabar Cancer Centre, Thalassery, during my data collection.

I would like to thank **Mr.Linse** and **Mrs.Arsha** for their support during the final phase of my Ph.D. research work.

I would like to thank my parents **Mr.Philip M D** and **Mrs.MarykuttyPhilip** and my in-laws **Mr. Denny.C.I** and **Mrs. Ponmani.K.I** for their ceaseless encouragement. Their affection and motivation were important for me in this endeavor.

I am grateful to my sons**, Kevin** and **Dhaniel** for their kind understanding.

I express my honest gratitude to every participant in my study who gave me their precious time and enriched my study with their experiences.

I thank God for providing me an opportunity to study at the prestigious institution, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

Phinse M Philip

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LIST OF ABBREVIATIONS

AJCC	: American Joint Committee on Cancer
APL	: Above Poverty Line
BPL	: Below Poverty Line
BPLAAY	: Below Poverty Line Antyodaya Anna Yojana
CCCC	: Comprehensive Cancer Care Centres
CCRC	:Cochin Cancer Centre and Research Centre
CDC	: Centre for Disease Control
CHC	:Community Health Centre
CHO	: Community Health Officers
CI	: Confidence Interval
COTPA	: Cigarettes and Other Tobacco Products Act
C-SIM	: Cancer Symptom Interval Measure
CVI	: Content Validity Index
DALYs	: Disability Adjusted Life Years
DHS	: Directorate of Health Services
DME	: Directorate of Medical Education
DOI	: Depth Of Invasion
ECDC	: Early Cancer Detection Centres
ENE	: Extra Nodal Extension
ENT	: Ear Nose Throat
GATS	: Global Adult Tobacco Survey
HBCR	: Hospital Based Cancer Registry

HCP	: Health Care Provider
IARC	:International Agency for Research on Cancer
ICD	: International Classification of Diseases
ICMR	: Indian Council of Medical Research
IEC	: Institutional Ethics Committee
INR	: Indian Rupee
IQR	: Interquartile Range
KASP	: Karunya Arogya Suraksha Padhathi
KCCG	: Kerala Cancer Care Grid
LSGI	: Local Self-Governing Institutions
MCC	: Malabar Cancer Centre
MGH	: Madras General Hospital
NCCP	: National Cancer Control Program
NGO	:Non-Governmental Organizations
NHM	: National Health Mission
NICE	: National Institute for Health and Care Excellence
NOHP	: National Oral Health Program
NPCDCS	: National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke
NTCP	: National Tobacco Control Program
OR	: Odds Ratio
PBCR	: Population Based Cancer Registry
PMD	: Potentially Malignant Disorders

PIOC	: Patient Interval in Oral Cancer
RCC	:Regional Cancer Centre
SCCB	: State Cancer Control Board
SE	: Standard Error
TNM	: Tumor Node Metastasis
UK	: United Kingdom
US	: United States
UICC	: Union for International Cancer Control
VIA VILI	: Visual Inspection with Acetic acid Visual Inspection with Lugol's Iodine
VIF	: Variance Inflation Factor
WHO	: World Health Organization

SYNOPSIS

Cancer incidence is generally increasing in the world every year. During the year 2020, nineteen million new cancer cases were reported and about half of them were from Asia. Oral cancer is the most common cancer among males and the fourth common cancer among females in south-central Asia. India as a country contributes 36% of oral cancer incidence and 42% of oral cancer-related deaths in the world in 2020. WHO predicted a 66% increase in the incidence of oral cancer in India by the end of the year 2040. Cancer registries from Kerala confirm a high incidence of oral cancer in the state.

The major risk factors for oral cancer are the consumption of tobacco, areca nut and alcohol, chronic trauma, and low dietary intake of fruits and vegetables. Oral cancer carries a considerable risk of mortality. The five-year survival rate of early-stage cancer exceeds 80%, while that of patients with advanced stages falls below 20%. Globally, more than half of the oral cancer patients report at later stages. Oral cancer is usually preceded by potentially malignant disorders that can be easily detected through simple oral visual examination by a trained health care professional. Despite the availability of simple techniques, many at times, the lesion is reported or diagnosed at advanced stages.

Early diagnosis is possible for those cancers having a recognizable sign or symptom in the early course of the disease. The time from recognition of bodily changes to the time when one first meets a health care provider for discussing that change constitutes Patient interval. Reporting delay, presentation delay, and patient delay are the other terminologies used for describing this period. The time from first meeting a health care provider to the time of definitive histopathological diagnosis constitutes diagnostic interval. Provider delay, professional delay, diagnostic delay are the other terminologies used to describe this period. The accepted patient interval duration is 90 days and the diagnostic interval duration is 30days.

At present, we do not have much information about the magnitude of delay in presentation and diagnosis or the contributing factors specific to our region or country. The existing literature on delay in presentation and diagnosis of oral cancer

were mainly from European countries. Very few studies have conducted in India. The 'Aarhus statement' provides guidance for improving the design and reporting of studies on early cancer diagnosis. The available research on early cancer diagnosis differs considerably in methodology and choice of summary measures. This makes comparisons across the studies challenging. The characteristics of patients affected by cancer vary according to cancer types. Oral cancer is more common among people belonging to lower socioeconomic strata and addicted to tobacco or alcohol use. The existing scientific enquiries on factors contributing to patient interval were largely confined to the socio-demographic domain. Enquiries about general health care, barriers to health-seeking, habits, social support, access and availability factors were scarce. These circumstances necessitate the conduct of an early cancer diagnosis study with specific reference to oral cancer in Kerala. This will help in identifying the magnitude of delay in presentation and delay in diagnosis and the factors contributing to it. The findings will help in planning interventions to promote the early diagnosis of oral cancer in Kerala. There are also no validated instruments available for measuring various time points in the diagnostic journey of oral cancer.

Objectives of the current study include the following. 1. To develop an instrument for capturing the duration of patient interval and contributing factors in the diagnostic journey of oral cancer. 2. To estimate the duration of patient interval in the diagnostic journey of oral cancer patients of a Tertiary Cancer Centre in northern Kerala. 3. To estimate the duration of diagnostic interval in the diagnostic journey of oral cancer patients of a Tertiary Cancer Centre in northern Kerala. 4. To study the various factors associated with the patient interval in the diagnostic journey of oral cancer patients of a Tertiary Cancer Centre in northern Kerala. 5. Mapping of structure and function of oral cancer control in the state.

The conceptual framework for the study was derived from the model put forth by Walter *et al*., Weller *et al*., and also from the 'Guide to early diagnosis' by World Health Organization.

A sequential explanatory design was used for this study. Sequential Explanatory Design is characterized by the collection and analysis of quantitative data followed by the collection and analysis of qualitative data. Priority is typically given

to the quantitative data. The purpose of this design is to use qualitative results to assist in explaining and interpreting the findings of the primary quantitative study.

This study was conducted in three phases. In Phase 1, we developed and validated an interview schedule for measuring patient and diagnostic intervals and a questionnaire to identify the various factors associated with the patient interval in oral cancer. The following steps were used.1. A literature review 2. Expert consultation 3.Content validity. 4. Translation-back translation. 5. Face validity

In phase 2, a cross-sectional study was conducted at a tertiary cancer centre in Kerala. Data collection was conducted during the period from December 2019 to August 2020.

Inclusion criteria: Newly registered Patients with malignant neoplasms of the lip and oral cavity (ICD Code C00 to C06) were included in the study.

Exclusion criteria: Those known to have, or had, other cancers; patients who were on routine surveillance for cancer and detected via that system**,** and those patients with recurrence were excluded from the study.

As reported from Uttar Pradesh, India, the proportion of oral cancer patients with a patient interval of more than 3 months was 60%. Taking 60% as the anticipated prevalence of oral cancer patients with a patient interval of more than 3 months, with a 95% confidence interval between 54% and 66%, the sample size is estimated to be 257 rounded off to 260. Each consecutive oral cancer patient who reported at the institution during the study period and who met the eligibility criteria and consented to participate were included in the study until the required sample size was reached. Data from each patient was collected within 3 months from the date of their registration at the institution to minimize recall bias.

Phase 3 constitutes the qualitative part of the study. Document review and in-depth interviews were conducted in this phase. Document review was done for identifying the existing public health facilities and their role in the prevention, early diagnosis and treatment of oral cancer. A checklist was prepared for reviewing the documents. In-depth Interviews with oral cancer patients, health care providers, health care administrators and community leaders were conducted. In-depth interview checklists were prepared based on the findings from the preliminary quantitative data

analysis. The participants for the in-depth interview were selected purposively. A total of 30 in-depth interviews were conducted.

The study received approval from the institutional Ethics Committee and Technical Advisory Committee of the institution where the principal investigator is a research scholar. Ethics committee approval was also obtained from the institution where the study was conducted.

Patient interval and Diagnostic interval were reported by median (interquartile range). Descriptive statistics of categorical variables were reported as frequencies and percentages. Pearson's chi-square test or Fisher's exact test was used to find associations between categorical variables. Multiple Binary logistic regression model was used for multivariate analyses. Qualitative data analysis was done by coding. Codes were categorised based on the patterns. Emerging themes and subthemes were identified using a largely deductive approach.

The study population consisted of 261 oral cancer patients, with a mean age of 60.77 ± 12.3 years. Males were 185 (70.9%) and females were 76 (29.1 %). The majority of the participants (94.3%) had education only up to high school level. Among the participants, 64% were from the Other Backward Class and only 18% belonged to the general category. More than three fourth of the participants were from panchayath. Majority (64.4%) was daily wagers and 13.8% were farmers. Most of the participants (73.9%) belonged to the Below Poverty Line category. The proportion of participants having Pucca type houses were 48.3%. Most of the participants live in nuclear families (73.7%).

The median (Inter Quartile Range) patient interval was 92(37.50-167.50) days [males-92(44.50-158.00), females- 90(31.25-179.50) days]. The proportion of Participants with a patient interval duration of more than 90 days was 54%. The median (Interquartile range) diagnostic interval was 36.00(14.00 to 76.50) days. The proportion of participants having diagnostic intervals of more than 30 days was 57.9% (n=151).

Those lived in semi pucca or kutcha type of houses were more likely to have increased patient interval than those lived in pucca type houses (OR, 1.87; 95% CI, 1.1 to 3.1). Those betel quid users who have reported to have continued or increased chewing even after identifying the cancer symptoms were 2.8 times more likely to

have patient interval more than 90 days compared to those who have decreased or quit the habit (OR, 2.76;95%CI, 1.3 to 5.7).

‘Patients who visit health facility only for urgent medical need’ were four times more likely to have a patient interval more than 90 days compared to those who underwent health screening periodically’(OR,4.1; 95% CI, 2.1 to 8.2). ‘Participants who practiced home remedy or over-the-counter medicines as their first response to any symptom’ were more likely to have prolonged patient interval compared to ‘those consulted a doctor or other health professional’ (OR, 3.870; 95% CI, 2.0 to 7.6). ‘Those participants who had previous experience with cancer patients were more likely to have a short patient interval (OR, 2.377; 95% CI, 1.3 to 4.3). Participants who had to travel by multiple vehicles to reach the health facility ’were two times more likely to have the patient interval more than 90 days compared to those who used single means of travel (OR, 2; 95%CI, 1.2 to 3.4).

Those participants who were in agreement with the below-mentioned barriers to help-seeking were more likely to have a patient interval of more than 90 days. The barriers include, ‘It is embarrassing to talk to the doctor about symptoms’, ‘too busy to make time to go to a doctor, ‘having many other things to worry about, ‘ worried about different tests the doctor will advise’, ‘having no one for accompanying to visit the hospital ’, ‘ did not have sufficient money to consult a doctor, ‘was worried about what the doctor might find out, ‘feeling comfortable in discussing the symptoms with a nurse compared to a doctor’ and ‘prefer alternative medicine’.

The following factors were found to be the predictors for patient interval. Based on the model, participants who finally consulted a doctor for the current problem in the oral cavity either due to ‘pain’ (OR, 8.30; 95% CI, 2.9 to 23.4) or ‘discomfort to daily routine’ (OR, 6.98; 95% CI, 2.5 to 19.3) had high chances of having patient interval more than 90 days in contrast to those consulted doctor due to ‘insistence from family or friends. Patients presented in late stages (stage 3 and 4) were more likely to have patient interval more than 90 days (OR, 2.62; 95% CI, 1.3 to 5.2) over those reported in early stages (stage 1 and 2). Status of smoking at the time of symptom recognition does contribute to the model, with high chances of the increased patient interval among ‘current smokers’ in contrast to ‘never smokers’

(OR, 2.51; 95% CI, 1.3 to 4.7). Those who ‘worried about what the doctor might find out in their mouth’ were more likely to have patient intervals above 90 days, in comparison with those who did not worry(OR, 2.54; 95% CI, 1.3 to 4.9). Participants who have to travel more than 30 minutes to reach the healthcare facility were more likely to have patient intervals above 90 days, over those who can reach the hospital within 10 minutes(OR,5.80; 95% CI,1.6 to 21.7).

Compared to married participants, those who were living single were more likely to get prolonged diagnostic interval (OR, 1.85; 95% CI, 1.02 to 3.37).Compared to those who consulted ‘general medical doctor’ first, participants who met practitioners of other systems of medicines were more likely to have diagnostic interval more than 30 days (OR, 9.50; 95% CI, 1.2 to 74.5) and those who went to a medical specialists had chances of having less diagnostic interval (OR,0.35; 95% CI, 0.2 to 0.7).

The following factors were found to be the predictors for a diagnostic interval. There is more likelihood of getting diagnostic interval ‘more than 30 days for those who aged less than or equal to 60 years (OR,2.09; 95% CI, 1.1 to 3.9). When compared to other backward classes, patients belonging to the General class (OR,2.68; 95% CI, 1.2 to 6.2) and Scheduled Tribal class (OR, 3.85; 95 CI, 1.3 to 11.1)were more likely to get a prolonged diagnostic interval. Those who had to meet ‘three HCPs’ (OR, 6.59; 95% CI, 2.3-19.0) and ‘four or more HCPs’ (OR, 4.74 95% CI, 1.5-15.5) before making a definitive diagnosis were more likely to have prolonged diagnostic interval compared to those who met only one HCP. Compared to participants who were referred to a higher centre for further evaluation, those who got their symptoms dismissed as minor by the consulting HCP were more likely to have a diagnostic interval of more than 30 days(OR, 5.71; 95% CI, 2.3 to 14.3). Those participants who had monthly income less than 5000 Indian rupees were more likely to have prolonged diagnostic intervals compared to those with a monthly income of more than 5000 Indian rupees (OR, 2.68; 95% CI, 1.2 to 6.2).

Document review found that the cancer control in Kerala is revolving around the comprehensive cancer care centers and oncology wings in government medical

colleges. The cancer care continuum is also tilted towards tertiary prevention than primary and secondary prevention. The plan to form a Kerala Cancer Care Grid to provide equitable, accessible and affordable cancer care within 50km of residence of an individual with the participation of public and private health care institutions is a pragmatic step. Reviewed documents opined about the need to provide appropriate training to all primary care providers in the health system for prompt identification of symptoms suggestive of cancer. This will reduce diagnostic interval. The establishment of referral guidelines for cancer diagnosis was suggested in all documents but has not materialised yet. Early detection of common cancers including oral cancer was discussed in documents but they differ in their strategies. The new Kerala cancer control strategy suggests augmenting efforts for early diagnosis through capacity building in the existing health care system by in-service training and infrastructure development.

The in-depth interviews with oral cancer patients clearly show how the financial dependency of dependents act as a barrier for timely seeking of care and treatment compliance. People generally believe that cancer treatment is too costly for them to afford. Many are unaware of the available treatment schemes. Assumptions about the signs and symptoms in the oral cavity affect a patient's health-seeking behaviour. Patients consider their symptoms as trivial if it doesn't affect their daily routine or it doesn't elicit pain. Patients often consider oral symptoms as self-limiting and expect spontaneous healing over time. A preference for alternative treatment or home remedies were observed in the period immediately after the recognition of oral symptoms. Continuity of care is an important factor influencing diagnostic interval and is often overlooked. People keep changing their health care providers for a variety of reasons, which often complicates disease evaluation and burdens the already overstretched health system. This results in delayed diagnosis. In-depth interviews with the community leaders suggested the necessity to augment the community level and system-level support for cancer care. According to them, the belief of incurability of cancer, and the fear of catastrophic treatment cost act as a deterrent for early diagnosis. Cancer treatment should be made free for all. The existing facilities for cancer early diagnosis are inadequate. Health care providers suggested the need for further training in early cancer detection. A loss to follow up and continuation of

habits was cited as a challenge for early cancer diagnosis in primary care. Health system administrators opined the need for professional reorientation for enabling early oral cancer diagnosis. Strengthening the referral system, integrating oral cancer control with the existing national programs like the national oral health program were identified as the potential areas for facilitating early diagnosis.

Conclusions: More than half of the participants reported increased patient interval and diagnostic interval indicating the urgent need for interventions to promote early diagnosis in Kerala. An interesting observation from the study is that the known risk factors for oral cancer like tobacco, alcohol and areca nut use are also associated with patient interval. The association of general health-seeking practices with patient interval reminds us of the importance of regular health check-ups and the dangers of alternative treatment in early diagnosis. Reporting symptoms only when it becomes unbearable contributes to the increased patient interval. Access to the health care facility should be improved and apprehensions about the health care setting should be alleviated for early diagnosis. The type of health care provider (HCP) first met for discussing the symptom, Advice received from that HCP and routes to diagnosis were significantly associated with diagnostic interval.

Recommendations: Information on patient interval and diagnostic interval should be collected routinely in the health system as part of the cancer registry program. Tailored interventions promoting early diagnosis targeting socioeconomically weaker sections should be planned. These programs should include habit cessation as a component. Health education on symptom appraisal and familiarisation of health care facilities in the context of cancer detection should be carried out. These programs should target the family and the society instead of focusing only on individual. The Health system should be strengthened at the primary care level by incorporating referral guidelines and in-service training of primary care practitioners. Further research is needed to understand the time points in the natural history of malignant transformation of oral potentially malignant disorders.

INTRODUCTION

Chapter 1

Introduction

1.1: Cancer

Cancer is the uncontrolled and unregulated proliferation and growth of cells in our body(Cooper, 2000). These cells further invade normal tissues and organs and gradually spread to other distant organs(Cooper, 2000). There are more than 100 types of cancer that exist. Cancer can develop in any part of the body and the characteristics of these cancers differ considerably from one another(National Institutes of Health (US), 2007). Cancers can be broadly classified into carcinomas, sarcomas, leukemia, and lymphomas. More than 90% of cancers fall into carcinomas and nearly eight percent belong to leukemia and lymphomas. Sarcomas are rare(Cooper, 2000). Cancers are also classified based on the site of diseases like breast cancer, oral cancer, lung cancer, etc. Though there are different types of cancers, some types occur more frequently like breast cancer, lung cancer, etc. (Cooper, 2000). Gender and geographical difference exist in cancer incidence (Ferlay J *et al*., 2020a). For example, breast cancer is more common among females, whereas oral and lung cancers are frequent among males. Causes of cancer include tobacco use, alcohol consumption, overweight and obesity, sedentary lifestyle, consumption of red meat, certain bacteria's like *Helicobacter pylori*, aflatoxins produced by the fungus *Aspergillus flavus*, parasites like *Schistosomahaematobium*, ultraviolet radiations, and infection with certain viruses like *Hepatitis B virus, Human papilloma virus, Epstein Barr virus and Human immunodeficiency virus*(Blackadar, 2016). In the year 2020, 19 million new cancer cases and ten million cancer deaths were reported in the world(Ferlay J *et al*., 2020a). Cancer incidence in the world is expected to increase to 30 million by 2040(Ferlay J *et al*., 2020b).

1.2: Oral cancer

The term 'Oral cancer' or 'oral cavity cancer' or 'Lip, oral cavity cancer' represents various malignant neoplasms occurring in oral tissues(Glick, 2015). Oral cancer

includes cancers of Lip, Base of tongue, Other and unspecified parts of the tongue, Gum, Floor of mouth, Palate, and Other unspecified parts of the mouth(Ferlay J *et al*., 2020a). The corresponding ICD-10(International Classification of Diseases version 10) coding for these sites are C00,C01,C02,C03,C04,C05 and C06 respectively(WHO, 2016) (Figure 1.1).

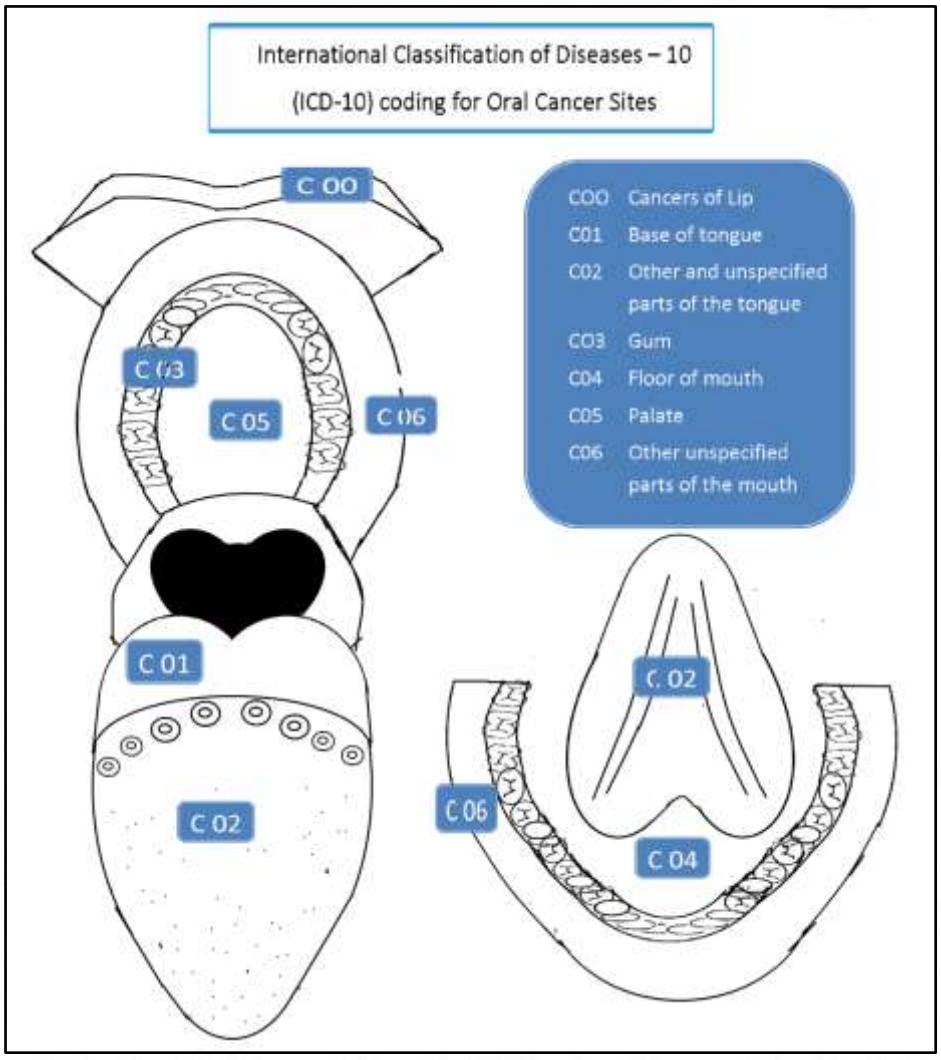


Figure 1.1: Pictorial representation of ICD-10 coding for Oral Cancer site

The majority of oral cancers are squamous cell carcinomas. Others include tumors of the bone, lymph node, salivary gland, and soft tissues(Glick, 2015). More than 90% of oral cavity cancers are squamous cell carcinomas arising from the lining

epithelium(Rivera, 2015). Oral cancer is a preventable disease with more than 90% of cases attributed to the use of tobacco and alcohol (Rivera, 2015). The disease can be identified through visual examination of the oral cavity by a trained health care provider(Gelband *et al*., 2015). Oral cancer is more common among males and elderly people. Tongue and buccal mucosa are the most common site of occurrence of oral cancer. Overall the disease has a poor survival rate(Gupta *et al*., 2016).

1.2.1: Oral cancer: The Global scenario

In the year 2020, lip and oral cavity cancers accounted for two percent of total cancer incidence in the world and it ranked 17th position among all cancers. The incidence of oral cancer is not evenly distributed among different countries of the world. For instance, Asia, Europe, and North America contribute to more than ninety percent of oral cancers(Ferlay J *et al*., 2020a). Asia dominates with 65.8% of the total incidence. In that, seventy percent of them were from the south-central Asian region. In that, 78% were reported from India. Africa, Oceania, Latin America, and Caribbean regions together had incidence less than 10% of all oral cancers(Ferlay J *et al*., 2020a). Melanesian region consisting of Fiji, New Caledonia (France), Papua New Guinea, Solomon Islands, Vanuatu reports the highest age-standardized incidence rate for oral cancer in the world followed by South Central Asia, Australia, New Zealand, and Central and Eastern Europe(Ferlay J *et al*., 2020a). Asia accounts for 74% of the total oral cancer related mortality in the world. The age-standardized mortality rate of oral cancer is highest in Melanesia, followed by South Central Asia, and Central and Eastern Europe(Ferlay J *et al*., 2020a).

1.2.2: Oral cancer: The Indian scenario

According to Global Cancer Observatory (2020), India had a 6.7% of the incidence of all types of cancers in the world. Further, it was also reported that oral cancer was the second most common cancer in India after breast cancer. It is the most common cancer among males and the fourth most common cancer among females in the country. Breast cancer and oral cancer contributed to 13.5% and 10.3% of total cancer incidence in the country respectively. Among males, oral cancer accounts for 16.2% of total new cancer cases followed by lung cancer (8%) (Ferlay J *et al*., 2020a). The

age-standardized incidence rate of oral cancer is 9.8 per one lakh population. India accounts for 36% of total oral cancer incidence in the world. Moreover, it is the third most common cause of cancer-related mortality in India. Globally, 42.35% of oral cancer-related mortality is reported from India in the year 2020(Ferlay J *et al*., 2020a). World Health organization projected a 54% increase in oral cancer incidence in India by 2040 compared to 2020(Ferlay J *et al*., 2020b). From 1990 to 2016, the mortality and Disability-Adjusted Life Years (DALYs) attributed to cancer had increased 90.9% and 112.8% respectively(Dhillon *et al*., 2018). Oral cancer was the first or second leading cause of cancer deaths among males in different states of India. Similarly, the age-standardized incidence rate of oral cancer also varied across different parts of the country(Dhillon *et al*., 2018). The population-based cancer registry (PBCR) of East Khasi Hill district in Meghalaya state reported the highest age-standardized incidence rate for tongue cancer (C01-C02) among men in the country, whereas Manipur reported the lowest rate(ICMR-NCDIR, 2020).

1.2.3: Oral cancer: The Kerala Scenario

The cancer-related information about Kerala was provided by the various population-based and hospital-based cancer registries (HBCR). There are three population-based cancer registries in the state of Kerala. They include, (a) the Trivandrum population-based cancer registry, (b) Kollam population-based cancer registry, and (c) Malabar regional registry covering Kannur, Kasaragod, and Mahe districts. Trivandrum district cancer registry reported a high incidence of oral cancer among men. It was the second common cancer in terms of incidence and mortality in men. The age-standardized cancer incidence rate for oral cancer among males was 15 per lakh population(Mathew *et al*., 2017). The hospital-based cancer registry reports from the two comprehensive cancer centers in Kerala provided an overview of the cancer scenario in Kerala. The HBCR report for the year 2016 from Malabar Cancer Centre reported the second-highest incidence of Lip, Oral Cavity cancers among males (11.86%) and females (8.6%)(Malabar Cancer Centre, 2020). The 2015 HBCR report from Regional Cancer Center Trivandrum reported the second-highest incidence of oral cancer among men(13.9%) and fourth-highest incidence among women(6.3%)

(Regional Cancer Centre, 2020). The report further stated that only 20.9% of cases were reported in the early stages.

1.2.4: Oral cancer: A historic overview

The three Indian classic Ayurveda texts, Sushruta Samhita, the Charaka Samhita, and the Ashtanga Hridaya mentioned cancer-like diseases(Smith and Mallath, 2019). Descriptions about various types of oral cancers were found in the 'Sushruta Samhita'(Inchingolo *et al*., 2020). The sixteenth chapter of the text was about oral pathologies which were described under the terms of "Mánsaja" referring to lip cancer, "Mahá-Saushira" and "Arvuda" referring to alveolar and palatal cancer, "Alása" for cancer of the tongue's base and "Adhjihva" for cancer of tongue's tip(Inchingolo *et al*., 2020). The detailed descriptions and categorization of oral cancers in the text suggest that the disease was frequent in India during that period. Interestingly, the text also identified betel quid consisting of areca nut, catechu, and betel leaf as a risk factor for oral cancers during that period. In the seventeenth century, oral cancers were misinterpreted as syphilitic chancres and hence considered infectious. This led to some setbacks in the management of oral cancers. The roots of current oral oncology practices can be traced back to the mid-nineteenth century. The introduction of general anesthesia and histopathological evaluations in the nineteenth century transformed the field of oncology(Inchingolo *et al*., 2020).

The situation in Kerala was also no different. The book titled 'A voyage to the East Indies' written by an Australian in the eighteenth century reported the prevalence of oral cancer in South India, particularly in the Malabar region(Raman and Raman, 2020). The extend of cancer cases reported in the Madras General Hospital(MGH) during the period 1892 to 1901 was mentioned by William James Niblock in his article 'Cancer in India'(Niblock, 1902). He reported the enormity of oral cancer cases in total cancer-related admissions in the hospital(Raman and Raman, 2020). The article further noted, " ..... *carcinoma of the cheek alone, among the cancer patients admitted into MGH, accounted for nearly a third, and the carcinoma of the cheek, jaws, and tongue taken together accounted for more than half of the total admissions for cancer in1892–1901"*(Niblock, 1902; Raman and Raman, 2020). He concluded

betel quid use as the reason for this high oral cancer incidence in south India(Niblock, 1902). He also noticed that carcinoma of buccal mucosa was more common among people of the Malabar region and attributed that to the high quantity of caustic lime and the presence of tobacco in their betel quid preparations (Niblock, 1902; Raman and Raman, 2020). He also identified betel quid use as the causative factor for Leukoplakia, the precursor lesion for oral cancer(Niblock, 1902). From antiquity to the modern age, oral cancer continues to be in epidemic proportion in India(Smith and Mallath, 2019).

1.2.5: Oral cancer: Risk factors

Carcinogenic agents with sufficient evidence to cause oral cancer in human beings include Alcoholic beverages, Betel quid with tobacco, Betel quid without tobacco, Human papillomavirus type 16, Smokeless tobacco, and Tobacco smoking(IARC, 2021). In addition to the above-mentioned agents, poor nutrition, genetic factors, mate drinking habits, and chronic trauma were also found to be causing cancer (Sankaranarayanan *et al*., 2015). Carcinogenic agents were classified according to the strength of evidence for their carcinogenicity as group 1 (Carcinogenic to humans), group 2A (Probably carcinogenic to humans), group 2B (Possibly carcinogenic to humans), and group 3 (Not classifiable as to its carcinogenicity to humans) (IARC, 2019). Tobacco smoking, Smokeless tobacco, Second-hand smoking, Betel quid with tobacco, Betel quid without tobacco, Alcoholic beverages, Ethanol in alcoholic beverages, Acetaldehyde associated with the consumption of alcoholic beverages, and Areca nut were classified as group 1 carcinogens (IARC, 2021).

In India, 28.6% of adults were using tobacco in some form during 2016-17. The country-made smoking aid called ‘beedi’ was the more commonly used form than branded cigarettes in India(GATS 2, 2018). Smokeless tobacco is used in a variety of forms in India. They include pan/betel quid (areca nut, betel leaf/inflorescence, slaked lime, catechu, condiments, with or without tobacco), Khaini (Tobacco and lime), Mishri (Burned tobacco), Gutka (areca nut, slaked lime, catechu, condiments, and powdered tobacco), Panmasala (Gutka without tobacco), Zarda (Boiled tobacco), Gadakhu (Tobacco and molasses), and Mawa (Tobacco, lime and areca nut)(IARC,

2004; Johnson, 2001). All these products cause oral cancer. Tobacco when used along with alcohol has a synergistic effect on cancer risk which is multiplicative for mouth cancer(Sankaranarayanan *et al*., 2015). More than 90% of head and neck cancers are attributed to the consumption of Tobacco along with heavy alcohol consumption and poor nutrition(Johnson, 2001). Though betel quid was considered a risk factor for oral cancer, the role of the areca nut was not recognized initially(Johnson, 2001). The betel quid consists of two group-one carcinogens, tobacco, and areca nut, and the presence of lime accelerates the release of alkaloids from them(Chu, 2001; IARC, 2004). This increases the risk of oral cancers among those who consume the betel quid.

Alcohol is an independent risk factor and leads to a two to six-fold increase in the risk of oral cancer(Sankaranarayanan *et al*., 2015). The risk of oral and pharyngeal cancers increases with an increase in the quantity of alcohol consumed(Goldstein *et al*., 2010). A meta-analysis on the association between fruits and vegetable intake and oral cancer risk has found that consumption of fruits and vegetables reduces the risk of oral cancer. It was found that there is a reduction of oral cancer risk at the rate of 49% and 50% by consuming fruits and vegetables respectively(Pavia *et al*., 2006). Chronic trauma of oral mucosa from dentures, broken teeth, faulty restorations were considered as risk factors for oral cancer. A study from Argentina reported chronic trauma of oral mucosa as an important risk factor for oral cancer but not for oral potentially malignant disorders(Piemonte *et al*., 2010). A literature review on the role of chronic mucosal trauma in oral cancer concluded that trauma from ill-fitting dentures may be considered as a risk factor for oral cancer(Singhvi *et al*., 2017).

1.2.6: Oral cancer: The process of disease progression

The natural history of a disease is defined as "the progression of a disease process in an individual over time, in the absence of treatment"(CDC, 2020). The normal oral squamous epithelium first undergoes hyperplastic changes due to mutation or deletion in genes whereby cells increase in number(Tanaka and Ishigamori, 2011). The epithelium further undergoes dysplastic changes whereby cells appear abnormal. All the hyperplastic and dysplastic cells may not transform into cancer. Those cells destined to become cancer form *carcinoma in situ*, here cancer cells remain in the

epithelium, the tissue of origin and did not break into the underlying connective tissue. Once the abnormal cells break into the underlying connective tissue and muscle, it becomes cancer. These abnormal cells over a period of time may spread to the nearby lymph nodes and later through blood or lymph system, to a distant organ resulting in metastasis(Tanaka and Ishigamori, 2011). Oral cancer has a long preclinical phase that is comprised of well-established oral potentially malignant disorders(Gelband *et al*., 2015). A consensus workshop organized by WHO recommended the term 'Potentially Malignant disorders' for all precancerous lesions and conditions(Warnakulasuriya *et al*., 2007). These lesions generally develop after exposure to a causative agent like tobacco or alcohol. The potentially malignant disorders (PMD) are at increased risk of developing hyperplastic and dysplastic changes and in some cases, they may further progress to cancer. The PMDs of concern in the oral cavity are leukoplakia and erythroplakia, palatal lesion of reverse cigar-smoking, oral lichen planus, oral sub mucous fibrosis, discoid lupus erythematosus, oral lichenoid reactions, graft-versus-host disease (GvHD), oral lupus erythematosus, hereditary disorders such as dyskeratosis congenita and epidermolysis bullosa(Napier and Speight, 2007; Warnakulasuriya, 2018) (Figure 1.2). Actinic cheilitis of the lower lip should also be considered for its potential for malignant transformation(Warnakulasuriya, 2018). From the above-discussed PMDs, only leukoplakia, erythroplakia, oral lichen planus, and oral sub mucous fibrosis, contribute more to oral cancer development(Napier and Speight, 2007). The development of oral cancer in a PMD is a multi-step process and not all PMDs develop into cancer(Warnakulasuriya *et al*., 2007). This precancerous phase offers leeway for interventions including medical and surgical management as well as habit cessation(Napier and Speight, 2007). The prevalence of PMDs varies between 1% to 5% globally(Napier and Speight, 2007). Oral PMDs are more common among males and the elderly. Though it can be found anywhere in the oral cavity, it is more frequently found in the buccal mucosa. The site of the lesion varies considerably based on tobacco use patterns (Napier and Speight, 2007). PMD may regress in size, disappear, increase in size, persist without any change or transform to the most feared oral squamous cell carcinoma(Napier and Speight, 2007).

Figure 1.2: Oral cancer and most common Precancerous lesions

Most of these PMDs are asymptomatic in their early course of the disease and often identified during a routine oral clinical examination(Warnakulasuriya, 2018). A cohort study of 12,212 tobacco users followed up annually over eight years reported 19 new oral cancer cases and 79% of these cases were developed from some preexisting oral precancerous lesions(Gupta *et al*., 1989).

1.2.7: Oral precancerous lesions

1.2.7.1: Oral precancerous lesions: Leukoplakia

Leukoplakia is the most common PMD encountered in clinical practice(Warnakulasuriya, 2018). “The term leukoplakia should be used to recognize white plaques of questionable risk having excluded (other) known diseases or disorders that carry no increased risk for cancer”. It should be considered as a clinical term and has no specific histopathological features(Warnakulasuriya *et al*., 2007). The possibility of other white conditions like frictional keratosis (cheek biting), alveolar ridge keratosis, leukoedema, white sponge nevus, and Fordyce granules should be considered before arriving at a diagnosis of leukoplakia. Leukoplakia is more common among smokers, alcohol users, and betel quid chewers. It is more frequent in males than females and those aged above 40 years(Warnakulasuriya, 2018). There are two main clinical types of leukoplakia, homogeneous and non-homogeneous types. The homogeneous type presents as a white uniformly flat and thin lesion with a low risk of malignant transformation. Non-homogeneous leukoplakia like nodular or speckled or erosive or verrucous leukoplakia has an increased risk for malignant transformation(Napier and Speight, 2007). Idiopathic leukoplakia also carries a higher risk for malignant changes. The predictors for malignant transformation of leukoplakia include age, gender, site, and clinical appearance of the lesion. There exist a higher potential for malignant transformation during the initial five years of their occurrence. PMDs in females were more likely to transform into oral cancer than those in males(Napier and Speight, 2007). Those leukoplakia presenting in the floor of the mouth and lateral border of the tongue were at higher risk for oral cancers(Napier and Speight, 2007). The malignant transformation rate varies considerably and ranges from 0.13% to 2.2% yearly(Nair *et al*., 2012). A ten-year follow-up study from Ernakulum, Kerala, India reported malignant transformation in four percent of cases(Gupta *et al*., 1980).

1.2.7.2: Oral precancerous lesions: Erythroplakia

Erythroplakia is a rare lesion with a higher potential for malignant transformation. The incidence rate varies from 0.02% to 0.83% and has no gender predilections(Nair

et al., 2012). WHO defined Erythroplakia as 'A fiery red patch that cannot be characterized clinically or pathologically as any other definable disease'(Warnakulasuriya *et al*., 2007). When a red lesion is found along with a white lesion, it should be considered as erythroleukoplakia(Warnakulasuriya *et al*., 2007). Erythroplakia is often found in the soft palate. The clinician should distinguish erythroplakia from other red lesions in the oral cavity like erythematous candidiasis, erythema migrans, erosive disorders, desquamative gingivitis, discoid lupus erythematosus, erosive lichen planus, and pemphigoid(Warnakulasuriya, 2018).

1.2.7.3: Oral precancerous lesions: Oral sub mucous fibrosis

Oral sub mucous fibrosis is a chronic condition characterized by the fibrosis of the connective tissue and lining of the oral cavity epithelium. In the early stages, the lesion presents as a burning sensation to hot and spicy food and blanching of the mucosa. The late stages are characterized by the fibrosis of oral mucosa, restricted mouth opening, and distortion of the uvula(Warnakulasuriya *et al*., 2007). This lesion is more common among those who use betel quids(Warnakulasuriya, 2018). A 17-year follow-up study of 66 oral sub mucous fibrosis patients in Kerala, India reported malignant transformation in 7.6% of patients(Murti *et al*., 1985).

1.2.7.4: Oral precancerous lesions: Oral lichen planus

Oral lichen planus is a chronic inflammatory condition caused by cell-mediated immune conditions and with no known etiology(Warnakulasuriya *et al*., 2007). There are contradicting reports on the malignant potential of oral lichen planus. The lesion can be clinically distinguished from oral leukoplakia except for the plaque type(Warnakulasuriya *et al*., 2007). The lesion is more common on the buccal mucosa and lateral border of the tongue. Usually asymptomatic, ulcerated lesions may cause a burning sensation. The lesion may last for several years with periods of remission and flare-ups(Warnakulasuriya, 2018). The annual malignant transformation rate of oral lichen planus is less than 1%(Nair *et al*., 2012).

1.2.8: Oral cancer: Signs, symptoms, and diagnosis

Pain is the most common symptom that leads a patient to seek care. Though pain is frequently reported, it most often occurs only when the lesion reaches a certain size. Generally, oral cancer is asymptomatic in the early stages(Bagan *et al*., 2010). In some anatomical locations like the tongue and floor of the mouth, pain may be reported in the early stage whereas, in buccal mucosa and lip, rarely experiences pain in the initial stages(Bagan *et al*., 2010). Individuals may also present with an awareness of a mass in the mouth or neck. Dysphagia, discomfort, odynophagia, otalgia, limited movement, oral bleeding, and neck masses may be reported in advanced stages(Glick, 2015). Tissue changes include red, white, or mixed red and white lesions, a change in the surface texture producing smooth, granular, rough, or crusted lesions, or the presence of a mass or ulceration(Glick, 2015). Oral cancer can be identified in a visual examination of the oral cavity by a dental surgeon or physician(Borse *et al*., 2020). A biopsy shall be done from the suspicious lesion for histopathological confirmation. Scalpel biopsy is the gold standard for the diagnosis of oral cancer. Several adjunct tests are also available for oral cancer diagnosis. They include vital staining, brush biopsy, and exfoliative cytology(Borse *et al*., 2020). A Cochrane review on the diagnostic tests for oral cancers and pre-cancers concluded that none of the adjunct tests can be recommended as a replacement for scalpel biopsy and histopathology(Macey *et al*., 2015).

1.2.9: Oral cancer: Disease staging, management, and survival

American Joint Committee on Cancer (AJCC) and the Union for International Cancer Control (UICC) developed the Tumor Node Metastasis (TNM) staging system for cancer. Staging depends on the histological characteristics of the lesion(Mupparapu and Shanti, 2018). Based on different scenarios, the staging may be clinical (cTNM) or pathological (pTNM). Those lesions treated non-surgically will have only clinical staging whereas those lesions treated surgically will have pathological staging after their surgery(Mupparapu and Shanti, 2018). The recent TNM staging will precede the previous one in determining the treatment strategies and prognosis evaluation(Mupparapu and Shanti, 2018). In the TNM staging system, ’T’ refers to

the extent of the disease based on the size of the primary tumor and its local invasiveness. 'N' refers to the presence or absence, size, and extent of regional lymph nodes. 'M' refers to the presence or absence of distant metastasis(Glick, 2015). Staging of cancer helps in treatment planning, assessing prognosis, and comparisons and evaluations of similar data(Mupparapu and Shanti, 2018).

The treatment of oral cancer should be decided on a case-to-case basis after discussion in an interdisciplinary tumor board(Wolff *et al*., 2012). Surgery and radiotherapy are the main modalities of treatment. For early-stage oral cancers, surgery or radiation is used and in selected cases, a combination of both may be used(Sankaranarayanan *et al*., 2015). Multimodality treatment consisting of surgery and or radiation and or chemotherapy was used in advanced stages(Sankaranarayanan *et al*., 2015). Nodal involvement and size of the tumor were significant predictors for prognosis. An overall five-year survival rate of 60.3% was reported from the USA whereas countries like China, Cuba, India, Pakistan, and Thailand reported an overall survival rate ranging from 26 to 45 percent(Sankaranarayanan *et al*., 2015).

1.3: The problem statement

Oral cavity cancer is the second most common cancer in India and is one of the most common cancers in Kerala(Ferlay J *et al*., 2020a; Malabar Cancer Centre, 2020; Mathew *et al*., 2017; Regional Cancer Centre, 2020). More than one-third of all oral cancer cases in the world were reported in India in 2020(Ferlay J *et al*., 2020a). Globally, more than half of the oral cancer patients reported at late stages(Güneri and Epstein, 2014; Sankaranarayanan *et al*., 2015; Warnakulasuriya, 2009a). A hospital-based study from India reported more than 90% of all oral cancers in advanced stages(Singh *et al*., 2015). Studies(Allison *et al*., 1998c; Cleveland and Thornton-Evans, 2012) had already shown that delay in reporting and diagnosing oral cancer resulted in advanced stage at diagnosis. The stage at diagnosis is an indicator of disease prognosis. This necessitated prioritizing the early diagnosis of oral cancer in India from a public health perspective (Coelho, 2012).

1.3.1: Oral cancer: Scope for early diagnosis

Globally one-third of all cancers are amenable to early detection(World Health Organization, 2006). While in the remaining, early detection is limited. Early diagnosis of a cancer type is recommended only if it brings improvement in the survival rates. The WHO recommends early diagnosis for oral cavity cancers(World Health Organization, 2006) indicating better disease outcome if diagnosed in early stages. There are several favorable factors for the early diagnosis of oral cancer. First and foremost is the availability of a simple oral visual examination test for the detection of oral cancer(Sankaranarayanan *et al*., 2015). The conventional oral visual inspection can be carried out in any clinical setting with a very minimum armamentarium. Secondly, several healthcare providers are capable to perform an oral visual inspection(Macey *et al*., 2015). Studies have even shown that community health volunteers can be trained to perform the visual inspection of the oral cavity with acceptable accuracy. The accessibility of the oral cavity for examination also favors early diagnosis(Brocklehurst and Speight, 2018). The presence of a long preclinical phase with known potentially malignant disorders often observed in the natural history of oral cancer facilitates early diagnosis and screening in oral cancer(Brocklehurst and Speight, 2018; Farah *et al*., 2014; Sankaranarayanan *et al*., 2015). Early identification and proper management of these lesions will prevent them from developing into cancer. The population at risk of developing oral cancer is known from their habit history as more than 90% of oral cavity cancers are observed in those who use tobacco and alcohol(Johnson, 2001). There exists some evidence for mortality reduction from oral cancer among the high-risk population through oral cancer screening(Brocklehurst *et al*., 2010). Despite all these favorable factors, most of the time, the lesion is reported or diagnosed at advanced stages(Güneri and Epstein, 2014).

1.3.2: Delayed diagnosis leads to poor prognosis

Delay in identifying cancer often leads to disease progression and poor prognosis. Oral cancer carries a considerable risk of mortality. The stage at diagnosis is the single most important prognostic factor for oral cancer. The five-year survival rate of

early-stage cancer exceeds 80%, while that of patients with advanced stages falls below 20%. Recent cancer survival data from England reiterated the need for early diagnosis for better survival. For most cancers, survival is much better if it is detected at an early stage(Hawkes, 2019). Optimal and curative treatment can be offered to those diagnosed in an early stage to benefit from it(Hiom, 2015).

1.3.3: Delayed diagnosis leads to the economic burden

Oral cancers detected in late stages often require lengthy and expensive multimodality treatment whereas early-stage lesions can be managed using single modality treatment which is less expensive and results in limited morbidity(World Health Organization, 2006). Most of the oral cancer patients belong to the low socio-economic strata of society(Ganesan *et al*., 2020; Warnakulasuriya, 2009a). Awareness about symptoms suggestive of oral cancer is also less among these people(Azimi *et al*., 2020). The direct and indirect cost of treatment associated with the late-stage diagnosis of oral cancer further deteriorates their already weak financial position and may have a destructive effect on their standard of living. The economic costs associated with the management of oral cancer exert enormous pressure on the health care system and individual families(Amarasinghe *et al*., 2019).

1.3.4: Components of the diagnostic journey: Theoretical framework

Pack and Gallo first introduced the concept of delay in 1938 and they defined it as an interval between the onset of symptoms and the first visit to a physician. The undue delay was arbitrarily defined as three months or more(Pack and Gallo, 1938). The symptom interpretation and help-seeking process in the oral cancer diagnostic journey can be comprehended using the theoretical framework of the model pathways to treatment. The model pathways to the treatment proposed by Walter *et al* is a refinement to The Andersen model of patient delay(Walter *et al*., 2012). The diagnostic journey consists of Appraisal interval, Help-seeking interval, and Diagnostic interval. The appraisal interval provides an insight into the symptom interpretation process(Walter *et al*., 2012). The nature of the initial symptom influences the duration of this interval. As oral cancer patients having lesions with pain or discomfort had short intervals and those who attributed symptoms to minor

oral illness had long intervals(Brouha *et al*., 2005). The period from symptom appraisal to consulting a health care provider constitutes the help-seeking interval. The period from the initial consultation to definitive cancer diagnosis gives diagnostic interval(Walter *et al*., 2012). The appraisal interval and help-seeking interval together is called patient interval(World Health Organization, 2017).“Patient interval” is the period between symptom recognition by the patient and the first consultation with a health care provider for evaluating the same(Walter *et al*., 2012; World Health Organization, 2017). A period of three months is considered a tolerable period for an interval(Pack and Gallo, 1938). ‘Diagnostic interval’ is the period between the first appointment with a health care provider for evaluating the symptom and the histopathological cancer diagnosis(Walter *et al*., 2012). A period of one month is considered a tolerable period for an interval(Allison *et al*., 1998b).

1.3.5: Paucity and poor quality of studies on early oral cancer diagnosis

Very few studies were conducted on various time intervals in the diagnostic journey of oral cancer in India. None of them were from Kerala. A recent meta-analysis on early diagnosis of oral cancer found that most of the studies were from European countries and only one study was from South East Asia(Seoane *et al*., 2016). It is saddening to observe the inadequacy of studies from South Central Asia, which contributes to most of the oral cancer incidence in the world. The existing studies on early oral cancer diagnosis were characterized by methodological flaws and heterogeneity in the definitions and reporting of the study findings(Weller *et al*., 2012). Measurements of time used in studies include days, weeks, and months and the summary measure chosen to report the findings include Mean, Median, and proportion(Philip and Kannan, 2019; Weller *et al*., 2012). This has constrained the scope of comparisons across studies necessitating further research in this field. Most of these studies also failed to include a theoretical framework for their research(Weller *et al*., 2012). A consensus workshop of researchers in early cancer diagnosis systematically assessed the existing early cancer diagnosis and suggested a guideline for early cancer researchers. This guideline called the “Aarhus statement” aims to overcome the methodological inconsistencies and other shortcomings observed in the early cancer research(Weller *et al*., 2012).

1.4: Duration of patient interval

Patient interval in oral cancer provides an understanding of the time taken by the patient to report to a health care provider for any symptom suggestive of oral cancer. Studies found Patient interval as the largest component of total diagnostic interval(Panzarella *et al*., 2014; Wang *et al*., 2018) indicating the need for a better understanding of the same to plan initiatives to shorten the duration. A review on oral cancer early diagnosis had reported a mean patient interval of three months in multiple studies(van der Waal *et al*., 2011). Different countries within the developed world reported different median intervals ranging from 35 days to 100days(van der Waal *et al*., 2011). Similarly, studies from the developing world also exhibit similar differences. A study from Iran(Esmaelbeigi *et al*., 2014) reported a median interval of 45 days whereas a study from northeast India reported a median interval of 90 days whereas another study from East India reported a median interval of 30days (Rath *et al*., 2018). This variability in the patient interval among countries belonging to different geographic and economic grouping indicates the need for region-specific studies on the magnitude of patient interval in oral cancer to plan early diagnosis interventions relevant to the local context.

1.4.1: Factors associated with patient interval

1.4.1.1: Socio-demographic characteristics

Researchers in early oral cancer diagnosis had explored the association of various socio-demographic factors with patient interval and many at times the results did not establish the association due to various reasons. There are studies(Kumar *et al*., 2001)that did not establish any association with socio-demographic factors, while some found a significant association with oral cancer(Akram *et al*., 2014; Baishya *et al*., 2015; Panzarella *et al*., 2014). The factors that were associated in one study may not be associated with another one. Akram *et al* reported place of residence as a significant factor associated with patient interval whereas Baishya *et al* did not establish any association(Akram *et al*., 2014; Baishya *et al*., 2015). These inconsistencies from the existing literature suggest exploring more on the association.

1.4.1.2: Role of tobacco and alcohol habits

Habit-related factors like tobacco smoking and alcohol use were examined in studies for ascertaining their possible association with the patient interval in oral cancer but no significant association was observed(Guggenheimer *et al*., 1989; Hollows *et al*., 2000; Onizawa *et al*., 2003). A study on lung cancer early diagnosis reported, delayed health-seeking by smokers for symptoms suggestive of lung cancer(Friedemann Smith *et al*., 2016). The role of tobacco and alcohol habits in oral cancer causation(Sankaranarayanan *et al*., 2015) is well established in the literature but its effect on oral cancer-related symptom appraisal and help-seeking is not found in the literature.

1.4.1.3: Health seeking behaviors

The effect of health-seeking behaviors on patient interval was rarely studied in the existing literature. Use of domestic remedies before consulting a doctor, a regular visit to a medical doctor(Kumar *et al*., 2001), and regularity of dental consultation(Panzarella *et al*., 2014) were examined for their possible association with patient interval but no significant association was found. Economic status is associated with health-seeking behavior. Those with high socioeconomic status were more likely to use high-end health services(Li *et al*., 2020). As the majority of oral cancer patients belong to low socioeconomic strata of the society(Warnakulasuriya, 2009b), it is important to study their health-seeking behaviors for establishing an association with patient interval.

1.4.1.4: Barriers to help-seeking

Understanding the various barriers to help-seeking is essential to remove those barriers in the diagnostic journey of oral cancers. A study on barriers to help-seeking had found emotional barriers like embarrassment were commonly reported by patients from low socioeconomic strata whereas those belonging to higher socioeconomic strata endorsed practical barriers like scheduling an appointment with a doctor(Robb *et al*., 2009). A qualitative study on help-seeking for alarm symptoms of cancer had identified symptom characteristics like persistence, social influence, instinct, and fear

of possible link to cancer as reasons for seeking help for their symptoms(Whitaker *et al*., 2015). Another study on the anticipated barriers to help-seeking observed gender, age, and occupation-based differences in their endorsement(Moffat *et al*., 2016). Knowing more about these socio-demographic differences in the endorsement of barriers to help-seeking will help in planning strategies to minimize the patient interval. Moreover, most of the studies on barriers to help-seeking had come from high-income countries(McCutchan *et al*., 2021) necessitates the need for such explorations in low-income countries such as India.

1.4.1.5: Role of social relationship

Studies had identified the association of social support, network size, and marital status on cancer survival(Pinquart and Duberstein, 2010). These associations varied for different cancer sites with the stronger association of social support observed in hematological malignancies and network size in breast cancers(Pinquart and Duberstein, 2010). A few studies which examined the association of social relationships on patient interval found that they vary for different cancer types(Macleod *et al*., 2009; Pedersen *et al*., 2011). A study that examined the association of perceived social support by the partner and other members in the social network found that partner support and support from others in the social network as well as disclosing the symptoms to others significantly reduced the patient interval among women. In men, partner support helped in reducing the patient interval in the diagnostic journey of cancer(Pedersen *et al*., 2011). A study on the role of social support on help-seeking among diabetes patients observed that the influence depends on the strength of relationship and level of trust(Low *et al*., 2016). The role of social support per se was not examined in the patient interval studies in oral cancer(Akram *et al*., 2014; Baishya *et al*., 2015; Hollows *et al*., 2000). Disclosure of symptoms with others was examined in one study but no significant association was observed(Akram *et al*., 2014). Similarly, the role of marital status was also examined but none of the studies could find any significant association with patient interval(Akram *et al*., 2014; Panzarella *et al*., 2014). The above-mentioned findings suggest the need for studying the association of social relationships with patient interval with specific reference to oral cancer.

1.4.1.6: Role of local remedies and traditional medicines

It is generally found that herbal and traditional medicines are in practice in most of the world. A study on the prevalence of herbal medicine use among cancer patients in the UK had found, there was nearly one-fifth of the study participants were practicing them(S Damery *et al*., 2011). Another study from Canada reported the usage of herbal medication in nearly one-fourth of head and neck cancer patients(Warrick *et al*., 1999). A study from India reported complementary and alternative medicine use among two-fifth of their cancer patients indicating a higher prevalence compared to the previous studies from high-income countries(Kumar *et al*., 2016). A study on early diagnosis of oral cancer from Thailand had reported a significant association of patient interval with the use of herbal medications(Kerdpon and Sriplung, 2001), while this was not found in a study that was conducted years later in the same country by the same researchers (Kerdpon *et al*., 2018). A review on barriers to help-seeking in low-income countries has identified a higher usage of traditional, alternative, and complementary medicine leading to a prolonged patient interval(McCutchan *et al*., 2021). This clearly shows the need for studying the role of herbal and traditional medicine on the oral cancer diagnostic journey.

1.4.1.7: Access to health care

Access to health care depends on the availability of services, adequacy of services, and the opportunity to obtain the services(Gulliford *et al*., 2002). A systematic review on the association between travel distance/ time to the health care facility and patients' health outcome had found a significant association in more than three fourth of the reviewed studies(Kelly *et al*., 2016). Those living farther away from the health facility had worse health outcomes than those living near to the health facility(Kelly *et al*., 2016). A study from the USA also identified distance as a barrier to healthcare delivery(Buzza *et al*., 2011). A review has identified inaccessibility of transportation resulted in poor health care utilization especially among those who belong to low socioeconomic strata(Syed *et al*., 2013). Personal, financial, and structural factors may influence the accessibility to care(Centelles *et al*., 2012). One study reported the association of limited accessibility of primary health facilities with increased patient

interval(van der Waal *et al*., 2011). The impact of access to health care in the diagnostic journey of oral cancer is rarely reported in the existing literature, necessitating further exploration of its association with patient interval.

1.5: Diagnostic interval in oral cancer

Studies measuring diagnostic interval in oral cancer are less compared to patient interval studies and their choice of definition for diagnostic intervals varied considerably(Weller *et al*., 2012). This constituted a serious problem in early oral cancer diagnosis research to visualize the course of the diagnostic journey in primary care. The median diagnostic interval reported in the existing literature varied from 11days(Jovanovic *et al*., 1992) to 60days(Allison *et al*., 1998b). The maximum duration acceptable for the diagnostic interval is 30days(van der Waal *et al*., 2011). It is important to know the average length of the diagnostic interval in the diagnostic journey of oral cancer to plan appropriate measures. Understanding various factors associated with diagnostic interval is also necessary for planning strategies.

Diagnostic interval is primarily associated with the healthcare provider and system-related factors(World Health Organization, 2017). A cohort study from Denmark on five common cancers found a significant association between diagnostic interval and mortality(Tørring *et al*., 2013). A review on factors affecting oral cancer diagnosis had identified the following provider-side factors as reasons for the diagnostic interval. They included a low index of suspicion, lack of familiarity and experience with the disease, and inadequate clinical examination as the reasons for the diagnostic interval(Centelles *et al*., 2012).

Oral cancer patients either consult general medical practitioners or dental surgeons for an initial consultation(Crossman *et al*., 2016). A study on oral cancer awareness of general medical and dental practitioners from the UK had identified lower awareness of oral cancer risk factors and clinical assessment by medical practitioners than dental practitioners(Carter and Ogden, 2007). This clearly shows that there is a need for training on early diagnostic procedures of oral cancer for medical practitioners, as more patients visit general medical practitioners compared to dental practitioners(Crossman *et al*., 2016). A study from Malaysia reported the association

of complementary and alternative medicines(CAM) use and delayed presentation and diagnosis among breast cancer patients(Mohd Mujar *et al*., 2017). However, there was no study on the role of CAM in oral cancer. Hence, the role of CAM on the diagnostic delay of oral cancer needs to be studied. While studying the provider side factors in oral cancer, it is important to study the availability of dental services in the public health system in Kerala(Ramanarayanan *et al*., 2020). It is also important to study the time constraints that affect clinical examination and diagnosis in primary health centers(Vallikunnu *et al*., 2014).

1.6: The conceptual framework for the study

The conceptual framework for the study was derived from the model put forth by Walter *et al*.(Walter *et al*., 2012), Weller *et al*.(Weller *et al*., 2012), and also from the 'Guide to early diagnosis' by World Health Organization. As per the model, the time interval from detecting a bodily change to perceiving a reason to discuss the symptoms with a healthcare provider constitutes 'symptom appraisal interval'. The time from perceiving a reason to discuss symptoms with the healthcare provider to consulting a healthcare provider is called 'health seeking interval'. The symptom appraisal interval and health-seeking interval together constitutes the 'patient interval'. The time period from meeting a healthcare provider for discussing the symptoms to the date of definitive histopathological confirmation of cancer diagnosis constitutes the 'diagnostic interval'. These intervals are influenced by various disease-specific factors (site of disease, stage of disease), individual-level factors (socioeconomic factors, habit- related factors, health seeking behaviors etc.), inter-personal factors (disclosure to significant others, social support etc.) and healthcare providers and system related factors (access and availability, type of healthcare provider etc.).

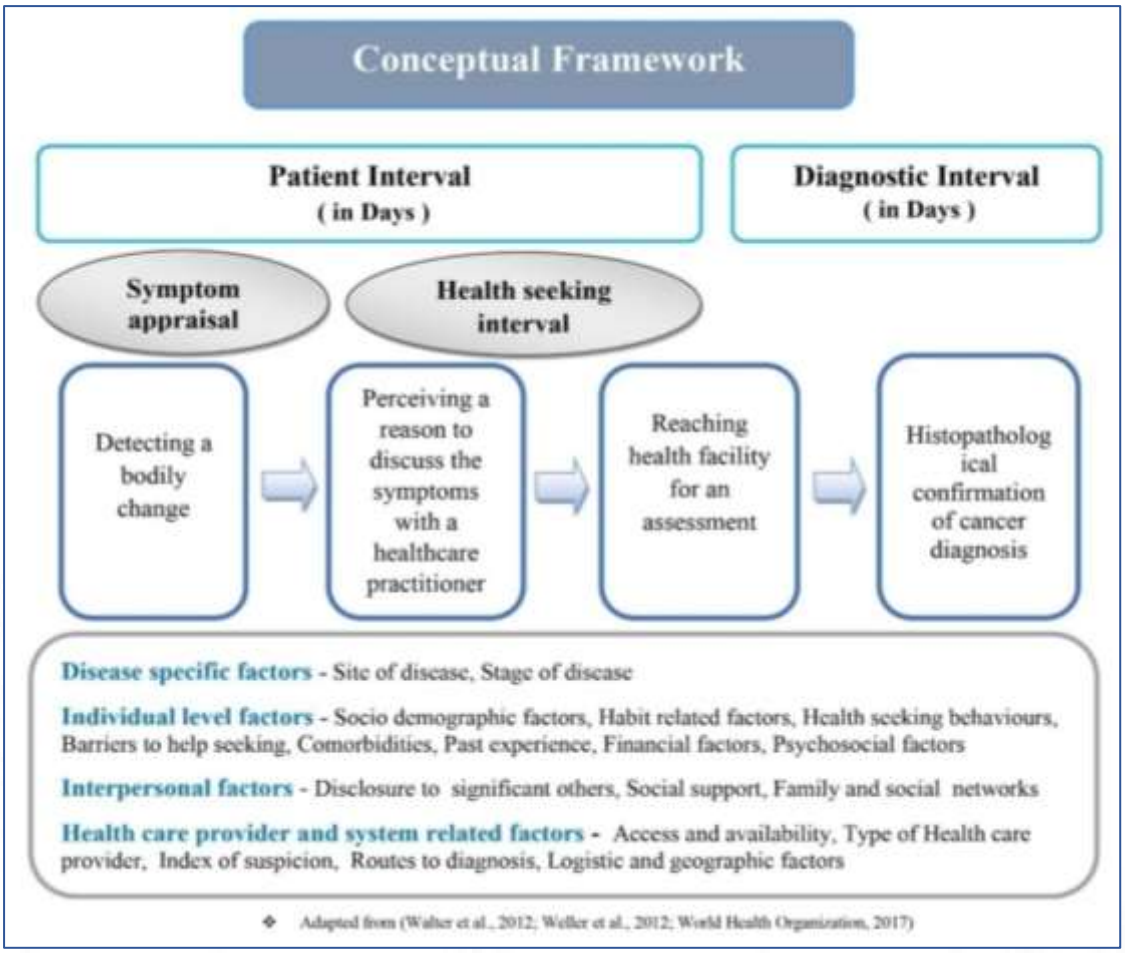


Figure 1.3: Conceptual framework for the study

1.7: .Objectives

- To develop an instrument for capturing the duration of patient interval and contributing factors in the diagnostic journey of oral cancer
- To estimate the duration of patient interval in the diagnostic journey of oral cancer patients of a tertiary cancer center in northern Kerala
- To estimate the duration of diagnostic interval in the diagnostic journey of oral cancer patients of a tertiary cancer center in northern Kerala

- To study the various factors associated with the patient interval in the diagnostic journey of oral cancer patients of a tertiary cancer center in northern Kerala
- Mapping of structure and function of oral cancer control in the state

1.8: Brief overview of chapters

Chapter one provides an overview of the oral cancer problem and the need and necessity of early diagnosis in oral cancer. Chapter two of this dissertation reviews the existing scientific literature on screening and early diagnosis of oral cancer, patient and diagnostic intervals in oral cancer, and factors contributing to those intervals. Chapter three describes the study designs and detailed methodology of various phases in the study. Chapter four reports the findings of the quantitative and qualitative components of the study. Chapter five discusses the findings of the study comprises the quantitative results in the beginning and explains them with the findings of the qualitative inquiry. Chapter six summarises and concludes the research.

LITERATURE REVIEW

Chapter 2

Literature review

2.1: Introduction

Cancer is a group of heterogeneous diseases that can affect almost any part of the body and has many anatomic and molecular subtypes, each requiring specific diagnostic and management strategies(World Health Organization, 2017). Cancer incidence is increasing in the world with a staggering nineteen million new cancer cases in 2020. Nearly half of these cases were reported from Asia. The age-standardized cancer incidence rate in the world is 220 per 100000 people (Ferlay J *et al*., 2020a). Around the world, 20.4% of people are at risk of developing cancer before the age of 75. (Ferlay J *et al*., 2020a). The cancer incidence pattern also varies across different world regions. Breast cancer is the most common cancer in all six WHO regions. If we look at the cancer incidence among men, the prostate is the most common cancer in WHO regions of Europe, Africa, and America, whereas lung cancer in western pacific and east Mediterranean regions and lip, oral cavity cancers in South East Asia region(Bray *et al*., 2018).

Oral cancer is the most common type of cancer among men in South Asian Countries like India, Sri Lanka, and Pakistan(Ferlay J *et al*., 2020a). Oral cancer is the second most common cancer in India and contributes to 10.3% of new cancer cases reported in the country in the year 2020. In 2012, India reported one-fifth of total oral cancer cases reported in the world, and in 2020, it reported one-third of all new cases indicating an alarming rise in the incidence of oral cancer in the country(Ferlay J *et al*., 2020a; Sankaranarayanan *et al*., 2015). Oral cancer is characterized by marked geographical variations in its incidence and prevalence rates(Warnakulasuriya, 2009a). The observed trends in incidence and mortality among men and women are closely correlated with the patterns and trends in tobacco and alcohol use(Sankaranarayanan *et al*., 2015).

The main risk factors for oral cancer include tobacco, areca nut, alcohol use, chronic trauma, low dietary intake of fruits and vegetables(Petti, 2009). The use of tobacco in all forms, like beedi, cigarette, pan masala, pan parag, and other commercial smokeless tobacco products, all lead to oral cancer. The use of betel quid, a mixture of betel leaf, areca nut, slaked lime, and tobacco, also put people at increased risk of oral cancer. Use of areca nut alone is also a risk factor (Sankaranarayanan *et al*., 2015). Areca nut, betel quid with tobacco, betel quid without tobacco are classified as group 1 carcinogen by International Agency for Research on Cancer (IARC) (IARC, 2012). The combined use of tobacco and alcohol has a multiplicative effect on the risk of developing oral cancer(Pelucchi *et al*., 2006). The presence of Human Papilloma Virus infection is also cited as a risk factor for certain oropharyngeal cancers (Sankaranarayanan *et al*., 2015). Oral cancer is linked to social and economic status and deprivation, with the highest rates occurring in the most disadvantaged sections of the population. The association is particularly strong for men(Warnakulasuriya, 2009a). Age is a non-modifiable risk factor for oral cancer. As age increases the risk of developing cancer also increases.

2.2: Oral cancer: Strategies for prevention

Oral cancer is unique among other cancers as it is amenable to primary, secondary, and tertiary prevention. Risk factors for oral cancer are well known and refraining from them reduces our chances of getting the disease. About 80% of oropharyngeal cancers in men and 65% of cases in women can be attributed to tobacco and alcohol use(Pelucchi *et al*., 2006). Detecting cancer early in the natural history of disease constitutes secondary prevention. Two strategies are used for this; screening and early diagnosis(World Health Organization, 2017). Screening is used to identify disease in an asymptomatic person. Screening can be population-based or opportunistic. Population-based screening is carried out in a community setting and it requires economic, logistic, and health infrastructure commitments which many of the developing economies couldn't afford(Shah *et al*., 2019; Sullivan *et al*., 2015). Opportunistic screening occurs when a health provider offers cancer screening to an

asymptomatic person or an individual expressing a desire for undergoing a screening test(Sullivan *et al*., 2015). Early detection differs from screening in such a way that here disease is detected at the possible earliest stage in symptomatic individual(World Health Organization, 2017). Fewer resources are required for early detection as only symptomatic people undergo diagnostic evaluations.

2.3: Oral cancer: Primary prevention

Understanding the natural history of the disease helps in planning various levels of cancer prevention(Isabel dos Santos Silva, 1999). The purpose of primary prevention is to limit the incidence of cancer by controlling exposure to risk factors or increasing an individual's resistance to them. The risk factors for oral cancer are well known and adopting appropriate behavioral and lifestyle changes will help in achieving primary prevention(Sankaranarayanan *et al*., 2015). Non-initiation of tobacco, alcohol and areca nut use in the adolescent group and habit cessation in the adult population through appropriate interventions constitutes the primary prevention in oral cancer(Sankaranarayanan *et al*., 2015). Measures like adherence to regular intake of fruits and vegetables and regular dental checkups for correcting causes of local irritation and trauma in the mouth should also be considered as part of primary prevention(Reichart, 2001; Sankaranarayanan *et al*., 2015). Conducting tobacco and alcohol awareness programs and strict implementation of provisions of the COTP Act will lead to risk reduction in the population(Gupta *et al*., 1992; Philip *et al*., 2013). A primary prevention trial conducted in India reported a reduction in risk factors as well as in the incidence of precancerous lesions(Gupta *et al*., 1992).

A meta-analysis of studies from India, China, and Taiwan has concluded that eliminating the most common type of betel quid use from these countries will result in a reduction of more than half of oral cancer cases in those countries(Hashim *et al*., 2019).

2.4: Oral cancer: Secondary prevention

Secondary prevention refers to the detection of cancer at an early stage when treatment is more effective than at the time of usual diagnosis. Secondary prevention, which revolves around the concept of early detection, consists of two components namely screening and early diagnosis(World Health Organization, 2017). Screening refers to the identification of asymptomatic disease in an apparently healthy population. For a disease to be included in a screening program, it should have a long detectable pre-clinical phase, and early treatment should offer a better prognosis (Isabel dos Santos Silva, 1999). Even though oral cancer fulfills these conditions, existing literature did not recommend a population-based oral cancer screening program except for the high-risk populations (Brocklehurst *et al*., 2013; USPSTF, 2013). Early diagnosis is the recognition of symptomatic cancer in patients(World Health Organization, 2007). There is consistent evidence that the early diagnosis of cancer, combined with accessible, affordable effective treatment, results in better disease outcomes (World Health Organization, 2017).

2.4.1: Oral cancer: Screening

Screening is defined as "*the presumptive identification of unrecognized disease or defect by the application of tests, examinations, or other procedures which can be applied rapidly. Screening tests sort out apparently well persons who probably have a disease from those who probably do not. A screening test is not intended to be diagnostic. Persons with positive or suspicious findings must be referred to their physicians for diagnosis and necessary treatment.*"(Wilson and Jungner, 1968). Population screening programs can be 'mass screening', 'selective screening' or 'opportunistic screening'(Brocklehurst and Speight, 2018). In 'mass screening', the entire population is screened whereas in selective screening a predefined population based on some risk assessment is screened. In 'opportunistic screening', the person may be offered a cancer screening test during an unrelated medical consultation(Brocklehurst and Speight, 2018). Oral cancer, if detected in the early stage, can be managed with less complex treatment modalities but advanced cases need expensive multimodality treatment with high morbidity and reduced survival

rates(Brocklehurst and Speight, 2018; Sankaranarayanan *et al*., 2015). Moreover, many a time, these oral cancer cases are preceded by a precancerous lesion which can be identified by a visual examination of the oral cavity(Brocklehurst and Speight, 2018). The anatomic location of the oral cavity favors easy access for clinical examination and oral cancers and precancers can be detected easily. Despite these favorable characteristics for implementing screening programs, no country has an established national mouth cancer screening program (Brocklehurst and Speight, 2018).

The primary outcome that decides the efficacy of any screening program is its ability in reducing death in the study population due to that disease. A large cluster randomized trial was carried out in Kerala that evaluated the efficacy of organized oral cancer screening but did not find any significant difference in mortality between intervention and control groups(Brocklehurst *et al*., 2013; Sankaranarayanan *et al*., 2013; Subramanian *et al*., 2009). Over the 15 year study period, screening significantly reduced mortality in the high-risk population in the intervention group compared to the high-risk population in the control group(Brocklehurst *et al*., 2013; Sankaranarayanan *et al*., 2013). A study on the cost-effectiveness of oral cancer screening in primary care found that targeted opportunity screening of high-risk populations by general medical practitioners or general dental practitioners is cost-effective(Speight *et al*., 2006). All these studies favor oral cancer screening for the high-risk population only(Brocklehurst and Speight, 2018). As the population-based screening of oral cancer is not recommended, the only other option for achieving early detection of oral cancer is to promote early diagnosis.

2.4.2: Oral cancer: Early diagnosis

In early diagnosis, people with initial signs and symptoms of cancer report to a health care provider for evaluation. The health care provider promptly refers the patient for confirmation of diagnosis(World Health Organization, 2007). Early diagnosis is the awareness about the signs and symptoms of the disease by the public and the health care provider to facilitate diagnosis before the disease becomes advanced. This is considered down staging(World Health Organization, 2007). The objective is to

identify the disease at the earliest possible opportunity and link it to diagnosis and treatment immediately(World Health Organization, 2017). Recognizing possible warning signs and symptoms of cancer and taking prompt action leads to early diagnosis(World Health Organization, 2007). Evidence shows a reduction in breast cancer mortality through early diagnosis(World Health Organization, 2017). Early diagnosis is possible for those cancers having a recognizable sign or symptom in the early course of the disease. Hence, it is particularly relevant for cancers of the breast, cervix, mouth, larynx, colon, and rectum, and skin(World Health Organization, 2007). The early-stage at the time of diagnosis of oral cancer favors better treatment outcomes and prognosis. Patients with shorter diagnostic delays often report an early stage at diagnosis(van der Waal *et al*., 2011). An early diagnosis is a cost-effective approach than screening as only people with symptoms were provided diagnostic services. This can be integrated into the health services of countries that did not have adequate infrastructure for conducting screening programs(World Health Organization, 2017).

2.5: Delay in cancer diagnosis

The delay in diagnosis, as well as difficulty in accessing appropriate care, leads to significant morbidity and mortality(World Health Organization, 2017). The lack of awareness about the signs and symptoms of oral cancer in the community and the rarity of the disease in the primary care setting and also the diversity of signs and symptoms delay disease identification and diagnosis(van der Waal *et al*., 2011). Apart from the symptom awareness and appraisal by the patient and the doctor, other organizational system factors may also contribute to delay in diagnosis. A systematic review on the influence of delay in the survival of breast cancer patients found lower survival in those with 3-6 months delay(Richards *et al*., 1999). The magnitude of survival benefit observed in those with shorter delay was comparable with the benefits on survival due to chemotherapy(Richards *et al*., 1999). Though early diagnosis improves outcomes, the benefit is not similar across different cancer types. A meta-analysis on diagnostic delay in oral cancer with the stage at diagnosis observed that patients with diagnostic delay had 30% higher chances of having advanced stage at diagnosis(Gómez *et al*., 2009). Some of the common cancers can be diagnosed in the

early stages and early treatment is known to improve outcome. They include breast, cervical, colorectal and oral cancers(World Health Organization, 2017).

The cancer diagnostic journey is affected by several factors. The contributing factors listed in the model pathways to treatment include patient factors (demographic, comorbidities, psychological, social, cultural, previous experience), health care provider and system factors (access, health care policy and delivery), and disease factors (site, size, growth rate)(Weller *et al*., 2012). WHO model has identified poor health literacy, cancer stigma, and limited access to primary care as possible barriers contributing to the patient interval(World Health Organization, 2017). Financial, geographic, and logistical factors, as well as sociocultural factors, were listed as possible barriers to treatment interval(World Health Organization, 2017).

2.6: Theories, Models, and Definitions in Delay in diagnosis

Pack and Gallo first introduced the concept of delay in 1938 and they defined it as an interval between the onset of symptoms and the first visit to a physician. The undue delay was arbitrarily defined as three months or more(Pack and Gallo, 1938). The first model to explain the delay in seeking cancer diagnosis was given by Andersen(Andersen *et al*., 1995). The general model of patient delay is comprised of a series of stages each characterized by a distinct set of definitions and appraisal processes. The first stage is 'appraisal delay', which spans from identification of body changes to inference of those changes as illness(Andersen *et al*., 1995). 'Illness delay' is defined as the number of days elapsing from the time an individual concludes he or she is ill to the day she or he decides to seek medical help(Andersen *et al*., 1995). The time that elapses between the decision to seek medical attention and the person acting on this decision by making an appointment constitutes 'behavioral delay'(Andersen *et al*., 1995). The time that elapsed between the person making an appointment and first receiving medical attention is called 'scheduling delay'(Andersen *et al*., 1995). 'Treatment delay' is the period between first medical advice to the initiation of treatment(Andersen *et al*., 1995). The early stages in the Andersen model were based on the psychophysiological comparison theory. Olesen *et al* proposed and defined various milestones and time intervals in the route from the first symptom until the

start of treatment(Olesen *et al*., 2009). They include total delay, patient delay, doctor delay, system delay, primary care delay, secondary care delay, diagnostic delay, and treatment delay(Olesen *et al*., 2009).

Walter *et al* refined the Andersen model and proposed the Model pathways to treatment(Walter *et al*., 2012). In this model, they combined appraisal delay and illness delay to form appraisal interval. It is defined as the time interval from detection or awareness of a bodily change to perceiving a reason to discuss symptoms with a Health Care Provider (HCP)(Walter *et al*., 2012). They also combined behavioral delay and scheduling delay and reframed it as 'Help-seeking interval'. It is described as the time interval from perceiving a reason to discuss symptoms with an HCP to the first consultation with an HCP about these symptoms(Walter *et al*., 2012). They described 'diagnostic interval' as the time between the first appointment with an HCP and the formal cancer diagnosis being made(Walter *et al*., 2012). Two important aspects of the new model are the greater clarity in the definition of various time intervals and the use of the term 'time interval' instead of 'delay' as the latter is more value-laden.

The recent WHO guide on early cancer diagnosis also insists on the use of 'time interval' instead of 'delay'(World Health Organization, 2017). The steps in early cancer diagnosis as per the model suggested by the WHO guide include Awareness and accessing care (patient interval), Clinical evaluation, diagnosis and staging (diagnostic interval), and access to treatment (treatment interval) (World Health Organization, 2017). The guide further suggests completing these three steps within 90 days to minimize the delay(World Health Organization, 2007). The WHO model has combined the appraisal interval and help-seeking interval of Walter's model to form patient interval but they have a similar definition for the diagnostic interval(Walter *et al*., 2012; World Health Organization, 2017).

2.6.1: Patient interval and diagnostic interval

The delay theories described above help in identifying the various events in the diagnostic journey of cancer. Two key events that can influence the length of the diagnostic journey as informed from these theories were patient interval and

diagnostic interval. Earlier these intervals were known as patient delay and diagnostic delay.

'Patient interval' is the period between the symptom recognition by the patient and the first consultation with a health care provider for evaluating the same(Walter *et al*., 2012; World Health Organization, 2017). A period of 3 months is considered an acceptable interval(Pack and Gallo, 1938).

'Diagnostic interval' is the period between the first appointment with a Health care provider for evaluating the symptom and the histopathological cancer diagnosis(Walter *et al*., 2012). A period of one month is considered an acceptable interval(Allison *et al*., 1998b; Fortin *et al*., 2002).

2.7: 'Aarhus statement' on early cancer diagnosis research

A greater understanding of the pre-diagnostic routes to a cancer diagnosis is essential for planning and implementing cancer control activities(Coxon *et al*., 2018). Unfortunately, most of the studies in early cancer diagnosis were marred by methodological inconsistencies making it difficult for comparisons and interpretations(Andersen *et al*., 2009; Weller *et al*., 2012). As a result of this, a consensus-working group was formed for evaluating existing research in this field and producing checklists and guidelines to guide early diagnosis researchers(Weller *et al*., 2012). The guideline put forwarded by them is known as the Aarhus statement. They concluded that 1) there is little consistency in the definitions and measurements of key time points and intervals, 2) There is little guidance for researchers in designing studies that require the measurement of diagnostic time points and intervals, 3) Little work in this field explicitly uses a theoretical framework to underpin definitions and measurements, 4) There is a lack of transparency and precision over methods and instruments in early diagnosis research. In addition, important study elements such as instrument development are poorly described(Weller *et al*., 2012). The Aarhus statement has given unambiguous definitions for 'date of the first symptom', 'date of the first presentation', 'date of referral', and 'date of diagnosis'(Weller *et al*., 2012). It also advises against the use of the term 'delay' in terminologies and suggests replacing it with the term 'interval'. it has also given recommendations regarding

methodological approaches like primary data collection from patients and or providers, case note audit, and primary care database audit(Weller *et al*., 2012). A 20-item checklist was also prepared for research involving the description and measurement of intervals in the cancer diagnostic journey. It is for promoting greater transparency and consistency in methods and measurements(Weller *et al*., 2012).

Multifarious study designs and summary measures were used in the articles published in the post-Aarhus period echoing similarities with the observations that lead to the preparation of the Aarhus Statement(Akram *et al*., 2014; Alahapperuma and Fernando, 2017; Andersen *et al*., 2009; Baishya *et al*., 2015; Esmaelbeigi *et al*., 2014; Joshi *et al*., 2014; Kerdpon *et al*., 2018; Naseer *et al*., 2016; Weller *et al*., 2012). These studies also failed to replace the term "delay" with "interval." Articles reported patient interval duration in days or weeks or months and were summarized using mean, median, or proportion. Another important measure used was arbitrary periods like "more than 3 months", "less than 1 month", "1- 3 months" etc. The only measure of dispersion reported in these studies was range. Cohort, cross-sectional, qualitative, and case-control study designs were used for conducting early diagnosis studies.

2.8: Patient Interval and Diagnostic interval in oral cancer

A systematic literature search was done in PubMed and Google Scholar using the search words "Oral cancer", "Patient interval", "Diagnostic interval", "Patient delay", "Diagnostic delay", "Professional delay", Doctor delay", "Provider delay" and "Presentation delay". Articles reporting patient interval duration or diagnostic interval duration or associated factors were included in the review. The final review included 27 articles. Four studies were from India and none of them from Kerala(Akram *et al*., 2014; Allison *et al*., 1998b; Baishya *et al*., 2015; Brouha *et al*., 2005; Crossman *et al*., 2016; Diz Dios *et al*., 2005; Esmaelbeigi *et al*., 2014; Friedrich, 2010; Gómez *et al*., 2009, 2009; Guggenheimer *et al*., 1989; Hollows *et al*., 2000; Jovanovic *et al*., 1992; Kerdpon and Sriplung, 2001; Kolude *et al*., 2013; Lee, 2011; Carrie D. Llewellyn *et al*., 2004; Morelatto *et al*., 2007; Onizawa *et al*., 2003; Peacock *et al*., 2008; Sandeep *et al*., 2000; Scott *et al*., 2008; Scott *et al*., 2006; Wildt *et al*., 1995).

2.8.1: Patient interval duration in oral cancer

The patient interval duration was reported as mean, median, range, and proportion of predefined interval duration. Table 2.1 gives a detailed description of patient interval duration reported in the reviewed articles. A study from Germany reported the highest patient interval duration of 187 days (6.26 months) (Friedrich, 2010), and the lowest was reported from Iran, 57.6 days(Esmaelbeigi *et al*., 2014). A study from the United States of America reported the highest median patient interval of 126 days and the longest patient interval of 731days(Peacock *et al*., 2008). An Indian study reported the maximum proportion of patients with a patient interval of more than three months(Akram *et al*., 2014). Apart from the choice of summary measures, articles also varied in their choice of unit of time for reporting the same, making comparisons difficult.

Table 2.1: Patient interval duration reported in the reviewed articles

S/n	Author & Country	Summary measures			
		Mean	Median	Range	Percentage
1	(Akram *et al.*, 2014) India				> 3 months: 60%
2	(Allison *et al.*, 1998a) Canada				< 1 month: 36.7% 1- 3 months: 25.0% >3 months: 25.0% "No symptom": 13.3%
3	(Esmaelbeigi *et al.*, 2014) Iran	57.6 days	45 days	0-354 days	
4	(Friedrich, 2010) Germany	6.26 months		.5-103 months	
5	(Hollows *et al.*, 2000) England	22.5 weeks			<4 Weeks: 39% > 3 months: 29%
6	(Jovanovic *et al.*, 1992) Netherland	103 days	35 days		
7	(Kolude *et al.*, 2013) Nigeria				65% of total interval
8	(Lee *et al.*, 2011) Malaysia	3.8 months		2 day - 2 year	
9	(Baishya *et al.*, 2015), India		90 days	7-365 days	
10	(Morelatto *et al.*, 2007) Argentina				>30 days :58%
11	(Peacock *et al.*, 2008) United States of America	104 days	129 days	0-730 days	
12	(Diz *et al.*, 2005), Spain				2 month: >66.67%
13	(Guggenheimer *et al.*, 1989) United States of America	17 weeks			
14	(Kerdpon and Sriplung, 2001) Thailand	90.6 days		0-720 days	
15	(Llewellyn *et al.*, 2004) England	9.81 weeks	5 weeks	1-104 weeks	
16	(Onizawa *et al.*, 2003) Japan		1.6 months	0-60 days	
17	(S. e. Scott *et al.*, 2006) England	11 weeks	3 weeks	1-48 weeks	
18	(Scott *et al.*, 2008) England	71.2 days	35 days		
19	(Wildt *et al.*, 1995) Denmark	106 days	71days		
20	(Joshi *et al.*, 2014) India	2.75 months			
21	(Kerdpon *et al.*, 2018)Thailand	100days	30days	0-1095 days	
22	(Naseer *et al.*, 2016) Pakistan				4 to 6 months: 42.7%
23	(Panzarella *et al.*, 2014) Italy				<1 month : 35.26% 1to3months:32.69% >3 months: 32.05%
24	(Rath *et al.*, 2018) India		30 days	4-500 days	
25	(Alahapperuma and Fernando, 2017) Sri Lanka				> 3 months: 19%

2.8.2: Factors affecting patient interval in oral cancer

Socio-demographic factors were frequently assessed for their association with patient interval whereas the association of psychosocial characteristics, health-seeking behaviors, symptom awareness, and appraisal-related factors with patient interval were rarely reported in the literature. Studies report an association of patient interval with age(Akram *et al*., 2014; Panzarella *et al*., 2014), low socioeconomic status(Akram *et al*., 2014; Scott *et al*., 2008), rural residence(Akram *et al*., 2014), an education level(Alahapperuma and Fernando, 2017; Baishya *et al*., 2015; Llewellyn *et al*., 2004), occupation(Kerdpon *et al*., 2018)and personal experience of cancer(Panzarella *et al*., 2014) (Table 2.2). Interestingly, there are studies which did not find any association between Gender (Akram *et al*., 2014; Baishya *et al*., 2015; Guggenheimer *et al*., 1989; Jovanovic *et al*., 1992; Kerdpon and Sriplung,2001), place of residence(Baishya *et al*., 2015; Kerdpon and Sriplung, 2001), marital status(Akram *et al*., 2014; Kerdpon and Sriplung, 2001), age(Guggenheimer *et al*., 1989; Kerdpon and Sriplung, 2001), education(Guggenheimer *et al*., 1989), religion, (Kerdpon and Sriplung, 2001), and occupation(Kerdpon and Sriplung, 2001) with patient interval. These contradictory observations on the association of various socio-demographic characteristics with the patient interval from different studies across the globe necessitate further studies.

Psychosocial characteristics like ‘Attribution of the symptom as minor’(Akram *et al*., 2014; Sandeep *et al*., 2000; Scott *et al*., 2008), ‘Absence of fear’(Akram *et al*., 2014), beliefs like ‘Ill-fated to have cancer', 'Cancer a curse', 'Prolonged Treatment renders family stressful'(Sandeep *et al*., 2000), and ‘Perceived ability to seek help for oral symptoms’(Scott *et al*., 2008) were associated with the patient interval in oral cancer. Motivation, disclosure to others (Akram *et al*., 2014), denial, and fear (Panzarella *et al*., 2014) were found to be not associated with patient interval. Health seeking behavior like the use of alternative therapy(Akram *et al*., 2014; Kerdpon and Sriplung, 2001) was associated with the patient interval in oral cancer whereas some other studies did not find any association between factors like frequency of dental visits, Regular visit to a doctor in the past 12 years, Domestic remedies/medicine before consulting a doctor(Sandeep *et al*., 2000), herbal medication (Kerdpon *et al*.,

2018) and patient interval. Disease factors like Tumor size, Lymph node metastasis, TNM stage(Kerdpon and Sriplung, 2001), Dental status, Tumor site(Jovanovic *et al*., 1992), Factors related to medical history, Oral hygiene were not associated with patient interval. Habit-related factors like tobacco use, betel quid chewing and alcohol consumption was also evaluated for identifying possible association but didn't find any(Kerdpon and Sriplung, 2001; Onizawa *et al*., 2003; Panzarella *et al*., 2014).

Table 2.2: Factors affecting patient interval in oral cancer

S/n	Country and Author	Factors associated with patient interval
1	India (Akram *et al*., 2014)	*Socio-demographic:* Older age, Low SES, Rural residence, Insufficient knowledge on H&N cancer *Psychosocial:* Attribution of the symptom as minor, Absence of fear, Use of alternate therapy
2	India (Baishya *et al*., 2015)	Education Awareness from TV programs
3	India (Sandeep *et al*., 2000)	Ill-fated to have cancer', 'Cancer a curse', 'Non-availability of transport', 'Trivial ulcers in the mouth are self-limiting, 'Prolonged Treatment renders family stressful'
4	Thailand (Kerdpon and Sriplung, 2001)	Traditional herbal medication
5	England (Llewellyn *et al*., 2004)	Lack of further education Perceptions of being under stress in the period prior to diagnosis Lower amounts of tobacco smoked per day.
6	England (Scott *et al*., 2008)	The gravity of patients initial symptom interpretation, The level of deprivation, Knowledge of oral cancer, Severity of life events in the patient delay period, Perceived ability to seek help for oral symptoms
7	Thailand (Kerdpon *et al*., 2018)	Education Occupation as Farmer
8	Italy (Panzarella *et al*., 2014)	Age, Personal experience of cancer, Knowledge of cancer, Unawareness
9	Sri Lanka (Alahapperuma and Fernando, 2017)	Level of education, Cost of traveling to the health facility

A qualitative inquiry for exploring the determinants of care-seeking behavior of oral cancer patients in India identified the following determinants. They include the 'Hope for the lesion to heal spontaneously', 'Patients perception of seriousness', 'Pain in the

lesion', 'Awareness regarding the sign and symptoms, 'Attitude towards oral lesions', 'Family and social pressure ', 'Fear of oral cancer', 'Finance', 'Perception about health care systems', 'Distance from hospitals' and 'Ignorance' (Rath *et al*., 2018). Another qualitative study from the United Kingdom identified the following determinants in addition to the above observation, they include 'Symptom interpretation', 'Expectations of simple diagnosis and recovery', 'Failure to attribute symptoms to cancer', and 'Self- treatment'(Scott *et al*., 2006). The studies which assessed the association of socio-demographic or psychosocial or disease-related factors or health-seeking behaviors differ from one another in their findings. The lack of uniformity in the study findings limits its use in designing early diagnosis interventions.

2.8.3: Diagnostic interval in oral cancer diagnosis

In the reviewed articles, the diagnostic interval was reported as mean, median, or a proportion of patients having a diagnostic interval of 1 month or three months. The highest diagnostic interval of 20 weeks (140days) was reported from a study from the United States conducted in 1989(Guggenheimer *et al*., 1989). The lowest mean and median diagnostic interval was reported from the Netherlands, 22 days and 11 days respectively(Jovanovic *et al*., 1992). Out of the 27 studies reviewed, only nine reported the diagnostic interval duration in their studies indicating a paucity of studies in oral cancer diagnostic interval duration (Table 2.3). A fundamental issue in comparing studies reporting diagnostic interval duration is the heterogeneity in the term as well as the definition used to measure that interval. Diagnostic delay, provider delay, professional delay, doctor delay were the terms frequently used to define the diagnostic interval. The interval also had different starting and completion time points. They include Time from symptom recognition to definitive diagnosis, time from first consultation to specialist referral, and time from first consultation to treatment initiation.

Table 2.3: Diagnostic interval duration reported in the reviewed articles

S/n	Country and Author	Mean	Median	3 month interval	1 month interval
1	Canada (Allison *et al*., 1998a)		2 month	14.9%	
2	Iran (Esmaelbeigi *et al*., 2014)	86 days	98.2		
3	Netherlands (Jovanovic *et al*., 1992)	22days	11 days		
4	Malaysia (Lee *et al*., 2011)	8.4 weeks			
5	Argentina (Morelatto *et al*., 2007)				64%
6	USA (Peacock *et al*., 2008)	36 days			
7	USA (Guggenheimer *et al*., 1989)	20 weeks			
8	Thailand (Kerdpon and Sriplung, 2001)	51.2 days			
9	Denmark (Wildt *et al*., 1995)	45 days	18 days		

2.8.4: Factors contributing to diagnostic interval in oral cancer

The association of diagnostic interval and various factors contributing to it were less investigated. A study from Iran assessed various factors determining the interval from the first consultation to initiation of treatment and found that patients education level, erroneous initial interventions, number of health care providers consulted before the initiation of treatment, and presence of loose teeth were found to be the significant predictors(Esmaelbeigi *et al*., 2014). Those patients who were suggested dental treatment or prescribed analgesics or other medicines were more likely to have increased diagnostic interval than those who were advised for endoscopy or biopsy. Association 'Adopting biopsy at the first clinical management' with diagnostic

interval was also reported in another study(Gao and Guo, 2009). Multiple visits to health care facilities for diagnosis and initiation of treatment were associated with increased patient interval(Esmaelbeigi *et al*., 2014; Gao and Guo, 2009; Onizawa *et al*., 2003).

A study from the Netherlands did not find any association between the type of health care provider first visited (dentists and physicians.), age, gender, and dental status of the patient with diagnostic interval (Jovanovic *et al*., 1992). Inaccurate clinical assessment at the point of entry in the health care system, poor connectivity of the primary institution with other higher institutions, primary provider's lack of skill in undertaking necessary clinical examinations, lack of time for evaluating cancer symptoms, inaccessibility of diagnostic service, lack of availability of diagnostic services, break-in follow-ups, lack of referral pathways, availability of health services were not assessed in the reviewed article even though these were listed as barriers for early diagnosis in the WHO guide for early cancer diagnosis(World Health Organization, 2017).

2.9: Patient interval and diagnostic interval in common cancers other than oral cancers

A literature search was done in Pub Med using the following keywords -"cancer", "delay in diagnosis", "delay in the presentation ", "delay in referral", "delay in reporting", " patient delay", "professional delay", "system delay", "delay in seeking care", "Provider delay", "Patient interval", "diagnostic interval" and 157 articles were identified. Based on inclusion-exclusion criteria, 43 articles were included in the final review. Articles reporting patient interval, diagnostic interval, and the contributing factors were only included. Those articles reporting patient interval and diagnostic interval in oral cancer were not included. Articles on barriers to cancer screening were excluded.

2.9.1: Patient and diagnostic interval duration in cancers other than oral cancer

A study on breast cancer diagnosis from Nigeria reported the longest mean patient interval of 12.12 months (364days) and the highest proportion of patients (81.6%) having more than three months patient interval (Ibrahim and Oludara, 2012). The highest median patient interval of 180 days was reported in an Indian study(Thakur *et al*., 2015) on breast cancer and the lowest was reported from a lung cancer study from Finland(Salomaa *et al*., 2005). A Swedish study on lung cancer reported the lowest median diagnostic interval of eight days (Koyi *et al*., 2002), and the longest mean diagnostic interval of 105 days was reported from a US study on breast cancer(Bourdeanu *et al*., 2013). From the review, it was found that patient interval and diagnostic interval did not show any discernible pattern across cancer types or countries (Table 2.4).

Both patient interval and diagnostic interval vary from study to study, necessitating geographical area-specific and cancer-type-specific research in early cancer diagnosis.

Table 2.4: Patient and Diagnostic interval duration in cancers other than oral cancer

S/n	Author/ Country/ Cancer type	Patient interval	Diagnostic interval
1	(A. M. Abu-Helalah *et al*., 2016), Jordan, Breast cancer	≥3 months: 32.2 % Mean: 201.1 days Median: of 30.0 days	≥1 month: 49.1% Mean: 97.5 days Median: 23.5 days
2	(Ibrahim and Oludara, 2012) , Nigeria, Breast cancer	≥3 month: 81.6% Mean :12.12 months	
3	(Bourdeanu *et al*., 2013) , USA, Breast cancer	Median: 12 week	Median: 15 week
4	(Ezeome, 2010) ,Nigeria Breast cancer	≥3 months: 45.3%	
5	(Gullatte *et al*., 2010) , USA, Breast cancer	Median: 5.5 months	
6	(Jassem *et al*., 2014), 11 European countries, Breast cancer	Mean: 4.7 weeks	
7	(Memon *et al*., 2013) Pakistan Breast cancer	Mean: 5.13±4.8 months,	
8	(Mohd Mujar *et al*., 2017), Malaysia, Breast cancer	≥3 month: 35% Median: 2.4 months	≥1 month: 41.8 % Median: 26 days
9	(Thakur *et al*., 2015), India Breast cancer	Median:6 months	
10	(M. A. Abu-Helalah *et al*., 2016), Jordan, Colorectal cancer	≥3 month: 33.9 %	≥1 month: 68.1%
11	(Koyi *et al*., 2002), Sweden Lung cancer	Mean: 43 days Median : 21days	Mean: 33 days Median: 9 days
12	(Salomaa *et al*., 2005), Finland Lung cancer	Median: 14 days	Median: 15 days
13	(Bowen and Rayner, 2002) England , Lung cancer	Mean: 3.2weeks	Mean: 10.5 weeks
14	(Ramachandran *et al*., 2016), India, Lung cancer	Mean; 5.8 months	
15	(Bjerager *et al*., 2006), England Lung cancer		Median: 11 days
16	(Fernández de la Vega *et al*., 2015), Cuba, Lung cancer	Mean: 24.3 days	Mean: 16.2 days

2.9.2: Factors contributing to the patient interval in cancers other than oral cancer

The following socio-demographic factors were found to be associated with patient interval cancer. They include Age (Gullatte *et al*., 2009; Hafström *et al*., 2011; Jassem *et al*., 2014; Memon *et al*., 2013; Yu *et al*., 2015) , Gender (A. M. Abu-Helalah *et al*., 2016; Chandra *et al*., 2009; Gullatte *et al*., 2009; Hafström *et al*., 2011; Jassem *et al*., 2014; Memon *et al*., 2013; Stuver *et al*., 2011; Thakur *et al*., 2015; Yu *et al*., 2015), Marital status(M. A. Abu-Helalah *et al*., 2016; Hafström *et al*., 2011; Jassem *et al*., 2014; Memon *et al*., 2013; Stuver *et al*., 2011; Thakur *et al*., 2015; Yu *et al*., 2015), Residential status(Chandra *et al*., 2009; Hafström *et al*., 2011; Jassem *et al*., 2014; Thakur *et al*., 2015), Religion(Hafström *et al*., 2011), Socioeconomic status(Jassem *et al*., 2014; Marlow *et al*., 2014), Education(Gullatte *et al*., 2009; Memon *et al*., 2013; Thakur *et al*., 2015), Ethnicity(Jassem *et al*., 2014; Memon *et al*., 2013), and Occupation(Hafström *et al*., 2011; Yu *et al*., 2015).

Habit related factors associated with patient interval include Cigarette smoking(Hafström *et al*., 2011; Memon *et al*., 2013; Thakur *et al*., 2015; Yu *et al*., 2015), Alcohol use(Gullatte *et al*., 2009; Hafström *et al*., 2011; Memon *et al*., 2013; Thakur *et al*., 2015; Yu *et al*., 2015), betel quid use(Hafström *et al*., 2011) and Knowledge of tobacco causes cancer(Marlow *et al*., 2014).

Healthcare-related factors associated with patient interval include regular medical consultation(Marlow *et al*., 2014), Consulting for early detection(Marlow *et al*., 2014), Use of alternate therapy(M. A. Abu-Helalah *et al*., 2016), and distance from a health facility (Hafström *et al*., 2011; Yu *et al*., 2015).

Psychosocial factors associated with patient interval include Attribution of the symptom as minor(M. A. Abu-Helalah *et al*., 2016), Absence of fear(M. A. Abu-Helalah *et al*., 2016), Negative thoughts on cancer(Marlow *et al*., 2014), Perceptions of being under stress in the period before diagnosis(Jassem *et al*., 2014), and Severity of life events in the patient interval period(Memon *et al*., 2013).

Disease factors associated with patient interval include Tumor site(Hafström *et al*., 2011; Stuver *et al*., 2011), Tumor size(Hafström *et al*., 2011; Stuver *et al*., 2011), comorbid conditions(Chandra *et al*., 2009), TNM stage(Hafström *et al*., 2011), Lymph node metastasis(Hafström *et al*., 2011), Initial sign or symptom(Hafström *et al*., 2011; Jassem *et al*., 2014), medical history(Jassem *et al*., 2014), Experience of symptoms(Thakur *et al*., 2015) and Initial self-diagnosis(Thakur *et al*., 2015).

2.9.3: Factors associated with the diagnostic interval in cancers other than oral cancer

Factors associated with diagnostic interval reported in the reviewed articles were largely related to the health care system. Misdiagnosis(A. M. Abu-Helalah *et al*., 2016; Mitchell *et al*., 2008) or incompetence(Yu *et al*., 2015) or low index of suspicion(Ramachandran *et al*., 2016) or dismissal of symptom(Bourdeanu *et al*., 2013; Cerdán-Santacruz *et al*., 2011; George *et al*., 2015; Koyi *et al*., 2002) by the primary care provider were reported as reasons for the increased diagnostic delay. Inadequate investigations(George *et al*., 2015; Hafström *et al*., 2011; Mitchell *et al*., 2008) or misinterpretation of findings(Hafström *et al*., 2011) or reluctance for investigations (Mitchell *et al*., 2008) like not suggesting a biopsy (Bourdeanu *et al*., 2013) also associated with increased diagnostic interval. Health care provider's reluctance or inability due to busy schedules for performing physical examinations were cited as reasons for diagnostic delay in colorectal cancer studies(Carter and Winslet, 1998; Esteva *et al*., 2013). Inappropriate, delayed or less specific referral from primary care was reported in studies as contributing to diagnostic delay (Carter and Winslet, 1998; S. Damery *et al*., 2011; Koyi *et al*., 2002; Oberoi *et al*., 2016). One study reported diagnosis by an oncologist over a general physician shortens diagnostic interval(Jassem *et al*., 2014). Health system weakness(Yu *et al*., 2015), distrust in the health care system(Jassem *et al*., 2014), lack of proper communication by the provider(Yu *et al*., 2015), long waiting period(Oberoi *et al*., 2016; Walton *et al*., 2013), and scheduling delay (George *et al*., 2015; Yu *et al*., 2015) were the other health system factors associated with diagnostic interval. Some patient-related factors were also implicated in the diagnostic interval like age, education, family history(Jassem *et al*., 2014), comorbidity, and socioeconomic status(Mitchell *et al*.,

2008). Long patient intervals(Jassem *et al*., 2014) and lack of adherence to follow-up instructions(Lim *et al*., 2014) were also identified as contributors to the increased diagnostic interval.

2.10: Measurement of patient and diagnostic intervals

Research in early cancer diagnosis was primarily focused on quantifying intervals like patient interval, diagnostic interval, total interval, etc., and also to explore the various factors related to these intervals. The published literature lacks methodological data on data collection instruments development and validation and was not available for use by other researchers(Weller *et al*., 2012). Several methods have been used to extract data on various time points used to measure the patient and diagnostic intervals which were often dictated by available data and resources(Weller *et al*., 2012). There were no validated instruments for measuring the time intervals in the diagnostic journey of cancer until Neal *et al* developed the Cancer Symptom Interval Measure (C-SIM) in 2014(Neal *et al*., 2014). The tool developed and validated by the Neal *et al* was useful in collecting patient-reported data pertaining to appraisal interval, help-seeking interval, and diagnostic interval. The final tool had 11 versions for measuring various intervals in the cancer diagnostic pathway of 11 cancers (lung, colorectal, breast, pancreatic, gastric/oesophageal, renal/bladder, endometrial/cervical, hematological, ovarian, prostate, and testicular cancers) (Neal *et al*., 2014). Unfortunately, Oral cancer was not included in any of the versions of the C-SIM tool(Neal *et al*., 2014). Similarly, validated questionnaires were not available for identifying various factors contributing to the patient interval in oral cancer. Those articles describing factors contributing to the patient interval in oral cancer did not elaborate on instrument development and also not shared the instrument for use by other researchers.

2.11: Rationale for the study

The paucity of studies on various time intervals and its determinants in the diagnostic journey of oral cancer from Kerala and India limit our capacity to develop oral cancer control strategies effectively. An international consensus working group (CWG) on early cancer research has observed the following challenges: (a) early diagnosis

research is characterized by its complexity, (b) poorly developed set of definitions and methodological tools are only available, (c) lack of transparency in disciplinary perspectives and (d) absence of a widely-accepted underlying theoretical model(Weller *et al*., 2012). The above-mentioned challenges are relevant in the present context of early oral cancer diagnosis research and there are also additional challenges that are specific to oral cancer.

The first and foremost challenge in early cancer diagnosis research is the heterogeneity of definitions and terminologies used to describe patient interval and diagnostic interval making it difficult to assess the extent of the problem. This has also made comparisons across studies difficult(Seoane *et al*., 2016; Weller *et al*., 2012). The methodological inconsistencies in the early cancer diagnosis research were previously reported in the literature(Neal *et al*., 2008). The definition of diagnostic interval often overlaps with that of patient interval or treatment interval in many studies. This may be attributed to the limited use of theoretical frameworks in the definitions and measurement of various time points and intervals in the diagnostic journey(Weller *et al*., 2012). The CWG further noted that there exists a "lack of transparency and precision over the methods and instruments used in early diagnosis research"(Weller *et al*., 2012). After the appraisal of the existing early cancer diagnosis research, the CWG developed the Aarhus statement consisting of definitions and recommendations for early diagnosis research in cancer(Weller *et al*., 2012).

A systematic review and meta-analysis conducted on Aarhus statement perspective of early oral cancer diagnosis have found limited fulfilment of Aarhus checklist in the reviewed articles, particularly on measurement of intervals and lack of use of a validated instrument for measurement(Seoane *et al*., 2016). The lack of validated tools for measurement of delay in cancer was previously reported(Neal *et al*., 2008). Recently, a tool was developed and validated for measuring various intervals in the diagnostic journey of 11 types of cancers(Neal *et al*., 2014). Unfortunately, it did not include oral cavity cancers and necessitates the development of a validated tool for measuring various time intervals in the diagnostic journey of oral cancer. The choice of research design in early cancer diagnosis research is important as social and

behavioral aspects need to be assessed and explored. Sequential explanatory study designs are used for the comprehensive understanding of the research problem as a quantitative design alone may not provide the patient-centered or community-centered perspective of the problem(O'Cathain *et al*., 2007). Qualitative methods help in understanding human behaviors and comprehending social realities(Kaur, 2016). Explanatory design is the most frequently used mixed methodology design in health service research(O'Cathain *et al*., 2007). The sequential explanatory design, where quantitative results are explained with qualitative findings, is popular in health research(Kaur, 2016). The perspective of patients, health care providers, community leaders, and health system administrators on oral cancer early diagnosis is necessary for the comprehensive understanding of the problem. Documents pertaining to cancer policy in the state will contribute to our understanding of the early oral cancer diagnosis in our state.

MATERIALS AND METHODS

Chapter 3

Materials and Methods

3.1: Study design

We used a sequential explanatory design for the study. This sequential explanatory study was conducted in three phases. In the sequential explanatory design, quantitative data is collected before the collection of qualitative data. In this design, precedence is given to the primary quantitative study. Qualitative data is usually used to explain and interpret the findings of the primary quantitative study. The visual model for the sequential explanatory design is given below (Figure 3.1).

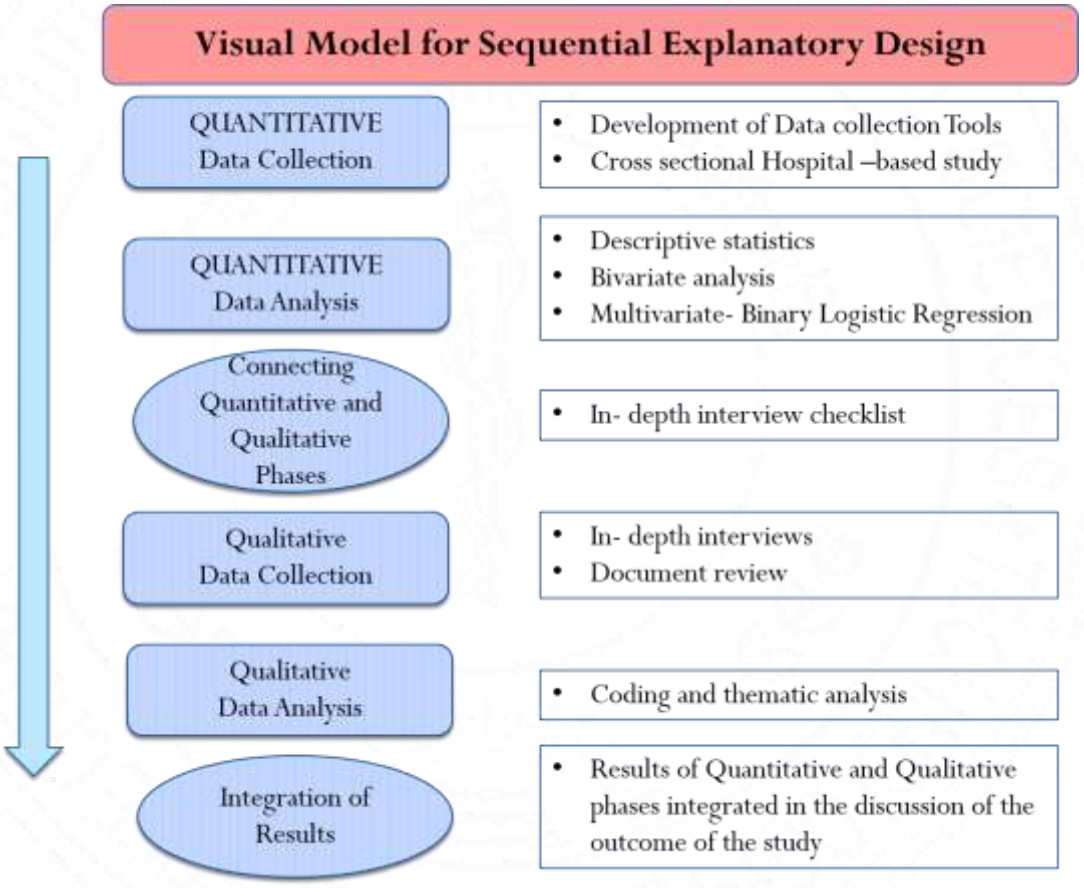


Figure 3.1: Visual Model for Sequential Explanatory Design

3.2: Phases of study

This sequential explanatory study was conducted in three phases. In the first phase, data collection instruments for the quantitative study were developed and validated. In the second phase, the hospital-based cross-sectional study was conducted. In the third and final phase, qualitative data were collected using in-depth interviews and cancer policy-related document reviews.

Phase 1: Development and validation of data collection instruments

Based on the study objectives, two instruments were needed for collecting quantitative data. One instrument is for the purpose of capturing the time intervals such as patient interval and diagnostic interval and the second instrument is to collect information on the associated factors for the patient interval among the oral cancer patients.

For the development of the instruments, number of steps were followed. At the outset, the principal investigator reviewed the literature related to the available instruments for the patient interval. Based on the review, draft instruments were developed and shared with the subject experts. After discussion with the experts, the researcher iterated the tool. Then, the content was validated with the help of the experts (Refer Section 3.5.1.2). After the validation, it was translated from English to Malayalam and the instrument was finalized with the minimum errors in translation. Then the researcher performed face validity by sharing with the potential participants and others.

An interview schedule for capturing the intervals and a questionnaire for identifying the factors were developed following the above steps. The instruments were submitted exclusively for the Technical Advisory Committee and Institutional Ethics Committee for review and obtained approval. The duration of instrument development was 5 months.

Phase 2: Hospital-based cross-sectional study

The hospital-based cross-sectional study was conducted at a Tertiary Cancer Centre in Northern Kerala. The study was conducted using the developed instruments. Through the cross-sectional survey, we were able to measure the patient interval, diagnostic interval, and the associated factors. Phase two was the lengthiest phase in the entire study. Data was collected from 261 oral cancer patients through one-to-one interviews in the study setting. The duration of data collection was 9 months.

Phase 3: In-Depth Interviews and Document Reviews

The qualitative component of the study consisted of in-depth interviews and document reviews. In-depth interview checklists were prepared based on the preliminary findings from the primary quantitative study. The In-depth interview checklists were submitted exclusively for the Technical Advisory Committee and Institutional Ethics Committee for review and obtained approval. In-depth interviews were conducted with the Patients, Health Care Providers, Community Leaders, and Administrators. A checklist was also prepared for reviewing the documents related to oral cancer control in the state. Documents were reviewed to map the structure and function of oral cancer control in Kerala. Government documents related to oral cancer prevention and control were collected and reviewed based on the document review checklist. Duration of data collection was 4 months.

3.3: Organization of phases of the study

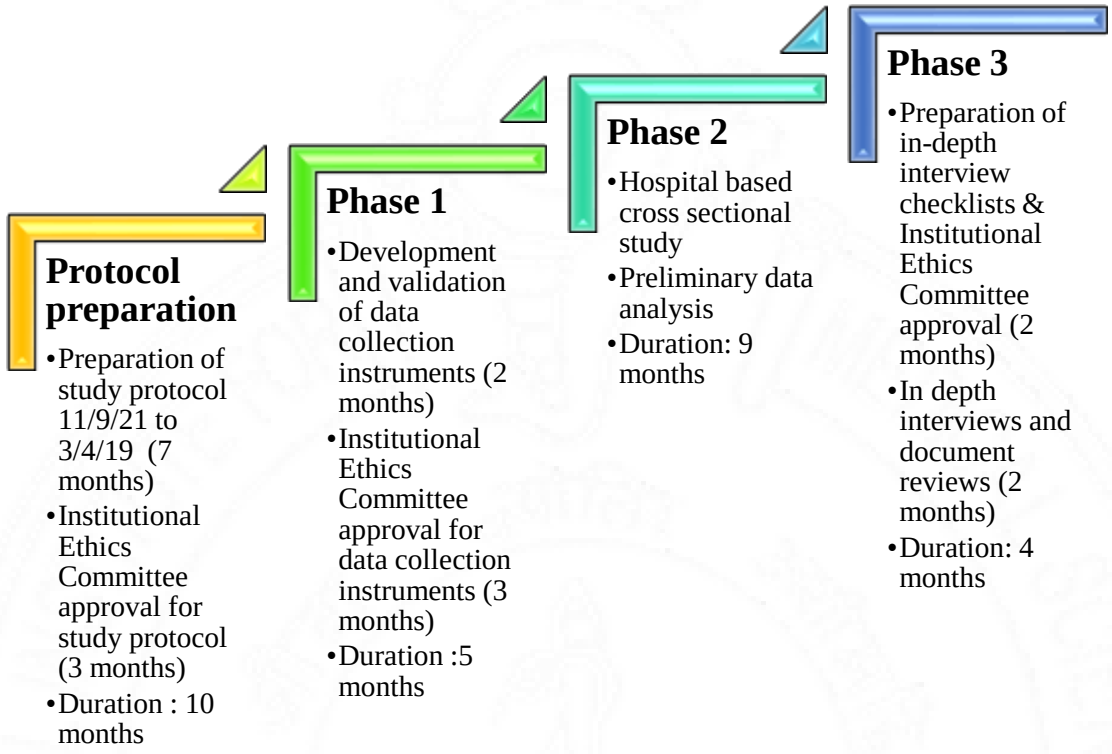


Figure 3.2: The organization phases of the study

3.4: Study setting

The study was conducted at a Comprehensive Cancer Centre in northern Kerala. The center is an autonomous tertiary cancer center under the Government of Kerala, providing a complete spectrum of cancer care to seven northern districts of Kerala and adjoining districts of Karnataka, Tamil Nadu, and Union Territory of Puducherry. Around 30 to 40 new cancer cases and 400 to 500 patients on follow-up and treatment reports at the institution every day. The majority of the patients registered for treatment at the center get financial assistance for their treatment through various government schemes. The institution has state-of-the-art facilities for cancer diagnosis, treatment, and rehabilitation. The institution has a hospital-based cancer registry (HBCR) and a Malabar Population-based cancer registry (PBCR). The PBCR collects information from Kannur, Kasaragod, and Mahe districts. The published

PBCR and HBCR report for the year 2014 show 405 and 456 oral cancer patients respectively. The marginal increase in oral cancer cases reported in the HBCR can be attributed to the wider catchment area of the hospital than the PBCR. Patients seeking treatment for oral cancer were identified from the head and neck OPD of the hospital and were interviewed during one of the subsequent visits before completion of their treatment. Interviews were conducted from those who registered for treatment at the hospital three months prior to the data collection. The participants for in-depth interviews of health care providers were identified from the Kerala health services. The participants for in-depth interviews with community leaders were identified from various non-governmental organizations and local self-governing institutions in the Kannur district. The participants for in-depth interviews with administrators in the health sector were identified from Tertiary Cancer Centers and the Directorate of Health Services in Kerala.

3.5: Development and validation of data collection instruments

3.5.1: Questionnaire to assess the factors contributing to Patient Interval in Oral Cancer: The PIOC Questionnaire

***3.5.1.1: Literature review and development of an inventory*:** The current literature was searched primarily for identifying tools for assessing various factors determining patient interval in oral cancer. The second objective of the literature search was to list out the various factors explored by other researchers as a possible determinant of patient interval in oral cancer. The literature search used the following keywords: "Mouth neoplasms", "oral cancer", "patient interval", "patient delay", and "presentation delay". These keywords were used in various combinations using Boolean operations "AND" and "OR". Zotero reference management software was used for removing duplicates. The PubMed search could not find any existing validated questionnaire for assessing the various factors that affect patient interval in oral cancer. The absence of a validated questionnaire for identifying the various factors contributing to the patient interval in oral cancer necessitated developing a new validated tool. The list of variables identified through the literature review was published elsewhere(Philip and Kannan, 2019). An inventory was developed largely

based on those findings. In addition, questionnaires retrieved through personal communications with authors of the identified articles also helped in developing the inventory (Haresaku *et al*., 2018; Pavão Spaulonci *et al*., 2018; Scott *et al*., 2009). The barriers to the help-seeking section of the inventory were largely derived from the Cancer awareness measures toolkit version 2 developed by cancer research UK (The Cancer Awareness Measures (CAM), 2014). The inventory comprised of seven components, namely, socio-demographic factors, society and family-related factors, habit-related factors, accessibility and availability-related factors, health-seeking behaviour related factors, barriers to help-seeking, and financial and treatment schemes. Under these sections, 57 questions were developed.

3.5.1.2:Expert consultation: The first draft of the questionnaire and its response categories developed out of the exercise described in the previous step was discussed with experts in the field of oncology, dentistry, medicine, and public health. Experts from these fields are directly or indirectly involved in the primary and secondary prevention of oral cancer. Dentists and oral medicine specialists diagnose oral health-related problems including oral cancers and pre-cancers. General medicine practitioners and ENT specialists also come across these oral lesions in their regular practice. Oncologists routinely diagnose and manage these lesions. They are also involved in community-based oral cancer prevention activities. Experts in the field of public health have proficiency in various aspects of non-communicable disease prevention. Exploiting the expertise and experience of these experts were inevitable for further development of the questionnaire. Twenty-one experts have given their feedback. They were from surgical oncology (n=2), Medical oncology (n=1), community oncology (n=2), Oral medicine (n=4), ENT (n=2), Public health (n=2), Psycho-oncology (n=2), Dentistry (n=4), and General medicine (n=2). They provided feedback either through face-to-face interactions or through e-mail or telephone. This process helped in identifying factors that were unaddressed in the past or in other studies that are relevant to the present study setting. Experts reviewed the adequacy and inclusiveness of the questionnaire. They also identified the redundant questions. The questionnaire was modified based on the expert comments. At the end some new questions were added, a few existing ones were removed and some were reframed.

Originally the inventory had 57questions distributed among seven components and the modified one had 55 questions with five components after the additions and deletions. Sections include Socio-demographic factors, Habit related factors, General health-seeking behavior, Barriers to health-seeking, and other factors.

3.5.1.3: Content validity: A ten-member expert panel reviewed the questionnaire to validate the content validity. They reviewed each question for its relevance and appropriateness for the study. They also examined the grammar and appropriate usage of language for each of the questions. They were requested to rate each question on a four-point ordinal scale as irrelevant(1), somewhat relevant(2), relevant(3), or very relevant(4) (Zamanzadeh *et al*., 2015).

The Content Validity Index (CVI) is an index that is estimated for each of the questions by computing the proportion of the number of experts who have assigned both three or four points and the total number of experts who have participated. (CVI= No. of experts scored 3 or 4 / total number of experts).

$$CVI = \frac{\text{No. of experts scored 3 or 4}}{\text{Total number of experts}}$$

CVI is the proportion of experts who agrees on the relevance of each item. Those questions that have received a content validity index of 0.8 or more were considered valid. Only valid questions were included in the questionnaire. The panel included experts from Community Oncology (n=3), Oral medicine (n=3), Dentistry (n=2), public health dentistry (n=1) and public health (n=1). The grammar and appropriate usage of language for each of the questions were also implemented based on the comments received from the experts.

3.5.1.4: Translation back translation: A conceptually equivalent version of the questionnaire in Malayalam was also prepared using the back-translation method.

3.5.1.5: Face validity: The Malayalam version of the questionnaire was administered to ten people as cognitive piloting. Participants included oral cancer patients (n=5) and tobacco cessation clinic patients (n=5). They were requested to review the questions and provide suggestions concerning the meaning, clarity, comprehension,

appropriateness of sentence structure, and difficulty for answering. The questionnaire was modified based on the feedback received from the study participants.

***3.5.1.6: Technical Advisory Committee review*:** The Technical Advisory Committee of the institution reviewed the newly developed questionnaire and recommended it for Institutional Ethics Committee for review.

3.5.1.7: Institutional Ethics committee review: The Institutional Ethics Committee reviewed and approved the final questionnaire after following the review procedures (Annexure- A.6).

3.5.2: Development and validation of Interview schedule to measure the patient and Diagnostic interval in oral cancer

3.5.2.1: Literature review and development of an inventory*:* The current literature was searched primarily for identifying tools for capturing patient interval and diagnostic interval in oral cancer. For the literature search following keywords were used: "Mouth neoplasms", "oral cancer", "patient interval", "patient delay", "presentation delay", "diagnostic interval", "diagnostic delay", "provider delay", and "professional delay". These keywords were used in various combinations using Boolean operations "AND" and "OR". Zotero reference management software was used for removing duplicates. The PubMed search could not find any existing tool for estimating the patient interval or diagnostic interval in oral cancer. The absence of a validated tool for estimating patient interval and diagnostic interval in oral cancer necessitated developing a new validated tool. Though the literature search did not fetch any relevant instrument for oral cancer, one validated instrument for measuring various time intervals in the diagnostic journey of 11 types of cancers was identified. The instrument was called as Cancer Symptom Interval Measure (C-SIM) that was developed by Neal *et al* in 2014. The tool was developed and tested for collecting patient-reported data relating to appraisal interval, help-seeking interval, and diagnostic interval in the cancer diagnostic pathway for 11 types of cancers including lung, breast, and colorectal cancers. However, it did not include oral cancer (Neal *et al*., 2014). The C-SIM tool helped in conceiving the inventory for estimating patient and diagnostic interval in oral cancer. The main purpose of the data collection

instrument was to identify three-time points in the diagnostic journey of oral cancer. They include the date of symptom recognition by the patient, the date of presentation of the above symptom at a health care facility, and the date of histopathological diagnosis of cancer. Identification of the date of symptom recognition always remains a challenge because it largely depends on the level of awareness about the symptom and how the patient interprets the symptom. Considering this, all symptoms suggestive of warning signs of oral cancer and oral pre-cancer were listed based on the existing literature. Apart from identifying these time points, the draft tool also had questions for identifying discussion interval and routes to diagnosis. The inventory listed 12 symptoms suggestive of oral cancer /oral pre-cancer and nine other questions to identify routes to diagnosis and other characteristics of help-seeking with respect to the current problem in the oral cavity.

3.5.2.2: Expert consultation: The first draft of the interview schedule and its response categories were developed out of the exercise described in the previous steps was discussed with practitioners in the field of Oncology, Dentistry, and Medicine. Practitioners from these fields are directly involved in the diagnosis and management of oral cancer. The understanding and experience of these practitioners concerning the oral cancer symptoms and management helped in modifying the interview schedule. These discussions also helped to delineate various symptoms reported by the patient when they report the disease condition to a health care provider. Sixteen practitioners (Surgical oncology (n=2), Community oncology (n=2), Oral medicine (n=4), ENT (n=2), Dentistry (n=4), and General medicine (n=2)) gave their feedback. They provided feedback through face-to-face interviews or e-mail or telephone. Experts reviewed the adequacy and inclusiveness of the Interview schedule. They also identified the redundant questions. The Interview schedule was modified based on their comments. In the end some new questions were added, a few existing ones were removed and some were reframed. The modified inventory had 18 symptom response questions and 18 other questions.

***3.5.2.3: Content validity*:** A ten-member expert panel reviewed the interview schedule to assess Content validity. They reviewed each question for its relevance and appropriateness for the study. They also examined the grammar and appropriate usage

of language for each of the questions. They were requested to rate each question on a four-point ordinal scale as irrelevant (1), somewhat relevant (2), relevant (3), or very relevant (4) (Zamanzadeh *et al*., 2015). The content validity index was calculated as described in section ***3.5.1.3.*** Those questions that have received a content validity index of 0.8 or more were only retained in the interview schedule. The panel include experts from Community Oncology (n=3), Oral medicine (n=3), Dentistry (n=2), ENT (n=2). The grammar and appropriate usage of language for each of the questions were also implemented based on the comments received from the experts. The modified interview schedule had 16 symptom response categories and 15 other questions. The symptom response categories were given below (Table 3.1).

Table: 3.1: Symptom response categories in oral cancer

S/n	Sign /Symptom/Change in the oral cavity
1	A non-scrapable white patch or plaque
2	A non-scrapable red patch or plaque
3	A non-healing oral ulcer with pain
4	A non-healing oral ulcer without pain
5	Burning sensation
6	Dryness
7	Inability to take hot or spicy food
8	Restricted mouth opening
9	The difficulty for tongue movements
10	An abnormal growth in the oral cavity without pain
11	An abnormal growth in the oral cavity with pain
12	Difficulty in swallowing
13	Un explained tooth mobility
14	Un explained bleeding from the oral cavity
15	Un explained change of sensation in the oral cavity
16	Mucosal erosions in the oral cavity

3.5.2.4: Translation and back translation*:* A conceptually equivalent version of the interview schedule in Malayalam was also prepared using the back-translation method.

3.5.2.5: Face validity: The Malayalam version of the interview schedule was administered to ten people as cognitive piloting. Participants include oral cancer patients (n=5) and tobacco cessation clinic patients (n=5). They were requested to review the questions and provide suggestions concerning their meaning, clarity, comprehension, appropriateness of sentence structure, and difficulty for answering. The interview schedule was modified based on the feedback received from the study participants.

3.5.2.6: Technical Advisory Committee review*:* The Technical Advisory Committee of the institution reviewed the newly developed interview schedule and recommended for Institutional Ethics Committee for review.

3.5.2.7: Institutional Ethics committee review: The Institutional Ethics Committee reviewed and approved the final interview schedule after following the review procedure (Annexure -6).

3.6: Protocols for calculating 'pseudo-exact' dates from estimated dates to calculate time intervals and validation

Patients often fail to provide the exact date for various time points in the diagnostic journey of cancer such as the date of symptom recognition, the date of first reporting of symptoms to a health care provider, and an estimated date of occurrence of mentioned events. In cases where the patient happened to forget the exact dates of events, the only alternative left is to identify a pseudo exact date of occurrence of an event from the estimated date provided by the patient. A protocol for calculating pseudo exact dates from the estimated dates was given by Neal *et al* (Neal *et al*., 2014). Another protocol was provided for the validation of the same (Neal *et al*., 2014). These two protocols were adapted to the local context considering the seasonal and cultural aspects of our country. Please refer Table 3.2 and Table 3.3.

Table 3.2: Protocol for calculating 'pseudo-exact' dates from estimated dates to calculate time intervals

(Adapted from the Protocol for calculating 'pseudo-exact' dates from estimated dates to calculate time intervals (Neal *et al*., 2014))

Text for estimated date	Rule	Example text	Example recode
'x days/weeks/months/years ago'		*'4 months ago'*	Count back 4 months from the completion date
Few / about / approx / range etc			
'Range of months or years ago'	Take midpoint of the range	*'2-3 years ago' 'Jan-Mar 19'*	Count back 2.5 years from the completion date 15.02.19
'about (or approx) x days/weeks/months/years ago'	Ignore 'about' or 'approx'	*'About 4 months ago'*	Count back 4 months from the completion date
'Two days'	Take the first date	*'3/4 Feb 2019'*	03.02.2019
'Early Feb/Late Jan 09' (or similar)	Take 1st Feb 09	*'Early Feb/Late Jan 09'*	01.02.09
Few weeks/months ago	Few=3	*'Few months ago'*	Count back 3 months from completion dates
Incomplete month/year			
'Year' (only)	01.07.xxxx	*'2019'*	01.07.2019
'Date/Month but no year	Take the first one	*'15th July'*	The first 15.19 before the completion date
'Month' (no date)	Take 15th of the month	*January 2019*	15.01.2019
Early/late/mid etc.			
'Early year' (only)	15.02.xxxx	*'Early 2019'*	15.02.2019
'End of year'	Take the last date in a year	*'End of 2019'*	31.12.2019
'Mid month'	Take 15th month	*'Mid-January 2019'*	15.01.2019
'Late month'	Take 23rd month	*'Late-January 2019'*	23.01.2019
'End of the month'	Take the last date of the month	*'End Jan 19'*	31.01.2019
'2nd week in the month'	Take 10th month	*'2nd week in Jan 19'*	10.01.2019
'Beginning of month'	1st date of the given month	*Beg Feb 19*	01.02.2019
'Beginning of month' (no year given)	1st date of the given month	*Beg Feb*	The first 01.02 counting back from the completion date
Seasons and holidays			
'Summer or pre-monsoon season – search March to May	15.04.xxxx	*'Summer 2019*	15.04.2019

'Early Summer'	15.03.xxxx	*'Early Summer 2019'*	15.03.2019
'Late summer'	15.05.xxxx	*'Late summer 2019'*	15.05.2019
Monsoon or rainy season – search June to August	15.07.xxxx	*'Monsoon 2019'*	15.07.2019
'Early Monsoon'	15.06.xxxx	*Early Monsoon 2019'*	15.06.2019
'Late Monsoon'	15.08.xxxx	*'Late monsoon 2019'*	15.08.2019
Post-monsoon– search September to November	15.10.xxxx	*'Autumn 2019'*	15.10.2019
'Early Autumn'	15.09.xxxx	*'Early Autumn 2019'*	15.09.2019
'Late Autumn'	15.11.xxxx	*'Late Autumn 2019'*	15.11.2019
Winter – search December to February	15.01.xxxx	*'Winter 2019'*	15.01.2019
'Early Winter'	15.12.xxxx	*'Early Winter 2019'*	15.12.2019
'Late Winter'	15.02.xxxx	*'Late Winter 2019'*	15.02.2019
Republic day	Recode to exact date	*Republic day 2019*	26-01-2019
Sivarathri	Recode to exact date	*Sivarathri 2019*	04-03-2019
Vishu	Recode to exact date	*Vishu 2019*	15-04-2019
'Good Friday'	Recode to exact date	*'Good Friday 2019'*	19.04.2019
Easter	Recode to exact date	*'Easter 2019'*	21.04.2019
Id uLFitr	Recode to exact date	*Id uLFitr*	05-06-2019
KarkkadaVavu	Recode to exact date	*KarkkadakaVavu 2019*	31-07-2019
Independence day	Recode to exact date	*Independence day 2019*	15-08-2019
Thiruvonam	Recode to exact date	*Thiruvonam 2019*	11-09-2019
Xmas	Recode to exact date	*'Xmas 2019'*	25.12.2019
Before Xmas	15.12.xxxx	*Before Xmas 2019*	15.12.2019
After Xmas	31.12.xxxx	*After Xmas 2019*	31.12.2019
Other			
'Week beginning…'	Code as that date	*'Week beginning 15.02.19'*	15.02.2019

Table 3.3: **Protocol for calculating 'pseudo-exact' dates from estimated dates for the validation**

(Adapted from the Protocol for calculating 'pseudo-exact' time windows from estimated dates for the validation (Neal *et al*., 2014))

Patient-reported time	Validation Action
Exact date	Search 14 days on either side of the exact date
Seasons	Summer or pre-monsoon season – search March to May Monsoon or rainy season – search June to August Post-monsoon or autumn season – search September to November Winter – search December to February
Month	Search 14 days before month beginning and 14 days after month-end
'early (month)' = day 1–10	Search 14 days either side days 1-10 inclusive
'mid (month)' = day 11–20	Search 14 days either side days 11–20 inclusive
'late (month)' = day 21–30/31	Search 14 days either side days 21 – 30/31 inclusive
'last week, last month'	Count back one and treat as week or month, and search 14 days either side (unless in future)
'x months/weeks ago'	Count x months/weeks back from date questionnaire completed, then search 2 weeks either side of that month/week ('about 3 weeks ago will be treated as 3 weeks ago)

3.7: Staging system for oral cancer

Staging of oral cancer is based on the TNM staging system(Glick, 2015). T refers to the extent of disease based on the size of the primary tumor and its local invasiveness. N refers to the presence or absence, size, and extent of regional lymph nodes. M refers to the presence or absence of distant metastasis. The current TNM staging system used for oral cancer is based on the eighth edition of the TNM manual published in 2017. The newer additions found in the eighth edition are DOI and ENE. DOI refers to the depth of invasion and ENE refers to Extra Nodal Extension(Mupparapu and Shanti, 2018). Please refer the Table 3.4.

Table 3.4: Tumor Node Metastasis (TNM) staging system for oral cancer
(Mupparapu and Shanti, 2018)

Category	Criteria	
1.Tumor		
Tumor category	**Tumor size**	**Additional criteria**
Tx	Not applicable	Primary tumor cannot be assessed
Tis	Not applicable	Carcinoma in situ
T1	≤2 cm, ≤5 mm DOI	No additional criteria
T2	≤2 cm, DOI≥ 5 mm, and ≤10 mmOR Tumor ≥2 cm but ≤4 cm andDOI ≤10 mm	No additional criteria
T3	≥4 cm or any tumor >10 mm DOI	No additional criteria
T4	Not applicable	Moderate to advanced local disease
T4a	Not applicable	Oral cavity, lip, chin, or nose tumor invading cortical bone or involving the inferior alveolar nerve, floor of the mouth, facial skin, bones of the mandible, or maxilla affecting basal bone
T4b	Not applicable	Advanced local disease in which tumorinvades masticator space, pterygoidplates, or skull base, and may or may not encase internal carotid artery
2. Node		
Node category		**Node criteria**
Nx	Regional lymph nodes cannot be assessed	
N0	No regional lymphadenopathy	

N1	Metastases in a single ipsilateral lymph node ≤ 3 cm and ENE negative (–ve)
N2	Ipsilateral node ≤ 3 cm, ENE positive (+ ve) 3–6 cm with ENE –ve Multiple ipsilateral metastatic lymph nodes none >6 cm and ENE –ve Metastatic bilateral or contralateral nodes <6 cm, ENE –ve
N2a	Ipsilateral single metastatic node ≤3 cm, ENE +ve Ipsilateral single metastatic node ≥ 3 cm but ≤6 cm, ENE –ve
N2b	Metastatic multiple ipsilateral nodes ≤ 6 cm, ENE –ve
N2c	Metastatic bilateral or contralateral lymph nodes≤ 6 cm, ENE –ve
N3	Metastatic lymph nodes ≥6 cm, ENE –ve; metastatic single ipsilateral lymph node ≥3 cm, ENE +ve; metastatic multiple ipsilateral, contralateral or bilateral lymph nodes, ENE +ve
N3a	Metastatic lymph node ≥6 cm, ENE +ve
N3b	Metastatic single lymph node ≥3 cm, ENE +ve or metastatic multipleipsilateral, bi or contralateral lymph nodes, ENE +ve
3. Metastasis	
Metastasis Category	**Metastasis criteria**
Mx	Metastasis not determined; Awaiting CT or PET examinations
M0	Distant metastasis not identified
M1	Distant metastasis identified
Stage grouping(Glick, 2015)	
Stage 0	Tis N0 M0
Stage 1	T1 N0 M0
Stage 2	T2 N0 M0
Stage 3	T3 N0 M0, T1 N1 M0, T2 N1 M0, T3 N1 M0
Stage 4A	T4a N0 M0, T4a N1 M0, T1 N2 M0, T2 N2 M0, T3 N2 M0 T4a N2 M0
Stage 4B	Any T,N3 M0, T4b Any N M0
Stage 4C	Any T, Any N M1

3.8: Operational definitions of selected variables and time points used in the study

Table 3.5 elaborates operational definitions of important variables in this study and various time points used.

Table 3.5: Operational definitions of selected variables and time points used in the study

Variable / Time point	Operational Definition
Date of first symptom	'The time point when first bodily changes and/or symptoms are noticed'
Date of first presentation	'The time point at which, given the presenting signs, symptoms, history and other risk factors, it would be at least possible for the clinician seeing the patient to have started investigation or referral for possible important pathology, including cancer".
Date of diagnosis	Measurement-based on "Hierarchy For Defining The Date Of Diagnosis" by European Network Of Cancer Registries. Date of first histological or cytological confirmation of this malignancy (with the exception of autopsy). This date should be, in the following order: (a) date when the specimen was taken (biopsy), (b) date of receipt by the pathologist, (c) date of the pathology report
Stage at diagnosis	Extent of the disease at the time of diagnosis as per the TNM staging
Patient interval	"Patient interval" is the period between the symptom recognition by the patient and first consultation with a health care provider for evaluating the same. Measured in days and categorized into up to 90 days and above 90 days.
Diagnostic interval	"Diagnostic interval' is the period between the first appointment with a Health care provider for evaluating the symptom and the histopathological cancer diagnosis. Measured in days and categorized into up to 30 days and above 30 days.
Discussion interval	Discussion interval is the time taken by the participant for discussing the problems in their oral cavity with someone in the family or among his or her social circle, before meeting a health care professional.
Route to diagnosis	'Routes to diagnosis' means the number of HCPs a patient met during their diagnostic journey, the time from recognizing a symptom suggestive of cancer to receiving a definitive diagnosis of cancer
Age	The age as reported by the patient
Sex	Being male, female, or transgender

Education	Self-reported education status categorized into five as 1) no formal education 2) Primary school education (1st to 7th standard) 3) Secondary school education (8th to 10th standard), 4) Higher secondary school education (11th -12th /plus one and plus two)/ diploma/certificate courses after 10th standard 5) Diploma after plus two/ degree and above.
Occupation	As reported by the patient
Religion	Self-reported religion categorized into Hindu, Christian, Muslim, and Others
Caste	Self-reported caste categorized into Scheduled Caste, Scheduled Tribe, Other Backward Class, General and others
Type of family	Categorized into nuclear, joint, and extended
Current marital status	Self-reported, categorized into married, widow/widower, divorced, separated
Family income	Self-reported monthly income from all sources
Pan masala	All commercial smokeless tobacco products like 'Pan Parag',' Hans', 'Gutka', etc. were grouped together as 'Pan Masala'
Betel quid	An indigenous preparation consists of betel leaf, areca nut, lime, and tobacco. Preparations without tobacco were also included as Betel quid.
Habit pattern after symptom recognition	Among those participants who were smokers or betel quid users or pan masala users or alcohol users, any change in their habit pattern after recognizing the symptoms suggestive of oral cancer was assessed as 'No Change;, 'Stopped', 'Reduced', 'Increased'.
Alternative medicine	Alternative medicines here refer to Herbal medicines, home remedies, and other traditional medicines which are not part of the standard modern medical practice.
Pucca House	A pucca house is one, which has walls and a roof made of the following material. Wall material: Burnt bricks, stones (packed with lime or cement), cement concrete, timber, ekra, etc (Government of India, 2011a)
Kutcha House	The walls and/or roof of which are made of material other than those mentioned above, such as unburnt bricks, bamboos, mud, grass, reeds, thatch, loosely packed stones, etc. are treated as kutcha house(Government of India, 2011a)
Semi -Pucca house	A house that has fixed walls made up of pucca material but the roof is made up of material other than those used for the pucca house(Government of India, 2011a)

3.9: Hospital-based cross-sectional study

A cross-sectional survey was conducted among oral cancer patients reported at the institution to calculate the patient interval and diagnostic interval and also to assess the various factors associated with the patient interval in oral cancer. The tools developed and validated for the purpose of collecting data were administered on the participants.

3.9.1: Sample size

The sample size was estimated by Epi info version 3.01. According to a study conducted in Uttar Pradesh, India, the proportion of oral cancer patients with a patient interval of more than 3 months was 60%. Taking 60% as the anticipated prevalence of oral cancer patients with a patient interval of more than 3 months, with a 95% confidence interval between 54% and 66%, the sample size was estimated to be 257 rounded off to 260. Based on the latest published hospital-based cancer registry data for the year 2015, there were 450 oral cancer patients have reported at the institution for treatment. Hence, we expected 260 oral cancer patients to report at the institution during seven months. Due to the unexpected COVID pandemic situation, data collection was extended by another two months. Each consecutive oral cancer patient who reported at the institution during the study period and who met the requisite criteria and consented to participate was included in the study until the required sample size was reached.

3.9.2: Sample selection procedure

3.9.2.1: Inclusion criteria

Newly registered patients with the following malignant neoplasms were included in the study:

Malignant neoplasm of 1. Lip (C00), 2. Base of tongue (C01), 3. Other and unspecified parts of tongue (C02), 4. Gum (C03), 5. Floor of mouth (C04), 6. Palate (C05), 7. Other and unspecified parts of mouth (C06)

3.9.2.2: Exclusion criteria

- Those known to have, or had, other cancers
- Patients who were on routine surveillance for cancer
- Those who were not consenting to participate
- Oral cancer patients who were unable to participate due to health reasons or any other reasons
- Oral cancer patients with recurrence
- Patients who have completed treatment for oral cancer

3.9.3: Data collection techniques:

A newly developed and validated interview schedule and questionnaire were used for data collection. Participants were identified from the head and neck oncology clinic and new case clinic of the institution. Participants who consented to participate in the study were interviewed by the investigator during one of the follow-up visits. Data from each patient was collected within three months from the date of patient registration at the institution to minimize recall bias. Data was not collected during the first visit to avoid embarrassment for the patient. The protocol for calculating the pseudo exact dates from the estimated dates to calculate intervals and the validation protocol were used for finalizing the time points. Data were collected from December 2019 to August 2020.

3.9.4: Study variables

The socio-demographic variables include Age, Sex, Caste, Religion, Place of residence, Education, Occupation, Monthly Income, Ration card type, Type of house, Type of family, Marital status, and Number of members in the family.

Habit-related variables include Use status at the time of symptom recognition and after symptom recognition, Duration, and frequency of tobacco smoking, Betel quid chewing, Commercial smokeless tobacco use, and alcohol use.

Healthcare-related variables include 'Pattern of medical and dental consultation', 'General first response to any illness', 'Previous experiences with cancer patients', 'Duration, distance and mode of travel to the nearest health facility'.

Variables specific to the current problem in the oral cavity include 'Stage of disease', 'First response to the initial symptom', 'Discussing symptoms with family/friends/colleagues before meeting a Health Care Provider (HCP)', 'The prod behind meeting an HCP', and 'Cancer stage at diagnosis'.

Barriers to help-seeking variables include 'It is embarrassing to talk to the doctor about symptoms', 'Too busy to make time to go to a doctor, 'Having many other things to worry about, 'Worried about different tests the doctor will advise', 'Having no one for accompanying to visit the hospital', 'Did not have sufficient money to consult a doctor', 'Was worried about what the doctor might find out', 'Feeling comfortable in discussing the symptoms with a nurse compared to a doctor' and 'Prefer alternative medicine'

Healthcare provider-specific variables include 'Type of HCP first met', 'Advice received from HCP', and 'Routes to diagnosis'.

Time intervals calculated in the study include Patient Interval, Diagnostic Interval, and Discussion Interval.

3.9.5: Data analysis

Data collection forms were inspected for finding out incomplete and inappropriate responses and data was entered in the appropriate statistical software program. A unique identification code was given for each respondent. Numerical coding of variables was performed after constructing a data dictionary since there were a large number of variables in this study. After data cleaning, data analysis was performed with appropriate statistical software having data management and analysis tools. Categorical variables were described in terms of frequencies and proportions. Mean and standard deviation was calculated for continuous variables which were normally distributed, and normality was checked by the Kolmogorov Smirnov test (p-value > .05). Non- normally distributed variables were described in terms of median and

interquartile range. Bivariate analysis of categorical variables was performed with the help of a contingency table and Chi-square statistics or Fischer's exact test. Significant alpha level was taken as .05 for Chi-square and Fisher's exact tests. Univariate logistic regression was performed with categorical interval as a dependent variable to calculate unadjusted odds ratio (OR) and 95% confidence interval. For comparing means of normally distributed variables, an independent sample t-test was done and non-normal variables were compared using the Mann-Whitney U test (to compare two groups) and the Kruskal-Wallis test (to compare three or more groups). Regression analysis was done finally to formulate a predictive model of patient interval and diagnostic interval.

3.9.5.1: Background characteristics of the Study population

3.9.5.1.1: Univariate analysis: Background characteristics of the study population were summarized using appropriate statistical tools. Age was described in terms of mean and standard deviation as well as frequencies (percentage) after categorizing into age groups. Frequencies and proportions were computed for most of the categorical socio-demographic variables, like sex, religion, caste, place of residence, house type, marital status, level of education, occupation, ration card type, type of family, and members of the family. Financial factors like monthly income category, earning members in the family, presence of debts, financial needs of family was met by whom, insurance status, etc. also were summarized in terms of frequencies and proportions. Other important continuous variables like monthly income (in INR), duration of education (in years), and members currently staying in the family were described as median and inter-quartile range, after checking normality.

3.9.5.1.2: Bivariate analysis: Relevant variables with possible interaction were analyzed for determining the empirical association between those variables. This was done by cross-tabulations and chi-square tests for independence between important demographic and socioeconomic factors, which were categorical. Fisher exact test was considered when the contingency table contained a count less than 5. An independent sample t-test was performed for comparing the mean age of males and females.

3.9.5.2: Patient interval and Diagnostic interval

Patient and Diagnostic intervals were measured in days. Both were checked for normality and were summarised in terms of median and inter-quartile range.

3.9.5.3: Patient interval and associated factors

All variables were classified into Socio-demographic factors, financial factors, pattern of deleterious habits, pattern of health care, access and experience of health care, factors related to the current oral problem, discussion of the current problem, help-seeking behavior, and meeting healthcare personnel and related factors. For identifying those factors having a decisive role in determining patient interval duration, we did a bivariate analysis. For this, the patient interval was dichotomized into less than or equal to 90 days and more than 90 days. Those variables which were significantly associated with patient interval were selected for multivariate analysis (p-value less than .05).

Binary logistic regression analysis was performed with dichotomized patient interval as the dependent variable and selected variables as covariates. By purposeful selection of covariates based on their significance, and through the process of model refitting and verification multiple times, we formulated the most predictive model of patient interval.

3.9.5.4: Diagnostic interval and associated factors

For identifying important determining factors of the diagnostic interval, the steps we followed were almost similar to those mentioned above. The continuous variable-diagnostic interval- was dichotomized into less than or equal to 30 days and more than 30 days. Socio-demographic and habit-related factors, factors related to the current oral problem, access and pattern of healthcare-related factors, help-seeking behavior, and meeting healthcare personnel, and related factors were analyzed by cross-tabulation and chi-square statistics. Since the dependent variable was binary, a binary logistic regression model was formed, which included significant predictors.

3.10: In-depth interviews with Patients, Health Care Providers, Community Leaders, and Administrators

3.10.1: Study type

In-depth interviews form the qualitative component of the study. The findings from this qualitative inquiry were used to explain and interpret the quantitative study findings. The qualitative study was conducted after the completion of the cross-sectional survey. The interview schedule was developed based on the preliminary findings from the quantitative study.

3.10.2: Sample size

In-depth interviews were conducted with eight oral cancer patients, eleven health care providers, five community leaders, and six health care administrators. Community leaders include leaders of social organizations and people's representatives in local self-governing institutions. Health care providers include four primary care medical practitioners, two ENT surgeons, three Dental Surgeons, one Head and Neck Oncologist, and one General Medicine Specialist. A total of 30 in-depth interviews were conducted. The sample size was informed by the principle of saturation. We concluded the data collection on the attainment of saturation.

3.10.3: Sample selection procedure

Participants for the in-depth interviews were conveniently selected from the hospital, institutional and community settings. Those oral cancer patients who had completed the treatment and on follow-up were interviewed. Health care providers working in Primary Health Centers, Community Health Centers, and Sub District Hospitals, and Tertiary Care Centers were interviewed. Community leaders associated with various social organizations and local self-governing institutions were interviewed. Health care administrators working in Comprehensive Cancer Centers and the Directorate of Health Services were interviewed. Those who did not consent were excluded from the study.

3.10.4: Data collection procedure

In-depth interview checklists were prepared for different categories of participants keeping in mind the preliminary results of the quantitative study. The checklist for the patient was prepared to assess their awareness about various symptoms suggestive of oral cancers and pre-cancers, their health-seeking behavior, the reaction of their family and society towards them, and the challenges they faced to access health care. The health care providers were asked about the frequency and pattern of oral cancers and pre-cancers in their routine clinical practice, adherence of patients towards follow-ups and management of oral cancers and pre-cancers, referral and training requirements, and challenges for implementing early detection of oral cancer in clinical settings. The community leaders were asked about general perceptions about oral cancer in the community, availability of facilities for cancer care, community-level support for cancer care, and the prevailing apprehensions about cancer in society. The administrators were asked about specific initiatives and programs for oral cancer prevention, various policies, plans, and strategies for oral cancer control in the state, and challenges for implementing the early diagnosis of oral cancer. Interview checklists for all categories of participants were initially prepared in English but a conceptually equivalent Malayalam version of the checklists for patients and community leaders were also prepared. The in-depth interview checklists were submitted to the Technical Advisory Committee and Institutional Ethics Committee and obtained their approval before the initiation of the study.

3.10.5: Data analysis

Qualitative data analysis was done manually. Interviews were transcribed after each interview. Field notes were also included. After transcription, they were coded. Codes were categorized based on the patterns. Emerging themes and subthemes were identified using a largely deductive approach.

3.11: Document review

A document review was conducted to identify the structure and function of oral cancer control in the state. For this, available Government documents, institutional documents other online resources related to cancer prevention were collected. We prepared a checklist for reviewing the documents and submitted that for the approval of the Technical Advisory Committee and Institutional Ethics Committee. After receiving their approvals, all health-related government portals were searched electronically. The medical libraries of the two comprehensive cancer care centers were hand searched for cancer-related policy documents. Personal inquiries with experts involved in the preparation of the cancer control strategy document were also carried out. A systematic search was done in PubMed using the keywords "Health Policy", "Cancer", "Oral cancer", "Guiding document" and "Kerala". We couldn't find any article with information pertaining to any cancer control documents in Kerala. We did target website browsing of all government of Kerala health-related websites. The websites included www.dhs.kerala.gov.in, www.dme.kerala.gov.in, www.kerala.gov.in, www.arogyakeralam.gov.in, www.rcctvm.gov.in, www.mcckerala.gov.in, and www.ccrc.kerala.gov.in. After these exercises, eighteen documents were identified and four documents were included in the review. Only those documents that mention cancer prevention or early diagnosis were included in the review. The following documents were included in the review: 1) Ten-year action plan for cancer control in Kerala (1988). 2) Draft Kerala Health Policy (2013). 3) Kerala Cancer Control Strategy 2018-2030 (2018). 4) Kerala Health policy (2019). The following policy documents did not mention oral cancer/cancer prevention or early diagnosis. They include Old age policy 2006, Pain and palliative care policy 2008, Women's policy 2009, Kerala liquor policy 2011, Draft Kerala labor policy 2011 and 2017, Youth policy 2012, and Kerala state labor policy 2017. The included documents were reviewed using the Document Review Checklist. The documents were reviewed to identify the key institutions and organizations involved in cancer prevention in the state and also to identify the roles and responsibilities of each participant in the cancer prevention program. The document was also assessed for

identifying initiatives and measures taken for early oral cancer diagnosis as well as the proposed strategies and plans for oral cancer prevention (Figure 3.3).

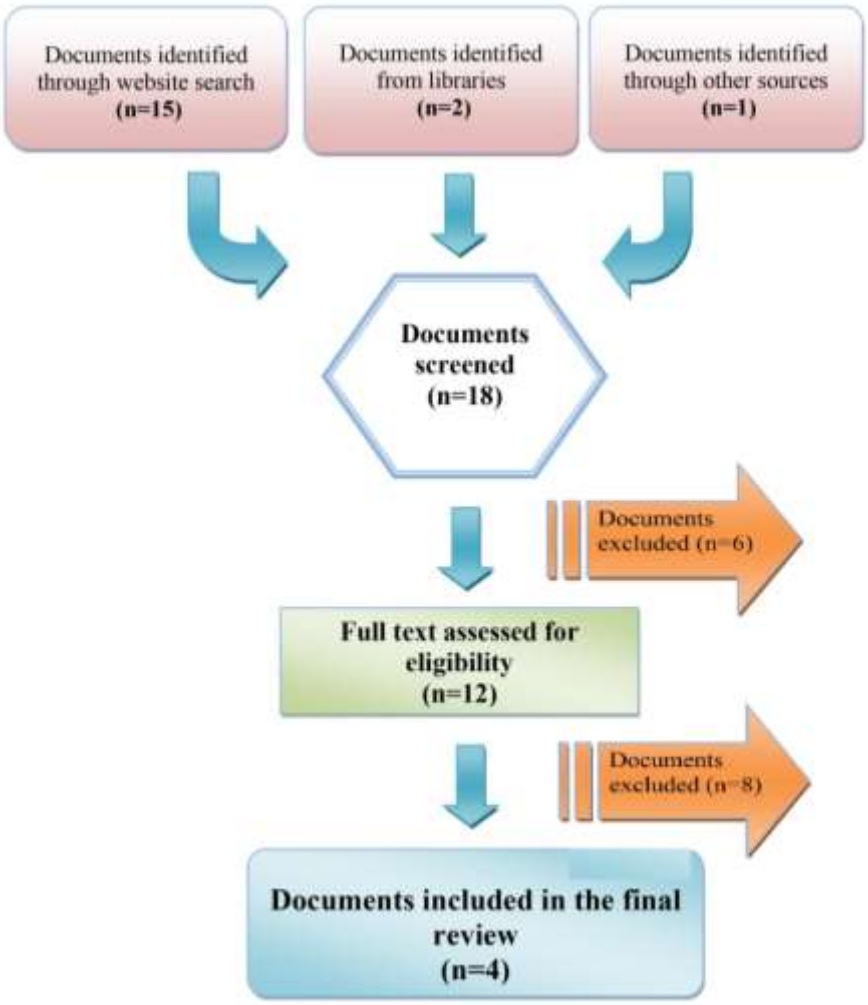


Figure 3.3: Flow chart depicting the document selection process

3.12: Ethical considerations

3.12.1: Permissions and approval

The Ethical clearance for the study was obtained from the Institutional Ethics Committee, Sree Chitra Tirunal Institute for Medical Science and Technology, Trivandrum, and the Institutional Ethics Committee, Malabar Cancer Centre, Thalassery. Before ethical clearance, the research proposal received approval from the institutional review board and technical advisory committee of Malabar Cancer

Centre, Thalassery, and Sree Chitra Tirunal Institute for Medical Science and Technology, Trivandrum respectively.

3.12.2: Respect for persons

3.12.2.1: Autonomy: Only those patients who voluntarily consented to the study were included in the study. They were advised about the voluntary nature of participation and their right to withdraw from the study whenever they feel so.

***3.12.2.2: Informed consent*:** The participant information sheet and informed consent form were prepared in lay language to make sure that each participant thoroughly comprehends the nature of the study and what is expected from them during the study.

3.12.3: Beneficence

***3.12.3.1: Benefits*:** By participating in this study, patients themselves did not receive any specific benefits but their contribution by participating in the study will benefit society.

3.12.3.2: Harms: The timing of the data collection was scheduled in such a way that it was not too close to the date of diagnosis as the majority of the patients find it difficult to accept the reality initially. They were informed about the study only after they received the psycho oncologist's counseling. All newly registered cancer patients routinely receive psycho-oncology counseling in the institution where data collection was carried out. Data collection was scheduled on a follow-up visit as convenient to them.

3.12.4: Justice

***3.12.4.1: Involvement of vulnerable population*:** The study was not directed at any particularly vulnerable population. No harm was involved in the study.

***3.12.4.2: Privacy and confidentiality*:** The principal investigator ensured the confidentiality of participants and data security by undertaking the following measures.

1. The communication details of the supervisor and IEC Secretary were given in the participant information sheet. Each participant can contact any of them for further clarifications if needed.

2. Data was collected at a place and time convenient for the participants.

3. Only the principal investigator was present in the room or space during the interview.

4. The personal information was masked by giving an identification number to each datasheet.

5. The principal investigator removed the face sheets containing identifiers from survey instruments after the data entry.

6. Data was not shared with anyone, other than the supervisor.

7. Data was kept safely in a locked cupboard.

RESULTS

Chapter 4

Results

4.1: Findings of the cross-sectional study

4.1.1: Profile of the study population

4.1.1.1: Socio demographic Factors

Among the total study population of 261, the mean age of the respondents was 60.77 ± 12.3 years, ranging from 33 years to 95 years (both years included). The 95% confidence interval for the mean was 59.27 – 62.27. The standard error of the mean was 0.76. The Median (IQR) age was 60.00 (52.50-70.00) and the mode was 60 years. Age distribution followed a normal distribution with Kolmogorov- Smirnov test D (261) = 0.046, p = .20 (Figure 4.1). Males were 70.9% (n=185) and females were 29.1% (n= 76), with male to female ratio 2.4:1**.**

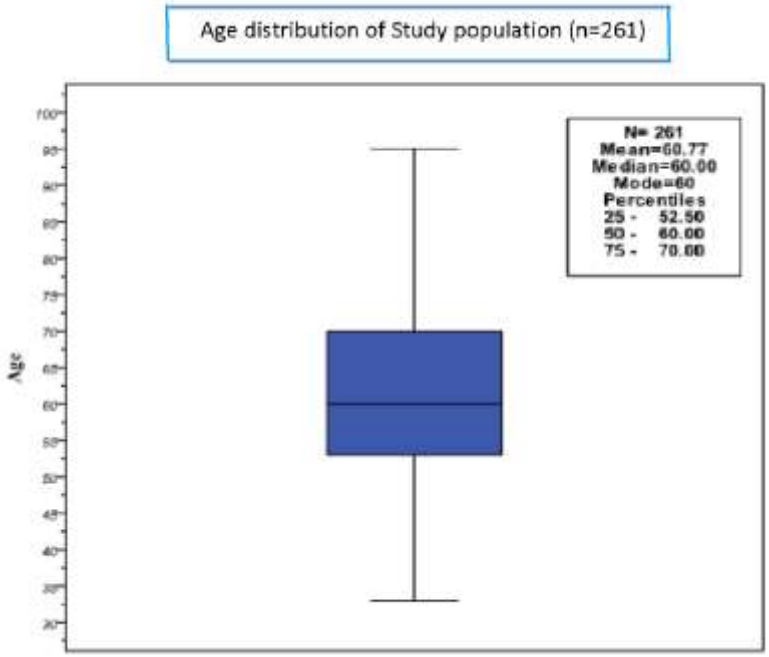


Figure 4.1: Box plot describing the age of study population (n=261)

The majority of the participants were Hindus (71%), followed by Muslims (21%) and Christians (8%). If we look at the caste affiliation of the participants, the majority were from the Other Backward Class of the community (64%) and 18% belong to the General category. One-tenth (10.7%) of the participants belong to the scheduled tribe. More than three fourth lived in the panchayath area (81.6%), 16.5% of participants were from the municipality area and nearly 2% were from the corporation region.

Among study participants, 28.4% did not have formal school education. The proportion of participants with pre-degree and above qualifications was 5.8%. The Median (IQR) duration of education was 8 (5-10) years. The majority (64.4%) were daily wagers, 13.6% were farmers and 10% were housewives. Six participants were government employees and five were working abroad.

The participants were holding the following types of ration cards, (i) Above Poverty Line (APL), (ii) Below Poverty Line (BPL), and (iii) Below Poverty Line Antyodaya Anna Yojana (BPLAAY). Most of the participants (73.9%) held BPL ration cards. More than half of the participants (58.2%) reported monthly income within 3000 to 10000 Indian Rupees. Six participants (2.3%) reported that they had no regular income, while others had some sources of income. The Median (IQR) income of respondents was 5000 (3400-9000) INR per month.

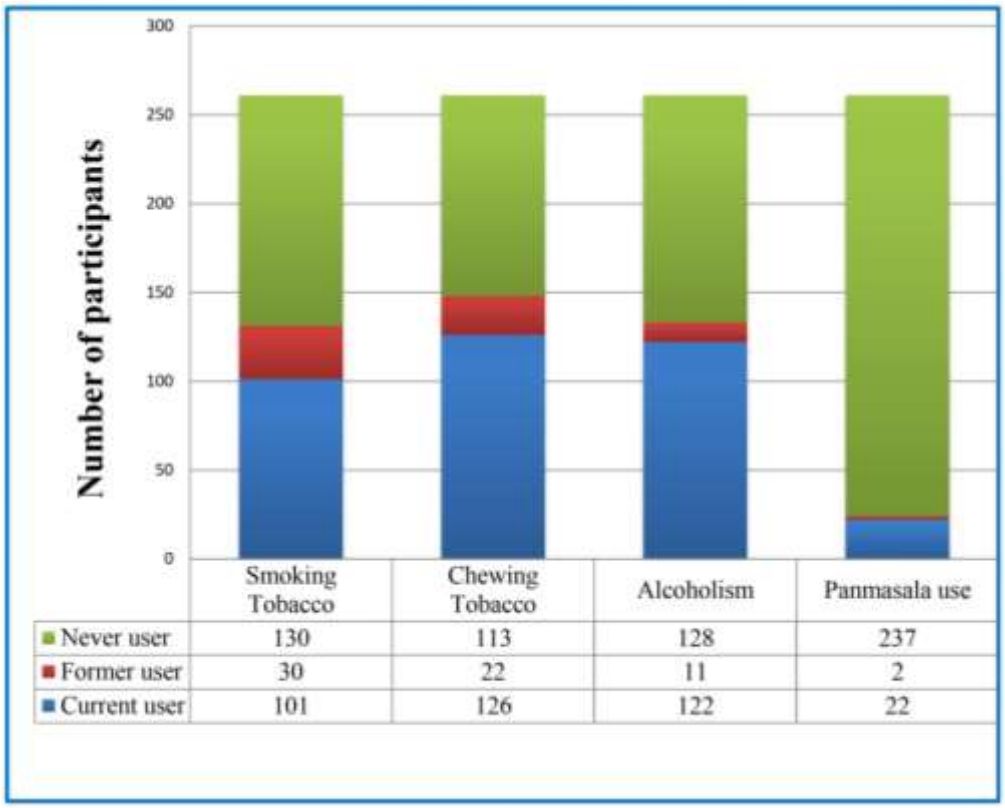
More than half of the participants (51.7%) were living in semipucca or kaccha-type houses. Nearly one-fifth (19.9%) of study participants were either widows/widowers or separated/divorced and nearly three fourth (74.3%) of the participants live in nuclear families. (Table 4.1).

Table 4.1: Socio demographic profile of the study population (n= 261)

Variable	Frequency (%)	Variable	Frequency (%)
Age in years	60.77±12.3yrs	**Occupation**	
Less than 40	16 (6.1)	Daily wage	168 (64.4)
41 – 50	39 (14.9)	Agriculture	36 (13.8)
51 – 60	81 (31.0)	House wife	26 (10.0)
61 – 70	70 (26.8)	Private office job	13 (5. 0)
71 – 80	40 (15.3)	Govt job	6 (2.3)
81 and above	15 (5.8)	Job abroad	5 (1.9)
Sex		Others	6 (2.8)
Male	185 (70.9)	**Income in Indian rupees**	
Female	76 (29.1)	≤ 5000/-	139 (53.3)
Religion		>5000/-	122 (46.7)
Hindu	185 (70.9)	**Ration card type**	
Muslim	55 (21.1)	APL	55 (21.1)
Christian	21 (8.0)	BPL	193 (73.9)
Caste		BPLAAY	13 (5. 0)
General class	47 (18.0)	**Marital status**	
Other Backward Class	167 (64.0)	Married	197 (75.5)
Scheduled Caste	19 (7.3)	Unmarried	12 (24.5)
Scheduled Tribes	28 (10.7)	Widow/ Separated/ Divorced	52 (19.9)
Place of residence		**House type**	
Panchayath	213 (81.6)	Pucca	126 (48.3)
Municipality	43 (16.5)	Semi pucca/ Kaccha	135 (51.7)
Corporation	5 (1.9)		
Education		**Members in family**	
No formal education	74 (28.4)	**(Mean±SD)**	4.24±1.93
Lower primary	48 (18.4)		
Upper primary	61 (23.4)	**Type of family**	
High school	63 (24.1)	Nuclear	194 (74.7)
Pre degree & Degree	13 (5. 0)	Joint	66 (25.3)
PG & Professional	2 (0.8)		
Education duration		**Members currently staying**	
(Mean±SD)	5.11±4.2 yrs	**(Mean±SD)**	3.96±1.40
Total	**261 (100)**	**Total**	**261 (100)**

4.1.1.2: Habit related factors

Deleterious habits assessed in this study were tobacco smoking, betel quid chewing, pan masala usage, and alcoholism. In the study population, 50%(131) were having the habit of smoking tobacco, 56% (148) were chewing tobacco, 9.2% (24) were pan-masala users and 50.9% (133) were alcoholic either before or during the period when they recognized some problem inside the oral cavity (Figure 4.2). Ninety percentage of this study group were having any of the above-mentioned habits either currently or in the past. Around one-tenth of the participant (9.6%) were non- habitués. How current tobacco and alcohol users changed their habit patterns after recognizing symptoms in their oral cavity was also assessed. They were given four choices to mark their response. They include 'No change', 'Reduced', 'Increased' and 'Stopped' (Figure 4.3).



	Smoking Tobacco	Chewing Tobacco	Alcoholism	Panmasala use
Never user	130	113	128	237
Former user	30	22	11	2
Current user	101	126	122	22

Figure 4.2: Habit use status of the study population at symptom initiation

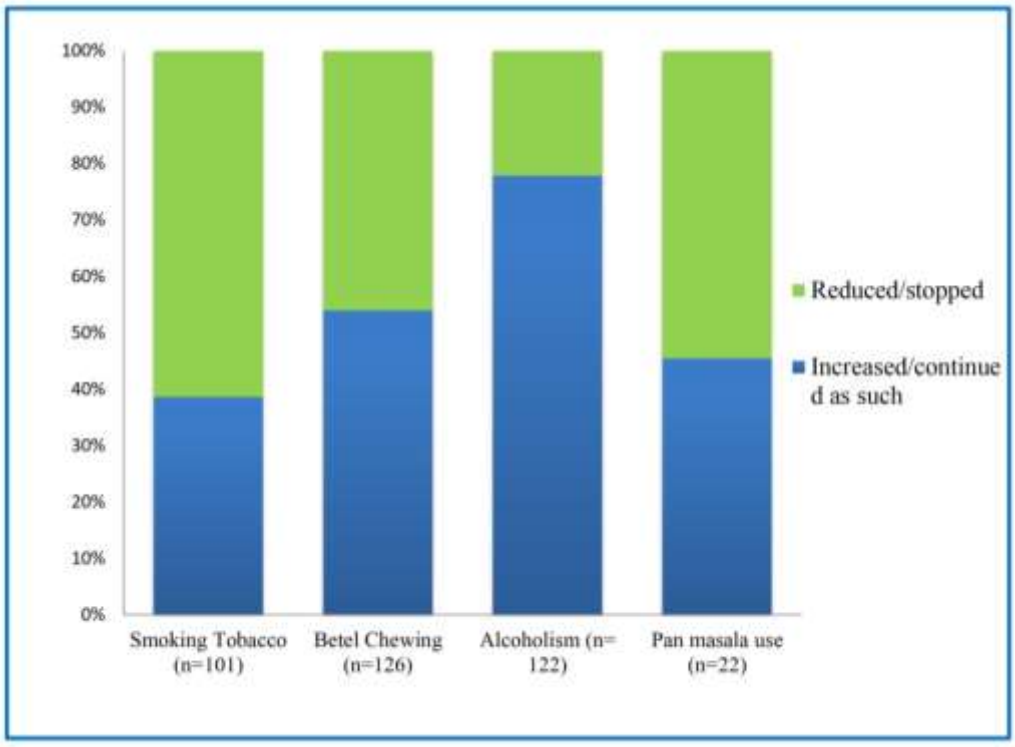


Figure 4.3: Habit pattern of study population after symptom recognition

4.1.1.2.1: Tobacco Smoking

At the time of symptom recognition, nearly half of the participants (49.8%) were 'never smokers', 38.7% were 'current smokers' (n=101) and 11.5% were 'former smokers' (n=30). More than half (50.2%) of the respondents reported ever tobacco use. The median duration of smoking habit was 30.00 (20.00- 40.00) years and the mean duration of usage was 31.85 ± 15.4 yrs. After identifying the symptoms, 61.4% (n=62) of smokers reduced their frequency or stopped the habit, while 38.6% (n=39) increased their frequency or continued at the same rate.

4.1.1.2.2: Betel quid chewing

The habit of chewing tobacco was assessed for its pattern and duration. At the time of symptom identification, 48.3% (n=126) were 'current chewers', 'former users' were 8.4% (n=22) and 'never users' 43.3% (n=113). The median duration of chewing was 30.00(20.25-45.00) years and the mean duration of usage was 33.53 ± 15.9 yrs. There were 68 participants (54% of chewers) who increased or continued the habit after

recognizing their oral problems, whereas 58 persons (46% of chewers) either stopped or reduced the frequency of chewing.

4.1.1.2.3: Pan Masala use

In this study population, only 8.4% had the habit of pan masala use at the time of symptom recognition. Two participants (0.8%) were 'ex-users' and 90.8% were 'never users'. The mean duration of pan masala use was 14.54±8.6 yrs. Among the habitués, more than half (54.5%) either stopped or reduced the habit frequency after noticing symptoms (Figure 4.3).

4.1.1.2.4: Alcohol use

Among the participants, 46.7% were current alcohol users, 4.2% were former users and 49% were ever users at the time of symptom recognition. The median duration of alcohol use was 30.00(20.00-36.50) years and the mean duration of usage was 29.31±13.7 years. More than three fourth of the current alcohol users continued or increased their alcohol use after recognizing the current oral problems.

4.1.1.3: Healthcare-related factors

4.1.1.3.1: Health seeking behaviors

The pattern of participants' medical and dental consultations was explored to get an insight into participants' general health-seeking behaviors. It was found that 22.2% (n=58) of the participants used to visit a health facility at least once in a year for some health check-ups, 39.5% (103) used to visit health facilities in case of illnesses, and another 38.3% visits only for managing a severe illness or emergency. Very few people (5.4%) visit dental clinics for regular check-ups and the majority visit when they have a severe toothache or other emergency conditions. (Table 4.2)

4.1.1.3.2: Immediate response when a person perceives a health problem in their body

It was found that that 44% of the participants preferred home remedies and herbal medicines for their health problems initially. Another 18.8% prefer to manage the

condition by using over-the-counter medicines from local medical stores. Only 37.2% consulted a doctor or other health care professional as the first response to their disease symptoms.

4.1.1.3.3: Presence of comorbidities

Among study participants, the majority were not having other medical problems at the time of diagnosis; only 36.4% (n=95) reported co-morbidities like diabetes, hypertension, and cardiovascular diseases.

4.1.1.3.4: Previous Experience with cancer patient

More than three fourth of the participants did not have any previous experience with cancer patients and only 24.1% had reported such experiences.

4.1.1.3.5: Transportation, duration, and distance to reach the health facility

Mode of transport and travel duration to the nearest healthcare facility was assessed. One-third of the participants (34.1%) have to depend on more than one vehicle to reach the nearest health facility. Nearly two-thirds of the patients (65.9%) needed only a single mode of transport to reach the nearest healthcare facility and 34.1% took multiple modes of transport. The majority could reach the health facility within 30 minutes (81.6%) of time; while 22.2% took less than 10 minutes and 59.4% took 11 to 30 minutes. When the distance to the health facility was assessed, 62.1% (n=162) of patients stayed more than three kilometers away from the facility. The rest lived within three kilometers. (Table 4.2)

4.1.1.4: Financial factors

More than one-third (38%) of the participants were the sole breadwinners for the family. Availability of treatment insurance schemes was assessed and most of them (84.3%) availed of government insurance schemes such as Karunya Arogya Suraksha Padhathi(KASP) and 5% of the participants had private insurance schemes. Nearly one-fourth of the study participants were having financial liabilities other than those related to the current cancer treatment (Table 4.2).

Table 4.2: Healthcare-related factors and financial factors of study population

Variable	Frequency	Percentage
Healthcare-related factors		
Pattern of medical consultation		
Health screening at intervals	58	22.2
Medical consultation for illness	103	39.5
Urgent medical care only	100	38.3
Pattern of dental consultation		
Dental screening at intervals	14	5.4
Dental consultation for illness	85	32.6
Urgent dental care only	162	62.0
Initial response to general health problems		
Consult physician /health-worker	97	37.2
Home remedy/Herbal medicines	115	44.0
Medicines from store	49	18.8
Co morbidities		
Present	95	36.4
Absent	166	63.6
Previous experience with cancer patients		
Yes	63	24.1
No	198	75.9
Travel options to nearest healthcare facility		
Single vehicle transport	172	65.9
Multiple vehicle transport	89	34.1
Distance to nearest healthcare facility		
≤ 3 kilometres	99	37.9
Above 3 kilometres	162	62.1
Time to reach nearest healthcare facility		
≤ 10 minutes	58	22.2
11 – 30 minutes	155	59.4
31 and above	48	18.4
Financial factors		
Available Health Insurance scheme		
Government insurance	220	84.3
Private insurance	13	5.0
Who meets your financial needs?		
Self	154	59.0
Spouse	16	6.1
Children	82	31.4
Other family members	9	3.5
Earning members in the family		
Participant alone	107	41.0
Other family members	154	59.0
Financial liabilities other than current treatment		
Present	64	24.5
Absent	197	75.5

4.1.1.5: Factors related to the current problem in the oral cavity

The first symptom recognized by the patient related to the current problem in their oral cavity was noted and summarised in Table 4.3.

Table 4.3: Initial symptoms reported by the Participants

Reported symptom	Frequency	Percentage
Non healing ulcer with pain	97	37.2
Tooth mobility	26	10.0
Non healing ulcer without pain	25	9.6
Difficulty in swallowing	23	8.8
White patch	18	6.9
Abnormal growth with pain	17	6.5
Abnormal growth without pain	16	6.1
Burning sensation	11	4.2
Restricted mouth opening	8	3.1
Inability to take hot and spicy	7	2.7
Difficult tongue movements	5	1.9
Mucosal erosions	4	1.5
Bleeding	3	1.1
Red patch	1	0.4
Total	**261**	**100.0**

4.1.1.5.1: Site of lesion and Stage at diagnosis

The International Classification of Diseases (ICD)-10 code as described in the methodology section for coding oral cancer of different sites in the oral cavity was used. The ICD-10 code-wise distribution of oral cancer in the study group was

Lip(C00) -2.7%, Base of tongue (C01)- 4.6%, Other and unspecified parts of tongue (C02)-37.2%, Gum (C03) - 9.6%, Floor of the mouth (C04) - 5.0%, Palate (C05) - 3.4% and Other and unspecified parts of mouth (C06) - 37.5%. TNM staging system as described in the methodology section was used to classify the cancer stage. We found that more than two-thirds of the participants (68.2%) were presented at advanced stages (Stage 3&4) (Table 4.4).

Table 4.4: Oral cancer stage at diagnosis of study participants

Stage of oral cancer	Number	Percentage
Early Stage		
Stage 1	24	9.2
Stage 2	59	22.6
Late Stage		
Stage 3	74	28.4
Stage 4	104	39.8
Total	**261**	**100.0**

4.1.1.5.2: Patients initial thought about the first symptom suggestive of oral cancer

Participants were asked about their initial thoughts about the first symptom in the oral cavity that led to the diagnosis of oral cancer. It was an open-ended question for getting an insight into the symptom appraisal process of the participant. Nearly half of the participants (46%) considered the initial symptom as a usual mouth ulcer or an ulcer from cheek or tongue bite or as tooth or denture-related trauma. Just 3.8% of the participant considered their initial symptom as abnormal or suggestive of cancer. Trivialisation of the symptoms, relating it to a pre-existing condition or attributing it to a previous history of trauma, or attributing to the existing habits were the other thoughts on their initial oral cancer symptom. Some people attributed the symptom as a sequel to their existing dental problem (Figure 4.4).

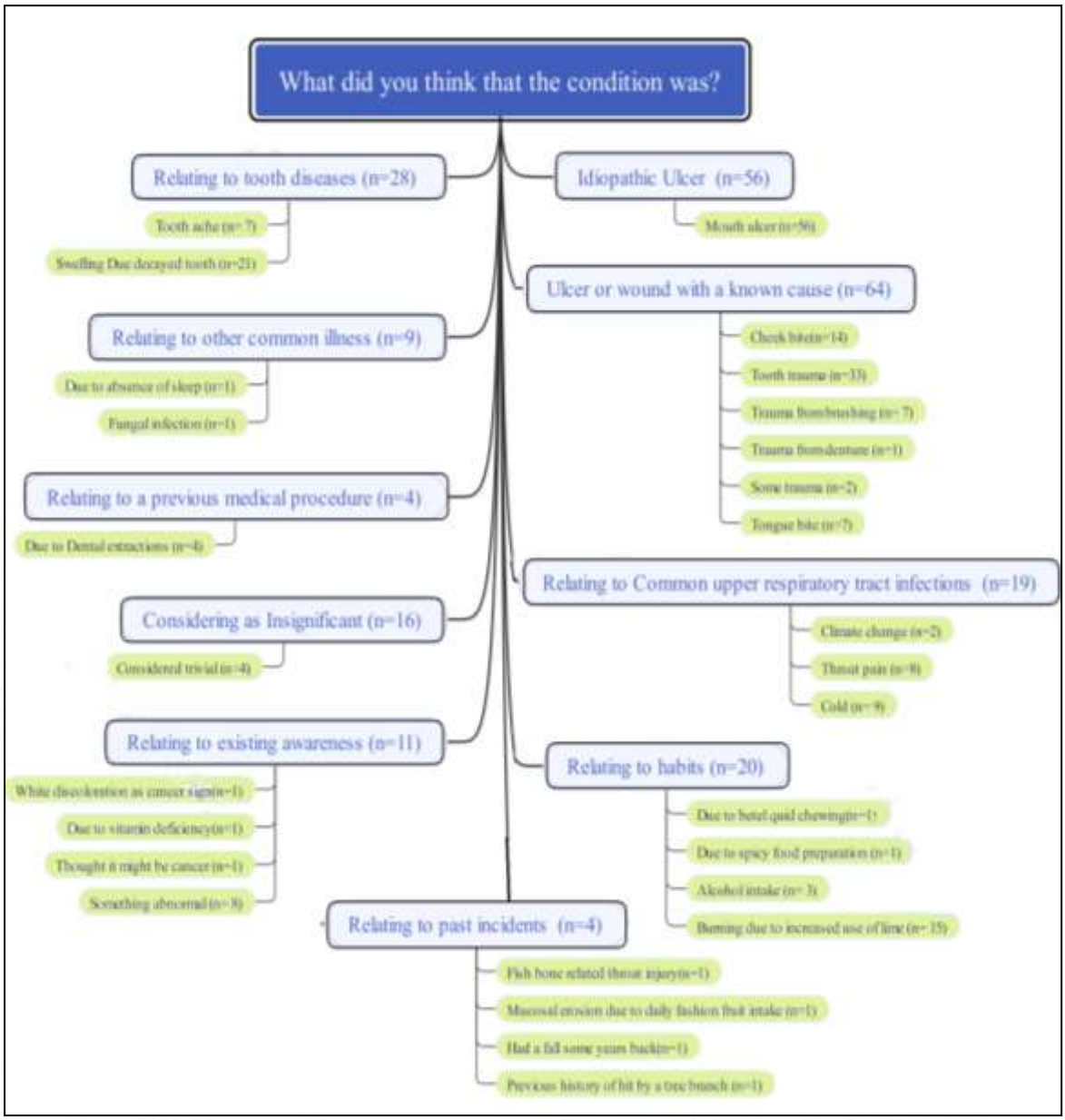


Figure 4.4: Flow chart showing participant's initial thought about the first symptom suggestive of oral cancer

4.1.1.5.2: First response to the current problem in the oral cavity

Participants' initial response to the first symptom in their oral cavity suggestive of cancer was recorded. More than half (51.3%) of the participants attributed their symptoms as minor and waited for their recovery. Only eighteen percent of the participants consulted a doctor and 30.7% took the home remedy and herbal medicines.

4.1.1.5.3: Discussion about a current problem in the oral cavity with significant others before meeting the Health Care Provider

Out of 261 participants, 180 (69%) discussed their problem with significant others after noticing the symptoms. They discussed their oral problem with their spouse (45%), son (18.3%), daughter (12.2%), and other family members, friends & relatives (25%). The time taken by them to discuss also varied, ranging from 0 – 445 days. The median time interval for the first discussion was 14.00 days with an inter-quartile range of 7.00- 30.00 days. Median (IQR) time interval taken for the first discussion was less with daughter 8.50 (6-30) days, and spouse 14.00(3-30) days but was high with friends & relatives 30.00 (14-75) days.

4.1.1.5.4: Suggestion received from the significant others after discussing their symptoms

An open-ended question was used to note the response received by the participants from their discussion with the significant others about their oral symptoms. Nearly two-thirds (64.4%) of the participants who discussed their problem with significant others were told to seek appropriate medical care. Others were advised for home remedies like saline gargle (16.6%) and habit cessation (4.4%). In 8.9% of cases, significant others dismissed the symptoms as minor (Figure 4.5).

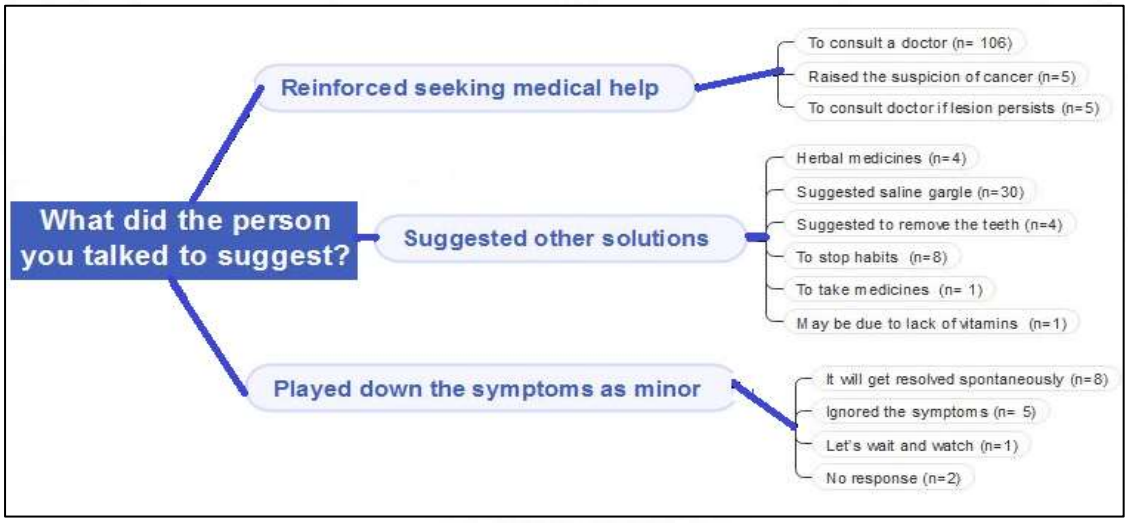


Figure 4.5: Diagrammatic representation of suggestion received from the significant others after discussing their symptoms

4.1.1.6: Barriers to help-seeking

Table 4.5 describes participants' endorsement of various barriers to help-seeking. Most of the participants (87.4%) endorsed the belief that disease symptoms "would get resolved themselves". Other frequent barriers observed in the study population were "Had too many other things to worry about", and "Was worried about what tests they might want to do".

Table 4.5: Barriers to help-seeking in the study population

Barriers	Frequency (%)
Found it embarrassing talking to the doctor about symptoms	67 (25.7)
Found it difficult to get an appointment with particular doctor	55 (21.1)
Was too busy to make time to go to the doctor	108 (41.4)
Had too many other things to worry about	131 (50.2)
Was worried about what tests they might want to do	99 (37.9)
Did not have a person to accompany me during hospital visits	64 (24.5)
Have had a bad experience with hospital/treatment in the past	24 (9.2)
Diseases, if any, would get resolved by themselves	228 (87.4)
Did not want to be seen as somebody who makes a fuss	62 (23.8)
Did not have money to consult a doctor/visit a hospital	70 (26.8)
Was worried about what the doctor might find out	87 (33.3)
Was worried about what others might think	46 (17.6)
Comfortable in discussing symptoms with a nurse than a doctor	87 (33.3)
Prefer alternative medicines than modern medicine	59 (22.6)
Total	**261 (100)**

Gender difference in barriers to help-seeking behaviour was examined and significant findings are described in Table 4.6. Females endorsed the non-availability of money and absence of a person to accompany for hospital visits as barriers to help-seeking

compared to males. Females also had more preference for alternative medicines than modern medicines. Males were more likely to report lack of time as a barrier to help-seeking in this study group when compared to females.

Table 4.6: Gender differences in endorsement of barriers to help-seeking

Variable	Endorsed n (%)	Not endorsed n (%)	Chi-square *p* value	OR (95% CI)
Was too busy to make time to go to the doctor				
Females	23 (30.2)	53 (69.7)	.019	Reference
Males	85 (45.9)	100 (65.4)		1.9 (1.1-3.5)
Did not have a person to accompany me during hospital visits/consultations				
Females	30 (39.5)	46 (60.5)	<.001	2.9 (1.6-5.2)
Males	34 (18.4)	151 (81.6)		Reference
Did not have money to consult a doctor/visit a hospital				
Females	35 (46.1)	41 (53.9)	<.001	3.7 (2.0-6.5)
Males	35 (18.9)	150 (81.1)		Reference
Prefer alternative medicines than modern medicine				
Females	25 (32.9)	51 (67.1)	.011	2.2 (1.2-4.0)
Males	34 (18.8)	151 (81.2)		Reference

4.1.1.7: Health Care setting related factors

4.1.1.7.1: Type of Health Care Provider (HCP) approached first and reasons

One-third of the participants first reported to a general medical practitioner after recognizing their problem. The next preferred HCP was a Medical specialist (30.7%) followed by a dental surgeon (28.4%) and the rest approached alternative therapists**.** Various reasons for consulting an HCP include discomfort to the daily routine (45.2%), experiencing pain (37.5%), and the insistence by family members and friends (17.2%) (Table 4.7)

Table 4.7: Healthcare setting related factors of study population

Variable	Frequency	Percentage
Number of HCPs consulted in the diagnostic pathway		
One	36	13.8
Two	93	35.6
Three	78	29.9
Four & above	54	20.7
Type of HCP first met		
Medical doctor	87	33.3
Dental surgeon	74	28.4
Other medical specialist	80	30.7
Other systems of medicine	20	7.7
Reason for meeting HCP		
Pain	98	37.5
Discomfort to routine	118	45.2
Insistence by family/friends	45	17.2
Advice by HCP		
Ignored symptom	81	31.0
Advised biopsy	102	39.1
Referred to higher centre	78	29.9
Total	**261**	**100**

4.1.1.7.2: Routes to diagnosis

Out of 261 participants, only 13.8% (n=36) could complete their diagnostic journey by meeting a single HCP. Other participants had to consult two HCPs (35.6%), three HCPs (29.9%), or four or more HCPs in their diagnostic journey. The HCPs met in the process include Medical practitioners in the primary health center, Dental surgeons, ENT specialists, General surgeons, Homeo doctors, Ayurveda doctors, and so on. People consult multiple health providers in the diagnostic journey due to referral instruction from the previous provider or provider switching by the patient.

The number of HCPs consulted was significantly related to the type of HCP met by participants ($\chi^2(9)= 34.67$, p=<.001). Those participants who met a Dental surgeon first are less likely to have more than one HCPs in their diagnostic journey when compared to those who met other HCPs (OR, 0.34; 95% CI0.13 to 0.90) (Figure 4.6).

The routes to diagnosis are often non-linear and complicated. The patient enters the health system from different levels of care.

4.1.1.7.3: Initial response from the first HCP met in the diagnostic journey

More than one-third of the participants (39%) were advised for biopsy during their initial consultation. About 30% were referred to higher centers for consultation. The remaining 31% of the participants were told that their symptoms were only minor and suggested review in case the symptom persisted. (Table 4.8).

Table 4.8: Initial response by different healthcare providers during the first consultation

Type of HCP first met	**Advice by HCP**				**TOTAL**
	Ignored the symptom as minor n (%)	**Asked for review** n (%)	**Advised biopsy** n (%)	**Referred to higher center** n (%)	
Medical doctor	12 (13.8)	24 (27.6)	12 (13.8)	39 (44.8)	**87 (33.3)**
Dental Surgeon	2 (2.7)	11 (14.9)	39 (52.7)	22 (29.7)	**74 (28.4)**
ENT surgeon	1 (2.5)	7 (17.5)	23 (57.5)	9 (22.5)	**40 (15.3)**
General surgeon	0 (0.0)	2 (8. 0)	19 (76.0)	4 (16.0)	**25 (99.6)**
Other medical specialists	0 (0.0)	3 (33.3)	4 (44.4)	2 (22.2)	**9 (3.4)**
Oncologist	0 (0.0)	1 (16.7)	5 (83.3)	0 (0. 0)	**6 (2.3)**
Ayurveda practitioner	3 (50.0)	3 (50.0)	0 (0.0)	0 (0.0)	**6 (2.3)**
Homeopathic practitioner	6 (85.7)	1 (14.3)	0 (0.0)	0 (0.0)	**7 (2.7)**
Traditional healers	4 (57.1)	1 (14.3)	0 (0.0)	0 (0.0)	**7 (2.7)**
TOTAL	28 (10.7)	53 (20.3)	102 (39.1)	78 (29.9)	**261 (100)**

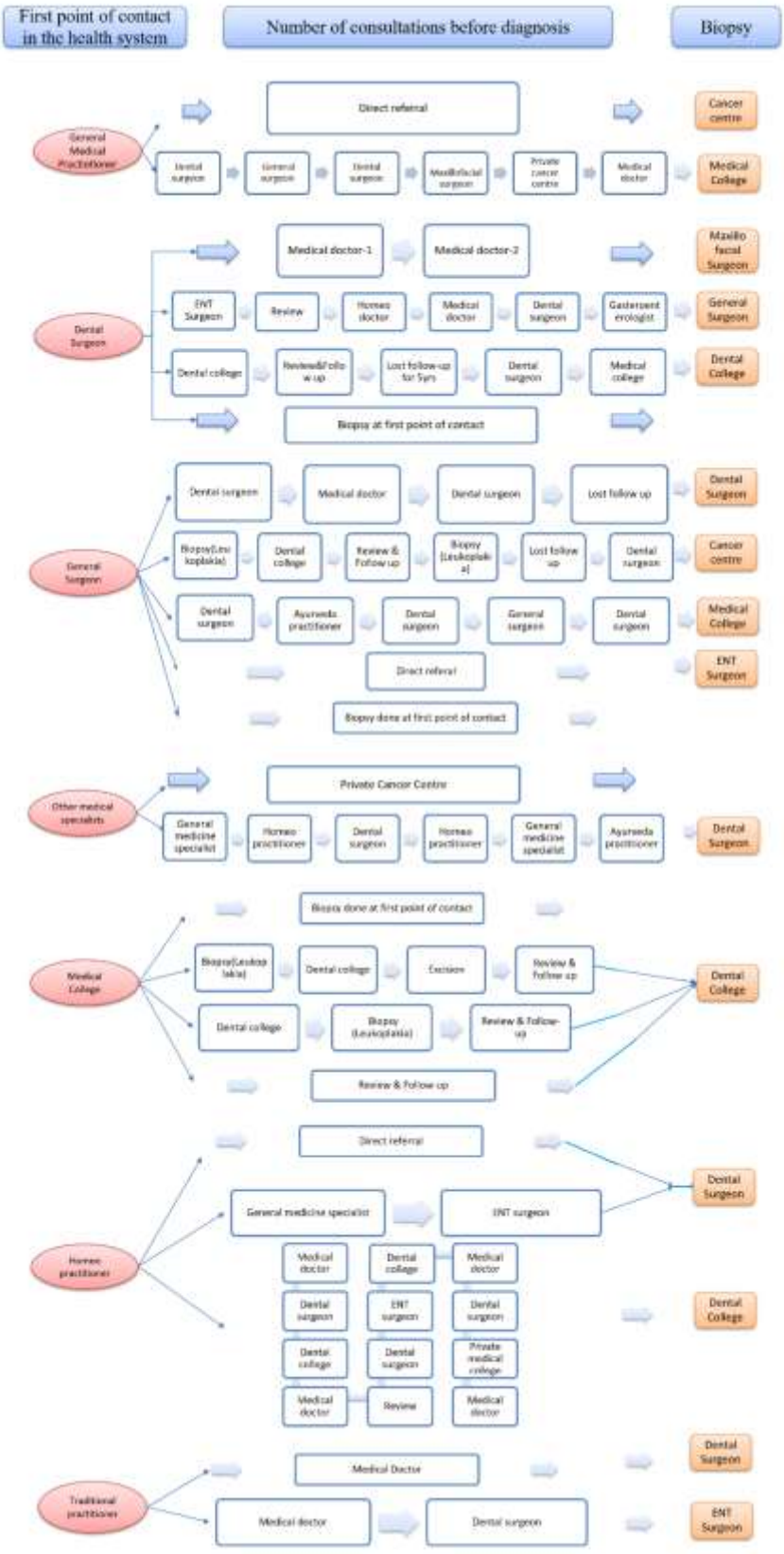


Figure 4.6: Diagram showing routes to diagnosis

4.1.1.8: Important events and incidents in life after symptom recognition

Participants were asked about important incidents and events that happened in their life in the period after they recognized the symptom in the oral cavity. The participants who reported such events as a response to that open-ended question were 15.33%. COVID 19 associated fear and lockdown were reported by more than half of the respondents (n=23) as a reason for postponing medical consultation for their oral symptoms. Other reported incidents include family functions like marriage and climatic conditions like the rainy season (Figure 4.7).

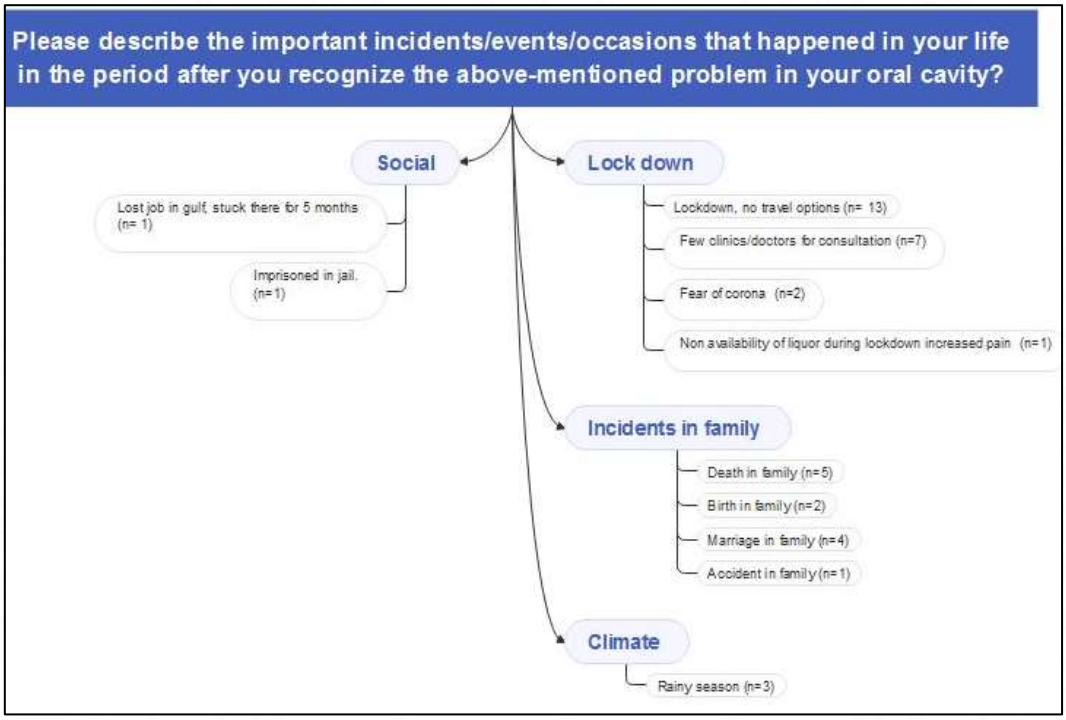


Fig 4.7: Important incidents/events/occasions that happened during the period in which participants recognized symptoms suggestive of oral cancer in their oral cavity

4.1.2: Patient and Diagnostic interval

4.1.2.1: Patient Interval

The patient interval was calculated in days, and the median (Interquartile range) patient interval was 92(37.50 -167.50) days (Figure 4.8). Mean was 123.29 ± 125.2

days and trimmed mean (excluding upper 5% values) was 106.90 days (Table 4.9). The value ranges from 0 to 923. A Kolmogorov-Smirnov test indicated that the patient interval do not follow a normal distribution, D (261) = .286, p < 0.001.

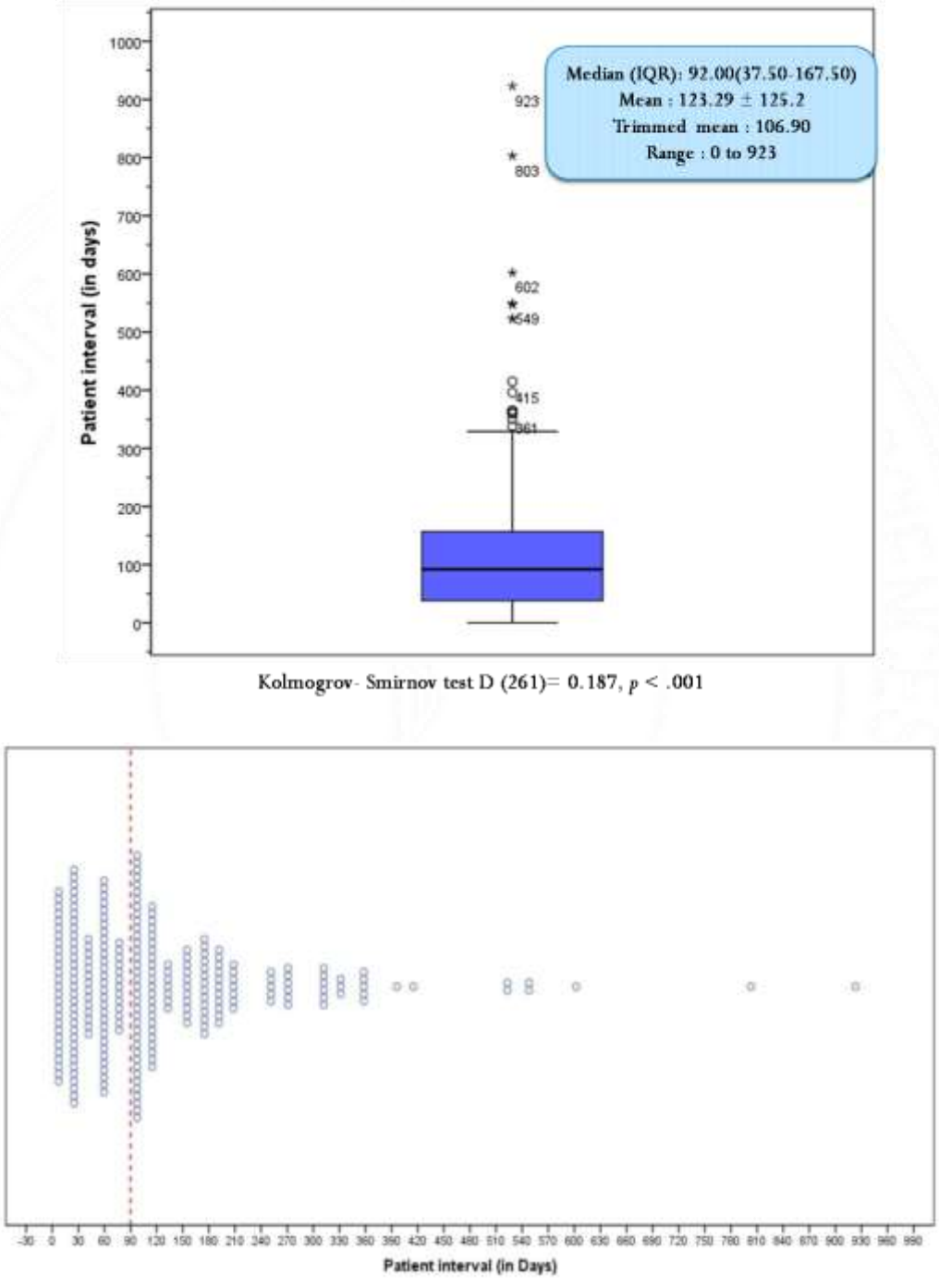


Figure 4.8: Patient interval of the study population

Table 4.9: Patient and Diagnostic interval

Interval	Frequency	Percentage	Median (IQR)	Mean±SD
Patient Interval			92.00(37.50-167.50)	123.29 ±125.2
≤ 90 days	120	46.0	34.00(21.00- 60.00)	40.17± 24.3
> 90 days	141	54.0	153.00(107.0-211.0)	194.04±132.9
Diagnostic interval			36.00(14.00 -76.50)	70.12 ± 122.3
≤30 days	110	42.1	12.00(7.00-19.00)	13.44 ± 8.16
>30 days	151	57.9	64.00(44.00-107.0)	111.41±147.6

As mentioned earlier in the methodology section, we dichotomized the patient interval data into 'less than or equal to 90 days' and 'more than 90 days'. This cut-off is closer to the median value of patient interval (92 days) among the study participants. The number of participants who had less than or equal to 90 days of patient interval was 120 (46%) and more than 90 days were 141 (54%).

4.1.2.2: Diagnostic interval

The median (Interquartile range) of the diagnostic interval was 36.00(14.00 to 76.50) days. The mode was 25 and the mean was 70.12 ± 122.3 days. The trimmed mean (5% highest values were excluded) was 45.21 days. The range of diagnostic interval was from 1 to 972. Diagnostic interval was non-normally distributed (Kolmogorov-Smirnov test, $D(261) = .179$, $p < 0.001$); with skewness of 4.76 (SE=0.15) and kurtosis of 26.43 (SE = 0.30) (Figure 4.9).

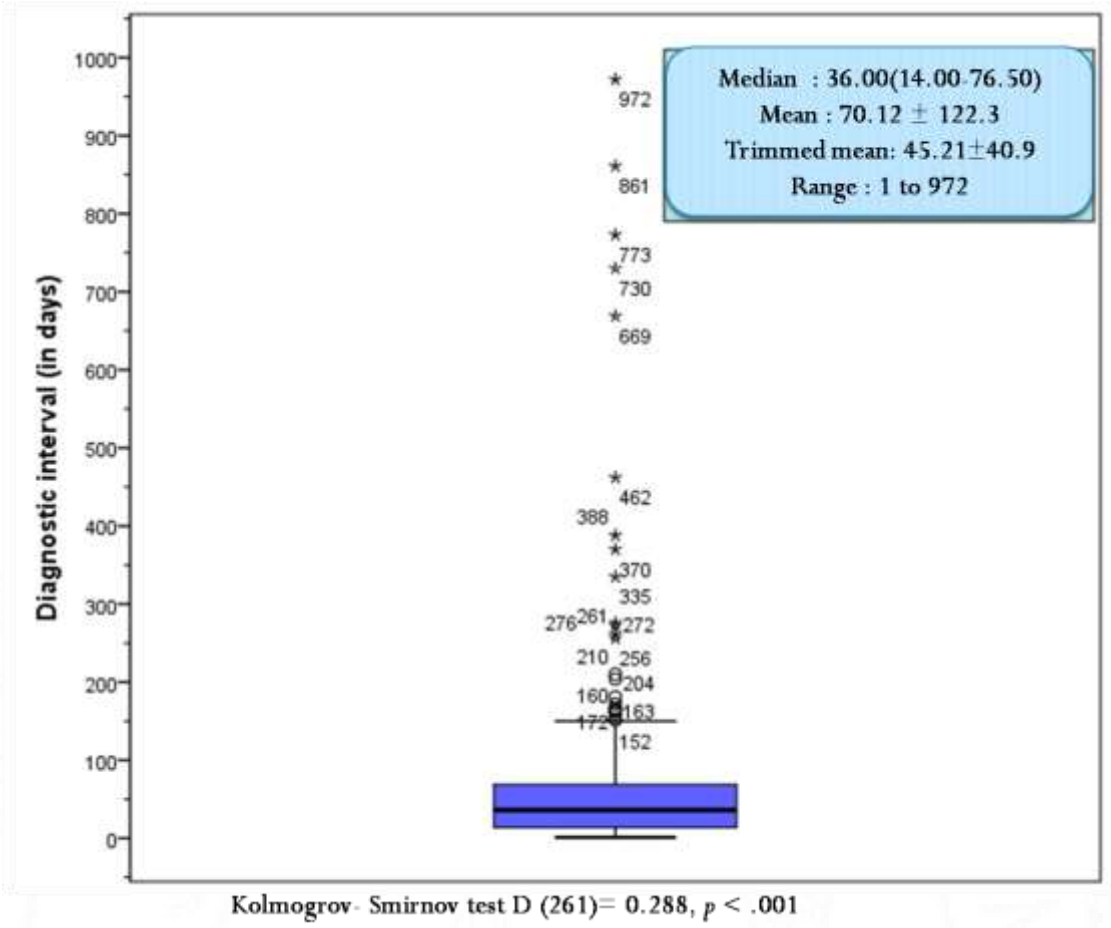


Figure 4.9: Diagnostic interval of the study population

Ninety percent of participants were diagnosed within 152 days after meeting the health care provider (HCP), and only 4.6% had diagnostic intervals for more than a year. The diagnostic interval of the total study population was grouped into two categories- 'Less than or equal to 30 days' and 'More than 30 days'. Participants with less than or equal to 30 days diagnostic interval were 110 (42.1%) and More than 30 days diagnostic interval was 151 (57.9%). This cut-off point is also closer to the median diagnostic interval value.

4.1.2.3: Impact of COVID-19 on Patient interval and Diagnostic interval

There were 45 patients (17.2%) in this study group who reported after a lockdown following COVID 19 outbreak (after 1stApril 2020). The median patient interval before COVID 19 lockdown period was 91.0 (32.25-158.25) days and after this period was 92.0 (64.0- 184.50) days. The diagnostic interval of those participants who

reported before COVID 19 lockdown was 37.0 (15.00- 78.50) days, whereas, after this span, it was 29.0 (10.50-65.00) days. Different study variables of these two groups were analyzed for any relevant findings, and no significant differences were observed. The median patient interval and diagnostic interval of important study variables are described in Table 4.10.

Table 4.10: Summary Statistics of Patient and Diagnostic intervals

Variable	n (%)	Patient interval Median (IQR)	Diagnostic interval Median (IQR)
Age			
Below 60 yrs	136 (52.1)	91.00(33.50-161.50)	41.00(18.25-80.00)
Above 60 yrs	125 (47.9)	92.00(46.00-172.50)	32.00(12.00-61.50)
Sex			
Female	76 (29.1)	90.00(31.25 –179.50)	38.50 (13.75-81.50)
Male	185 (70.9)	92.00 (44.50-158.00)	36.00(14.00-67.00)
House type			
Pucca	126(48.3)	78.50(31.75-124.50)	39.50(14.50-80.00)
Semi pucca/Kutcha	135(51.7)	103.00(57.00-184.00)	36.00(14.00-74.00)
Marital status			
Married	197(75.5)	91.00(35.50-158.00)	33.00(12.00-68.00)
Unmarried	12 (4.6)	107.50(66.50-151.50)	33.50(10.50-55.50)
Widow/Separated/ Divorced	52(19.9)	106.00(53.75-183.75)	53.00(29.25-95.00)
Tobacco smoking			
Current user	101 (38.7)	105.00(60.00-182.50)	38.00(13.50-63.50)
Former user	30 (11.5)	48.00(21.00-122.00)	23.50(9.00-113.75)
Never user	130 (49.8)	95.00(47.00-181.00)	35.50(15.00-80.50)
Betel quid chewing after symptom recognition			
Increased/No change	68 (26.1)	120.50(61.00-183.00)	32.00(13.00-62.50)
Decreased/Stopped	58 (22.2)	75.50(31.00-160.00)	48.00(12.75-86.75)
Pattern of medical consultation			
Regular check-ups	58 (22.2)	60.50(30.00-115.00)	28.50(14.00-61.25)
In case of illness	103 (39.5)	90.00(35.00-159.00)	39.00(13.00-80.00)
In case of emergency	100 (38.3)	116.50(61.00-189.00)	37.00(13.00-78.50)

Pattern of dental consultation			
Regular check-ups	14 (05.4)	39.00(24.75-133.75)	31.00(11.00-116.50)
In case of illness	85 (32.6)	61.00(30.00-117.00)	31.00(13.50-60.00)
In case of emergency	162(62.1)	106.00(60.00-184.00)	38.50(16.00-79.25)
First response			
Consult doctor	134 (51.3)	60.00(30.00-102.00)	36.00(12.00-64.50)
Home/Herbal remedy	80 (30.7)	112.00(61.00-184.00)	44.00(16.00-93.00)
Medicines from store	47 (18.0)	94.00(51.00-209.00)	32.00(14.50-51.00)
Previous experience with cancer			
Yes	63 (24.1)	60.00(30.00-157.00)	36.00(15.00-64.00)
No	198 (75.9)	92.00(59.00-170.00)	36.00(13.00-73.50)
Travel options to nearest healthcare facility			
Single vehicle transport	172(65.9)	81.50(31.00-152.75)	36.00(14.25-80.00)
Multiple vehicle transport	89 (34.1)	104.0(60.50-180.00)	39.00(13.50-62.00)
Distance to nearest healthcare facility			
≤ 3 kms	99 (37.9)	67.00(30.00-152.00)	32.00(13.00-67.00)
Above 3 kilometres	162 (62.1)	94.50(59.00-175.50)	39.00(14.00-79.25)
Time to reach nearest healthcare facility			
≤ 10 minutes	58 (22.2)	61.00(30.00-108.50)	31.00(12.75-79.25)
11 – 30 minutes	155 (59.4)	91.00(37.00-157.00)	41.00(16.00-80.00)
31 and above	48 (18.4)	120.50(85.00-232.75)	30.00(12.00-58.00)
First response to the current problem in oral cavity			
Attributed as minor	125 (47.9)	98.00(60.00-183.25)	34.50(12.00-77.75)
Home remedy	47 (18.0)	110.00(61.5-181.50)	34.00(13.00-59.50)
Consulted doctor	88 (33.7)	30.00 (14.00-45.00)	51.00(18.00-80.00)
Discussed present problem in oral cavity with someone before meeting HCP			
Yes	180 (70.0)	77.00(30.00-122.75)	37.00(15.00-75.75)
No	81 (30.0)	137.00(76.50-209.50)	33.00(12.50-86.00)
Reason for meeting HCP for current problem in oral cavity			
Pain	98 (37.5)	108.50(61.00-185.25)	31.50(12.00-61.00)
Discomfort to routine	118 (45.2)	94.50(54.25-159.50)	40.00(13.75-80.75)
Insistence by family/ friends	45 (17.2)	31.00 (16.00-61.00)	38.00(17.00-80.00)
Cancer stage			
Early (Stage 1 or 2)	83 (31.8)	45.00 (30.00-92.00)	37.00(15.00-79.00)
Late (Stage 3 or 4)	178 (68.2)	107.50(61.00-183.00)	36.00(13.00-76.25)
Found it embarrassing talking to the doctor about symptoms			
Yes	67 (25.7)	121.00(73.00-190.00)	42.00(18.00-89.00)
No	194 (74.3)	86.00(31.00-141.00)	36.00(12.75-68.25)

Found it difficult to get an appointment with a particular doctor			
Yes	55 (21.1)	105.00(48.00-184.00)	36.00(13.00-73.00)
No	206 (78.9)	91.00(35.25-156.25)	37.50(14.75-79.25)
Was too busy to make time to go to the doctor			
Yes	108 (41.4)	93.00(60.25-164.25)	28.50(12.00-54.75)
No	153 (58.6)	82.00(30.50-171.00)	44.00(16.50-86.00)
Had too many other things to worry about			
Yes	131 (50.2)	94.00(61.00-177.00)	32.00(12.00-60.00)
No	130 (49.8)	69.50(30.00-158.50)	41.50(15.75-85.25)
Was worried about what tests they might want to do			
Yes	99 (37.9)	112.00(82.99-183.00)	33.00(13.00-60.00)
No	162 (62.1)	69.00(31.00-152.25)	39.50(14.00-80.00)
Did not have a person to accompany me during hospital visits/consultations			
Yes	64 (24.5)	121.50(75.25-202.00)	36.50(18.00-60.75)
No	197 (75.5)	83.00(31.00-143.50)	36.00(12.50-79.00)
Did not want to be seen as somebody who makes a fuss			
Yes	62 (23.8)	92.00(60.00-183.25)	32.50(9.75-59.25)
No	199 (76.2)	91.00(31.00-153.00)	38.00(15.00-80.00)
Did not have money to consult a doctor/visit a hospital			
Yes	70 (26.8)	107.50(66.75-200.50)	38.00(18.00-70.25)
No	191 (73.2)	83.00(31.00-147.00)	36.00(13.00-77.00)
Was worried about what the doctor might find out			
Yes	87 (33.3)	126.00(90.00-190.00)	36.00(13.00-74.00)
No	174 (66.7)	69.00(31.00-122.00)	36.50(15.00-80.00)
Was worried about what others might think			
Yes	46 (17.6)	92.00(58.50-181.25)	31.50(10.75-45.50)
No	215 (82.4)	91.00(33.00-157.00)	39.00(15.00-80.00)
Comfortable in discussing symptoms with a nurse than a doctor			
Yes	87 (33.3)	120.00(61.00-183.00)	35.00(14.00-75.00)
No	174 (66.7)	80.50(31.00-153.75)	37.00(13.75-77.50)
Prefer alternative medicines than modern medicine			
Yes	59 (22.6)	122.00(90.00-190.00)	37.00(11.00-76.00)
No	143 (77.4)	80.50(31.00-153.00)	36.00(15.00-77.50)
Total participants	**261 (100)**	**92.00(37.50-167.50)**	**36.00(14.00-76.50)**

4.1.3: Patient interval and associated factors

4.1.3.1: Patient interval and Socio-demographic factors

4.1.3.1.1: Age

The mean age of participants having patients interval less than or equal to 90 days is 60.58± 11.96 yrs. and more than 90 days is 60.93± 12.62yrs. Independent sample t-test showed no significant difference in their means (t (259) = 0.231, p = .817).

4.1.3.1.2: Gender

The median (IQR) patient interval for females was 90.00 (31.25 –179.50) days and for males, it was 92.00(44.50-158.00) days. The interval ranges from 1 – 803 days in the case of males and 0 – 923 days in females. The male to female ratio in the 'less than or equal to 90 days' group was 2.1:1 and in the 'More than 90 days' group was 2.8:1.

4.1.3.1.3: Other relevant Socio-economic factors and Patient interval

No significant difference in socio-demographic profile was observed between participants having patient interval more than or equal to 90 days and those having patient interval less than 90 days except for the type of house. The pucca-type house was common in the 'below 90 days patient interval' category, and semi pucca/ kutcha type houses were reported more in the 'above 90 days patient interval' group. A significant association was obtained between house type and patient interval with Chi-square statistics χ^2 (1) = 6.26, p= .012. Participants living in semi-pucca/ kutcha houses had more chances of having a patient interval of more than 90 days compared to those living in pucca houses (OR, 1.871; 95% CI, 1.1 to 3.1). A Kruskal-Wallis H test showed that there was a statistically significant difference in patient interval between the type of house, H (1) = 6.13, p= .013, with a mean rank patient interval of 119.03 for those living in a pucca house and 142.17 for those participants with semi pucca/ kutcha type of house. The association of socio-demographic factors of the study population and the patient interval was described in Table 4.11.

Table 4.11: Socio-demographic profile of study population and Patient interval

Variable Categories	≤90 days patient interval		>90 days patient interval	
	Female n (%)	Male n (%)	Female n (%)	Male n (%)
Age	**60.58±11.96 years***		**60.93±12.6 years***	
Less than 40	0 (0.0)	9(100.0)	1 (14.3)	6 (85.7)
41 – 50	6 (46.2)	7 (53.8)	2 (7.7)	24 (92.3)
51 – 60	14 (34.1)	27 (65.9)	9 (22.5)	31 (77.5)
61 – 70	11 (32.4)	23 (67.6)	11 (30.6)	25 (69.4)
71 – 80	7 (38.9)	11 (61.1)	10 (45.5)	12 (54.5)
81 and above	1 (20.0)	4 (80.0)	4 (40.0)	6 (60.0)
Religion				
Hindu	29 (34.5)	55 (65.5)	28 (27.7)	73 (72.3)
Muslim	9 (36.0)	16 (64.0)	9 (30.0)	21 (70.0)
Christian	1 (9.1)	10 (90.9)	0 (0.0)	10 (100)
Caste				
General class	6 (24.0)	19 (76.0)	2 (9.1)	20 (90.9)
OBC	23 (31.9)	49 (68.1)	24 (25.3)	71 (74.7)
Scheduled Caste	3 (27.3)	8 (72.7)	2 (25.0)	6 (75.0)
Scheduled Tribe	7 (58.3)	5 (41.7)	9 (56.3)	7 (43.7)
Place of residence				
Panchayath	34 (34.3)	65 (65.7)	28 (24.6)	86 (75.4)
Muncipality	5 (25.0)	15 (75.0)	8 (34.8)	15 (65.2)
Corporation	0 (0.0)	1 (100)	1 (25.0)	3 (75.0)
Education				
No formal education	22 (73.3)	8 (26.7)	21 (47.7)	23 (52.3)
Lower primary	6 (31.6)	13 (68.4)	7 (24.1)	22 (75.9)
Upper primary	6 (18.2)	27 (81.8)	3 (10.7)	25 (89.3)
High school	3 (10.0)	27 (90.0)	5 (15.2)	28 (84.8)
Pre-degree&Degree	2 (28.6)	5 (71.4)	1 (16.7)	5 (83.3)
PG & Professional	0 (0.0)	1 (100)	0 (0.0)	1 (100)
Education duration (in years)	**5.45±4.2 years***		**4.79±4.2 years***	

Occupation				
Daily wage	19 (26.0)	54 (74.0)	20 (21.1)	75 (78.9)
Agriculture	2 (14.3)	12 (85.7)	2 (9.1)	20 (90.9)
Govt job	2 (40.0)	3 (60.0)	0 (0.0)	1 (100)
Private office job	1 (14.3)	6 (85.7)	2 (33.3)	4 (66.7)
House wife	15 (100)	0 (0.0)	11 (100)	0 (0.0)
Others	0 (0.0)	2 (100)	2 (33.3)	4 (66.7)
Ration card type				
APL	3 (12.0)	22 (88.0)	7 (23.3)	23 (76.7)
BPL	33 (37.9)	54 (62.1)	29 (27.4)	77 (72.6)
BPLAAY	3 (37.5)	5 (62.5)	1 (25.0)	4 (75.0)
Monthly Income				
≤5000/-	23 (38.3)	37 (61.7)	28 (35.4)	51 (64.6)
>5000/-	16 (26.7)	44(73.3)	9 (14.5)	53 (85.5)
House type**				
Pucca	18 (26.5)	50 (73.5)	16 (27.6)	42 (72.4)
Semi pucca/Kutcha	21 (40.4)	31 (59.6)	21 (25.3)	62 (74.7)
Marital status				
Married	20 (21.1)	75 (78.9)	14 (13.7)	88 (86.3)
Unmarried	2 (50.0)	2 (50.0)	0 (0.0)	8 (100)
Widow/Separated/ Divorced	17 (81.0)	4 (19.0)	23 (74.2)	8 (25.8)
Total number of members in family		**4.46±1.9***		**4.04±1.9***
Members currently staying with		**4.13±1.8***		**3.64±1.9***
Type of family				
Nuclear	25 (28.7)	62 (71.3)	24 (22.2)	84 (77.8)
Joint	14 (42.4)	19 (57.6)	13 (39.4)	20 (60.6)
Total	**39 (100)**	**81 (100)**	**37 (100)**	**104 (100)**

* Mean± Standard Deviation ** p = .012, Unadjusted OR =1.871 (1.1 – 3.1)

4.1.3.2: Habit related factors

Association of habit patterns with patient interval was appraised (Table 4.12). The habit of tobacco smoking, betel quid chewing, pan masala use, and alcohol consumption were assessed. Among participants with a patient interval of more than 90 days, 52.5% were ‘ever smokers’ (44.7% current smokers, 7.8% former smokers)

and 47.5% were 'never smokers' and this association was found to be statistically significant (p=.033).

Table 4.12: Association of Habit related factors and Patient interval

Variable	≤ 90 days n (%)	> 90 days n (%)	Total n (%)	Chi-square *p*-value
Habit status at the time of symptom recognition				
Tobacco smoking				
Current smoker	38 (37.6)	63 (62.4)	101 (100)	
Former smoker	19 (63.3)	11 (36.7)	30 (100)	.033*
Never smoker	63 (48.5)	67 (51.5)	130 (100)	
Duration of smoking††	**30.84±16.6**	**32.62±14.5**	**31.85±15.4**	
Betel quid chewing				
Current user	56 (44.4)	70 (55.6)	126 (100)	
Former- user	9 (40.9)	13 (59.1)	22 (100)	.713
Non- user	55 (45.8)	58 (41.1)	113 (43.3)	
Duration of chewing††	**32.58±15.9**	**34.27±15.9**	**33.53±15.89**	
Pan masala usage				
Current user	11 (50.0)	11 (50.0)	21 (100)	
Former- user	1 (50.0)	1 (50.0)	2 (100)	.917
Non – user	108(45.6)	129 (54.4)	238 (100)	
Duration of use††	**14.42±9.4**	**14.67±8.1**	**14.54±8.6**	
Alcohol usage				
Current user	51 (41.8)	71 (58.2)	122 (100)	
Former- user	5 (45.5)	6 (54.5)	11 (100)	.429
Non –user	64 (50.0)	64 (50.0)	128 (100)	
Duration of use††	**29.93±14.1**	**28.86±13.5**	**29.31±13.7**	
Habit pattern after symptom recognition				
Tobacco smoking (n=101)				
Increased/No change	12 (30.8)	27 (69.2)	39 (100)	.259
Decreased/Stopped	26 (41.9)	36 (58.1)	62 (100)	
Betel quid chewing (n=126)				
Increased/No change	22 (32.4)	46 (67.6)	68 (100)	.006*
Decreased/Stopped	33 (56.9)	25 (43.1)	58 (100)	
Pan masala usage (n=22)				
Increased/No change	2 (20.0)	8 (80.0)	10 (100)	.030†
Decreased/Stopped	9 (75.0)	3 (25.0)	12 (100)	
Alcohol usage (n=122)				
Increased/No change	36 (37.9)	59 (62.1)	95 (100)	.101
Decreased/Stopped	15 (55.6)	12 (44.4)	27 (100)	

* p value less than .05 † Fisher exact test †† Duration in years

More than half of the participants were ever users of betel quid (56.7%), alcohol (50.6%), and smoking tobacco products (50.2%) but only 8.8% reported to have used pan masala. Among current users, 60.8% (n=62)of smokers,46% (n=58)of betel quid users, 56.5% (n=13) of pan masala users, and 22.8% (n=28) of alcohol users either reduced or stopped that habit, while the remaining participants have either continued or increased the frequency after identifying the symptoms suggestive of cancer. Those betel quid users who have reported to have continued or increased chewing after identifying the cancer symptoms were 2.8 times more likely to have patient interval more than 90 days compared to those who have decreased or quit the habit (OR, 2.76 95%CI, 1.3 to 5.7).

A Kruskal-Wallis H test showed that there was a statistically significant difference in patient interval between the change in betel quid usage pattern after symptom recognition, H (1) = 5.34, p = 0.021, with a mean rank of 70.44 for those 'who increased the chewing or did not change the frequency' and 55.36 for participants 'who either reduced the frequency or stopped the habit'.

There was strong evidence of association on Chi-square analysis between patient interval and habit status of the participant. Significant difference in patient interval exists between habitués and non- habitués ($\chi^2(1)= 5.40$, p=.020). There were 2.7 times more chances for habitués for getting patient interval more than 90 days when compared with non- habitués (OR, 2.74; 95% CI, 1.1 to 6.6).

4.1.3.3: Healthcare-related factors

Healthcare-related factors such as general health-seeking behaviors, the initial response to any general medical conditions, presence of comorbidities, previous experience with cancer patients, transportation, travel duration, and distance to health facility were analyzed for exploring possible associations with patient interval (Table 4.13). Those participants who did not have any co-morbidities at the time of symptom recognition were presented with prolonged patient interval (Median (IQR) = 92.00 (60.25 – 149.75) days) compared to those with co-morbidities (Median (IQR) = 84.50 (44.75 – 193.25) days [Kruskal-Wallis test showed no significant difference (H=.002, df=1, p=.961)].

Table 4.13: Association of Access and pattern of Healthcare-related factors and Patient interval

Variable	≤ 90 days n (%)	> 90 days n (%)	Chi-square *p*-value	Unadjusted OR (95% CI)
Pattern of medical consultation				
Health screening at intervals	37 (63.8)	21 (36.2)	<.001**	(Ref)
Medical consultation for illness	53 (51.5)	50 (48.5)		1.662(0.9-3.2)
Urgent medical care only	30 (30.0)	70 (70.0)		**4.111(2.1-8.2)**
Pattern of dental consultation				
Dental screening at intervals	10 (71.4)	4 (28.6)	<.001**	(Ref)
Dental consultation for illness	54 (63.5)	31 (36.5)		1.435(0.4- 4.9)
Urgent dental care only	56 (34.7)	106 (65.4)		**4.732(1.4-15.8)**
Initial response to general health problems				
Consult physician /health-worker	65 (67.0)	32 (33.0)	<.001*	(Ref)
Home remedy/Herbal medicines	38 (33.0)	77 (67.0)		**3.870(2.0-7.6)**
Medicines from store	17 (34.7)	32 (65.3)		**4.471(2.1-9.5)**
Co morbidities				
Present	48 (50.5)	47 (49.5)	.265	
Absent	72 (43.4)	94 (56.6)		
Previous experience with cancer				
Yes	39 (61.9)	24 (38.1)	.007*	(Ref)
No	81 (40.9)	117 (59.1)		**2.377(1.3-4.3)**
Travel options to nearest healthcare facility				
Single vehicle transport	89 (51.7)	83 (48.3)	.009*	(Ref)
Multiple vehicle transport	31 (34.8)	58 (65.2)		**2.006(1.2-3.4)**
Distance to nearest healthcare facility				
≤ 3 kilometres	58 (58.6)	41 (41.4)	.001*	(Ref)
Above 3 kilometres	62 (38.3)	100(61.7)		**2.282(1.4-3.8)**
Time to reach nearest healthcare facility				
≤ 10 minutes	36 (62.1)	22 (37.9)		(Ref)
11 – 30 minutes	72 (46.5)	83 (53.5)	.001*	1.886(1.0- 3.5)
31 and above	12 (25.0)	36 (75.0)		**4.909(2.1-11.4)**
Total	**120 (100)**	**141 (100)**		

OR – Odds ratio * *p* value less than .05 ** *p* value less than .001

4.1.3.4: Financial factors

Among those participants who were earning members of the family, 57% reported a longer patient interval. Though no significant association was observed between the presence of debts and patient interval, 62.5% of those with debts had patient interval higher than 90 days. No statistically significant association was observed with the presence of insurance schemes and the duration of the patient interval.

4.1.3.5: Factors associated with the current problem in the oral cavity

Various factors associated with the current problem in the oral cavity with patient interval were assessed and the following were found to be statistically significant. They include 'discussing about the current problem in the oral cavity with significant others before meeting a healthcare provider', 'Reason behind meeting a healthcare provider', 'patient's first response to the current problem in the oral cavity', and 'stage of cancer'. Table 4.14 provides further details about the current problem in the oral cavity with Patient interval.

Table 4.14: Association of the current problem in the oral cavity and Patient interval

Variable	≤ 90 days n (%)	> 90 days n (%)	Chi-square *p* value	Unadjusted OR (95% CI)
Discussed present problem in oral cavity with someone before meeting HCP				
Yes	99 (82.5)	81 (57.4)	<.001**	(Ref)
No	21 (17.5)	60 (42.6)		**3.492(1.96-6.2)**
Time interval for first discussion				
Median (IQR) days	7 (3 – 15)	30 (14-45)		
Reason for meeting HCP for current problem in oral cavity				
Pain	36 (30.0)	62 (44.0)		**11.19(4.3-29.0)**
Discomfort to daily routine	45 (37.5)	73 (51.8)	<.001**	**10.54(4.1-26.9)**
Insistence by family/friends	39 (32.5)	6 (4. 3)		(Ref)
Cancer stage				
Early (Stage 1&2)	60 (50.0)	23 (16.3)	<.001**	(Ref)
Late (Stage 3&4)	60 (50.0)	118 (83.7)		**5.130(2.9-9.1)**
First response to the current problem in oral cavity				
Ignored the symptoms	54 (45.0)	80 (56.7)		(Ref)
Tried local remedies	27 (22.5)	53 (37.6)	<.001**	1.325 (0.7-2.4)
Consulted Doctor	39 (32.5)	8 (5.7)		**0.138(.06-0.32)**

HCP – Health Care Personnel OR- Odds ratio ** *p*-value less than .001

The patient interval varies across different sites in the oral cavity. All the patients affected with carcinoma of the base of the tongue were having patient interval of more than 90 days. But the majority of patients (60.8%) with carcinoma of other parts of the tongue had patient interval lesser than 90 days. Very strong evidence of association exists between patient interval and discussion about oral problems with someone (Table 4.13). More than half of those who discussed their problems with friends/relatives had high patient interval (Figure 4.10).

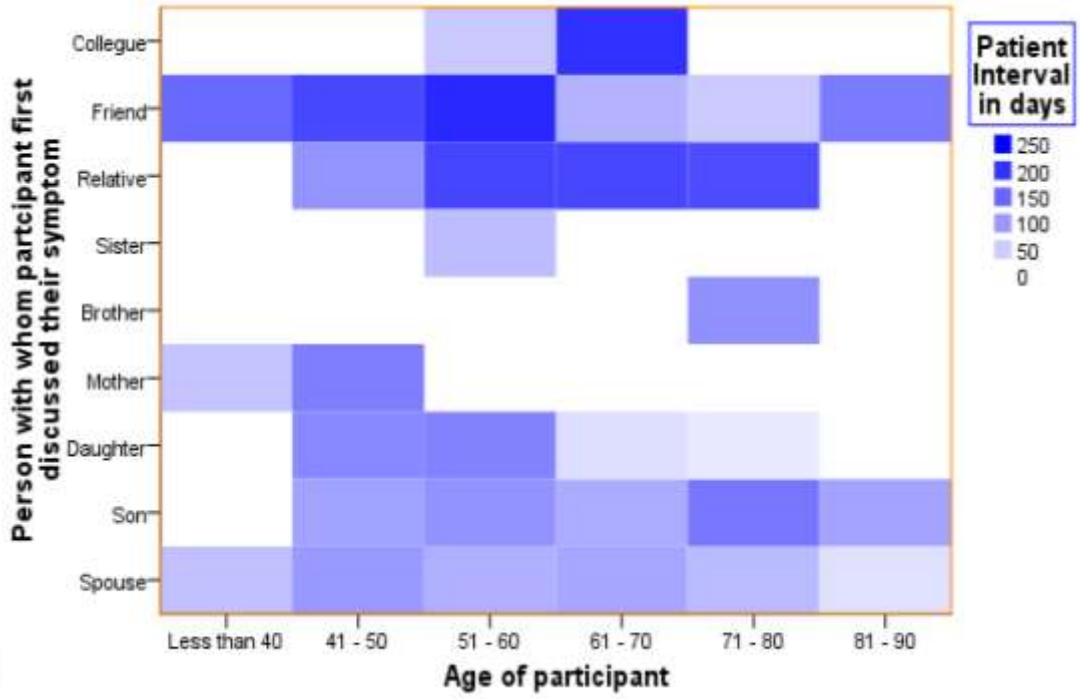


Figure 4.10: Heat map showing Patient interval and Person with whom participants first discussed their symptom across different age groups

Time taken for the first discussion about their symptom with significant others was analyzed for possible association with patient interval. Out of 180 respondents who discussed their problems with significant others before meeting an HCP, 55.6% discussed within one month of noticing the symptoms and 44.4% took more than one month for discussion. Among those who discussed early, 76% had patient intervals less than 90 days. Most persons (71.3%) who discussed their problems after one

month had prolonged patient interval ($\chi^2(1)= 40.09$, $p<.001$). Those who discussed after one month of symptom recognition were more likely to have prolonged patient interval than those who discussed within a month (OR, 7.85; 95% CI, 4.03 to 15.29).

4.1.3.6: Help-seeking behavior

Association between patient interval and participant endorsed barriers towards help-seeking was also analyzed (Table 4.15). The majority of participants who endorsed these barriers as a deterrent to medical consultation had patient interval of more than 90 days.

Table 4.15: Endorsement of barriers to help-seeking and patient interval in oral cancer patients

Endorsement of barriers to help-seeking	p-value	Unadjusted OR (95%CI)
Found it embarrassing talking to the doctor about symptoms*	.005	2.283(1.3-4.1)
Was too busy to make time to go to the doctor*	.017	1.863(1.1-3.1)
Had too many other things to worry about*	.006	2.014 (1.2-3.3)
Was worried about what tests they might want to do *	<.001	3.094(1.8-5.3)
Did not have a person to accompany me during hospital visits/consultations*	.009	2.268(1.2-4.1)
Did not have money to consult a doctor/visit a hospital*	.012	2.109(1.2-3.7)
Was worried about what the doctor might find out*	<.001	3.505(2.0-6.2)
Comfortable in discussing symptoms with a nurse than a doctor*	.048	1.759(1.03-3.0)
Prefer alternative medicines than modern medicine*	.003	2.570(1.4-4.8)

* Yes Vs No Reference category is 'No'

4.1.4: Diagnostic interval and associated factors

4.1.4.1: Socio demographic factors

The median (IQR) diagnostic interval for males was 36.00(13.75-81.50) days and for females was 36.00 (14.00-65.00) days (Figure 4.11).

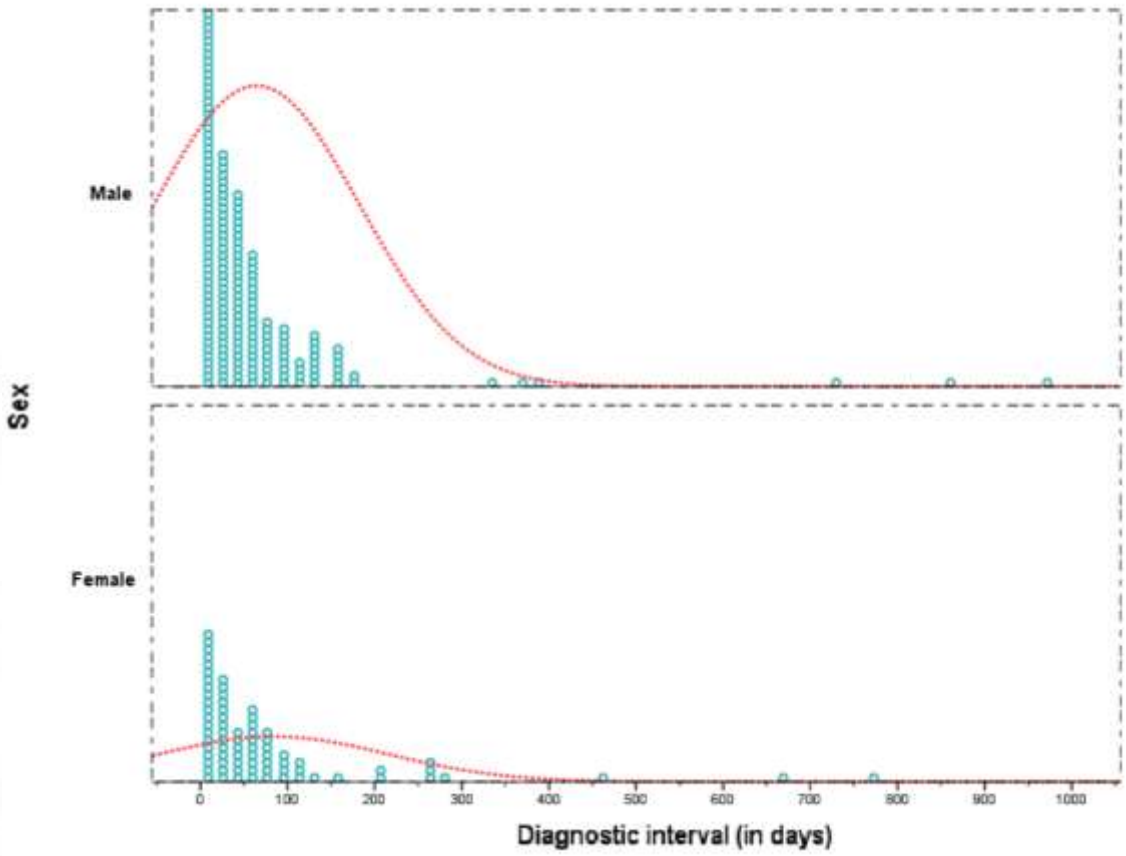


Figure 4.11: Diagnostic interval and Sex

Association of various socio-demographic factors with diagnostic interval was provided in Table 4.16. The age and sex of the participants were not significantly related to the diagnostic interval, whereas the significant association was observed with Caste ($\chi^2(3)= 9.714$, p= .021) and Marital status ($\chi^2(1)= 4.128$, p= .042).

Table 4.16: Association of Socio demographic factors and Diagnostic interval

Variable		≤ 30 days n (%)	> 30 days n (%)	Total	Chi-square test *p* value
Age					
	≤60 yrs	50 (36.8)	86 (63.2)	136 (100)	.066
	> 60 yrs	60 (48.0)	65 (52.0)	125 (100)	
Sex					
	Female	27 (35.5)	49 (64.5)	76 (100)	.165
	Male	83 (44.9)	102 (55.1)	185 (100)	
Caste					
	General	15 (31.9)	32 (68.1)	47 (100)	
	Other Backward Caste	81 (48.5)	86 (51.5)	167 (100)	.021*
	Scheduled Caste	8 (42.1)	11 (57.9)	19 (100)	
	Scheduled Tribe	6 (21.4)	22 (78.6)	28 (100)	
Education level					
	No formal education	25 (33.8)	49 (66.2)	74 (100)	
	Lower primary	21 (43.8)	27 (56.3)	48 (100)	
	Upper primary	28 (45.9)	33 (54.1)	61 (100)	.635
	High school	30 (47.6)	33 (52.4)	63 (100)	
	Pre degree & Degree	5 (38.5)	8 (61.5)	13 (100)	
	PG & Professional	1 (50.0)	1 (50.0)	2 (100)	
Occupation					
	Daily wage	69 (41.1)	99 (58.9)	168 (100)	
	Agriculture	15 (41.7)	21 (58.3)	36 (100)	
	Govt job	4 (66.7)	2 (33.3)	6 (100)	
	Private office job	6 (46.2)	7 (53.8)	13 (100)	.378
	Job abroad	0 (0. 0)	5 (100)	5 (100)	
	House wife	13 (50.0)	13 (50.0)	26 (100)	
	Others	3 (42.9)	4 (57.1)	7 (100)	
Income					
	≤ 5000 rupee	53 (38.1)	86 (61.9)	139 (100)	.161
	> 5000 rupee	57 (46.7)	65 (53.3)	122 (100)	
Marital status					
	Married	90 (45.7)	107 (54.3)	197 (100)	.042*
	Single	20 (31.3)	44 (68.8)	64 (100)	
Total		**110 (42.1)**	**151 (57.9)**	**261 (100)**	

* *p* value less than .05

4.1.4.2: Habit related factors and Diagnostic interval

The Association of various habit-related factors with diagnostic interval was analyzed and it is presented in Table 4.17. None of the factors were significantly associated with diagnostic interval.

Table 4.17: Association of various Habit related factors and Diagnostic interval

Variable	≤ 30 days n (%)	> 30 days n (%)	Total n (%)	Chi-square *p* value
Habit status at the time of symptom recognition				
Tobacco smoking				
Current user	40 (39.6)	61 (60.4)	101 (100)	
Ex- user	17 (56.7)	13 (43.3)	130 (100)	.227
Non – user	53 (40.8)	77 (59.2)	30 (100)	
Duration of smoking†	**30.91±15.1**	**32.57±15.7**	**31.85±15.4**	
Betel quid chewing				
Current user	55 (43.7)	71 (56.3)	126 (100)	
Ex- user	10 (45.5)	12 (54.5)	22 (100)	.792
Non- user	45 (39.8)	68 (60.2)	113 (100)	
Duration of chewing†	**34.66±15.4**	**32.64±16.3**	**33.53±15.89**	
Pan masala usage				
Current user	8 (38.1)	13 (61.9)	21 (100)	
Ex- user	1 (50.0)	1 (50.0)	2 (100)	.905††
Non – user	101 (42.4)	137 (57.6)	238 (100)	
Duration of pan masala use†	**15.89±7.6**	**13.73±9.3**	**14.54±8.6**	
Alcohol usage				
Current user	47 (38.8)	74 (61.2)	121 (100)	
Ex- user	5 (45.5)	6 (54.5)	11 (100)	.603
Non –user	58 (45.5)	71 (55.0)	129 (100)	
Duration of alcohol use†	**30.32±14.8**	**28.64±13.1**	**29.31±13.7**	
Habit pattern after symptom recognition				
Tobacco smoking (n=101)				
Increased/No change	15 (38.5)	24 (61.5)	39 (100)	.852
Decreased/Stopped	25 (40.3)	37 (59.7)	62 (100)	
Betel quid chewing (n=126)				
Increased/No change	31 (45.6)	37 (54.4)	68 (100)	.780
Decreased/Stopped	25 (43.1)	33 (56.9)	58 (100)	
Pan masala usage (n=22)				
Increased/No change	3 (30.0)	7 (70.0)	10 (100)	.675††
Decreased/Stopped	5 (41.7)	7 (58.3)	12 (100)	
Alcohol usage (n=122)				
Increased/No change	36 (37.9)	59 (62.1)	95 (100)	.539
Decreased/Stopped	12 (44.4)	15 (55.6)	27 (100)	

† Mean and Standard deviation in Years †† Fisher exact test

4.1.4.3: Healthcare related factors

Access to the nearest healthcare facility like transport options, distance to the healthcare facility, time taken to reach the nearest health center, etc. was not found to be significantly associated with diagnostic interval. Similarly, the pattern of medical or dental consultation, first response to general health problems were also not associated with diagnostic interval (Table 4.18).

4.1.4.4: Factors associated with Current problem in oral cavity

Cancer site, cancer stage, and presence of pre-existing co-morbidities were not significantly associated with diagnostic interval. The type of HCP whom the patient first met to discuss their problem was significantly associated with diagnostic interval ($p<.001$). Other factors which were significantly associated with diagnostic interval include 'Number of HCPs met during the diagnostic journey' and 'Type of advice given by HCP' (Table 4.19).

Table 4.18: Access and pattern of Healthcare related factors with Diagnostic interval in oral cancer patients

Variable	≤ 30 days n (%)	> 30 days n (%)	Chi-square test *p* value
Pattern of medical consultation			
Regular check-ups	31 (53.4)	27 (46.6)	.142
In case of illness	40 (38.8)	63 (61.2)	
In case of emergency	39 (39.0)	61 (61.0)	
Pattern of dental consultation			
Regular check-ups	7 (50.0)	7 (50.0)	.296
In case of illness	41 (48.2)	44 (51.8)	
In case of emergency	59 (38.6)	94 (61.4)	
First response to general health problems			
Consult physician /health-worker	42(43.3)	55 (56.7)	.624
Home remedy/Herbal medicines	45 (39.1)	70 (60.9)	
Medicines from store	23 (46.9)	26(53.1)	
Previous experience with cancer			
Yes	25 (39.7)	38 (60.3)	.617
No	85 (42.9)	113(57.1)	
Travel options to nearest healthcare facility			
Single vehicle transport	75(43.6)	97 (56.4)	.507
Multiple vehicle transport	35 (39.3)	54 (60.7)	
Distance to nearest healthcare facility			
≤ 3 kilometres	47 (47.5)	52 (52.5)	.173
Above 3 kilometres	63 (38.9)	99 (61.1)	
Time to reach nearest healthcare facility			
≤ 10 minutes	28 (48.3)	30 (51.7)	
11 – 30 minutes	58 (37.4)	97 (62.6)	.171
31 and above	24 (50.0)	24 (50.0)	
Total	**110 (42.1)**	**151 (57.9)**	

* *p* value less than .05

Table 4.19: Association of Diagnostic interval with factors related to current problem in oral cavity and Meeting of HCP

Variable	≤ 30 days	> 30 days	Total	Fisher exact test
	n (%)	n (%)	n (%)	*p* value
Type of HCP first met				
Medical doctor	29 (33.3)	58 (66.7)	87(100)	
Dental surgeon	33 (44.6)	41 (55.4)	74 (100)	< .001*
Other medical specialist	47(58.8)	33 (41.3)	80 (100)	
Other systems of medicine	1(5.0)	19 (95.0)	20 (100)	
Advice by HCP				
Ignored symptom	10 (12.3)	71 (87.7)	81 (100)	< .001*
Advised biopsy	61 (59.8)	41 (40.2)	102 (100)	
Referred to higher centre	39 (50.0)	39 (50.0)	78 (100)	
Number of HCPs consulted in the diagnostic pathway				
One	27 (75.0)	9 (25.0)	36 (100)	
Two	51 (54.8)	42 (45.2)	93 (100)	
Three	20 (25.6)	58 (74.4)	78 (100)	< .001*
Four & above	12 (22.2)	42 (77.8)	54 (100)	
Cancer site				
Lip	2 (28.6)	5 (71.4)	7 (100)	
Tongue	52 (47.7)	57 (52.3)	109 (100)	
Gum	10 (40.0)	15 (60.0)	25 (100)	.743†
Floor of mouth	5 (38.5)	8 (61.5)	13 (100)	
Palate	4 (44.4)	5 (55.6)	9 (100)	
Other unspecified	37 (37.8)	61 (62.2)	98 (100)	
Cancer stage				
Early (Stage 1&2)	36 (43.4)	47 (56.6)	83 (100)	.929
Advanced (Stage 3&4)	74 (41.6)	104 (58.4)	178 (100)	
Presence of co-morbidities				
Yes	46 (48.4)	49 (51.6)	95 (100)	.120†
No	64 (38.6)	102 (61.4)	166 (100)	
Total	**110 (42.1)**	**151 (57.9)**	**261 (100)**	

HCP – Health Care Personnel * *p* value less than .05 † Fischer exact test

4.1.5: Factors associated with the patient interval using Binary logistic regression

Binary logistic regression analysis was performed for identifying the possible predictors for the patient interval. Before performing the analysis, we verified the various assumptions which need to be satisfied for formulating a prediction model and found the following. The Dependent variable was dichotomous and the Independent variables were categorical. Observations were independent, with mutually exclusive categories. There was an absence of high intercorrelations (multicollinearity) among independent variables, with Variance Inflation Factor (VIF) less than 2. Also, the sample size was adequate for the analysis.

The model was built by the purposeful selection of covariates. Variables included in the model were those having a statistically significant relation with patient interval (Chi-square statistics p value< .05) and those variables were found to be predictors of patient interval based on existing literature. Binary logistic regression analysis was performed with all those variables identified based on the above conditions. After fitting the model, Wald statistics for each covariate were noted and variables with a p-value above 0.25 were eliminated from the full model and a new model was created. We compared the values of Log Likelihood ratio, Nagelkerke R Square test, improvement in hit ratio (percentage correctness), and Hosmer and Lemeshow test for significance (p>.05) of the new model with the previous model. We compared the coefficients of each variable in the new model with the values in the full model. After repeatedly deleting, refitting, and verifying, we formulated a best-fitting main effect model (Figure 4.12).

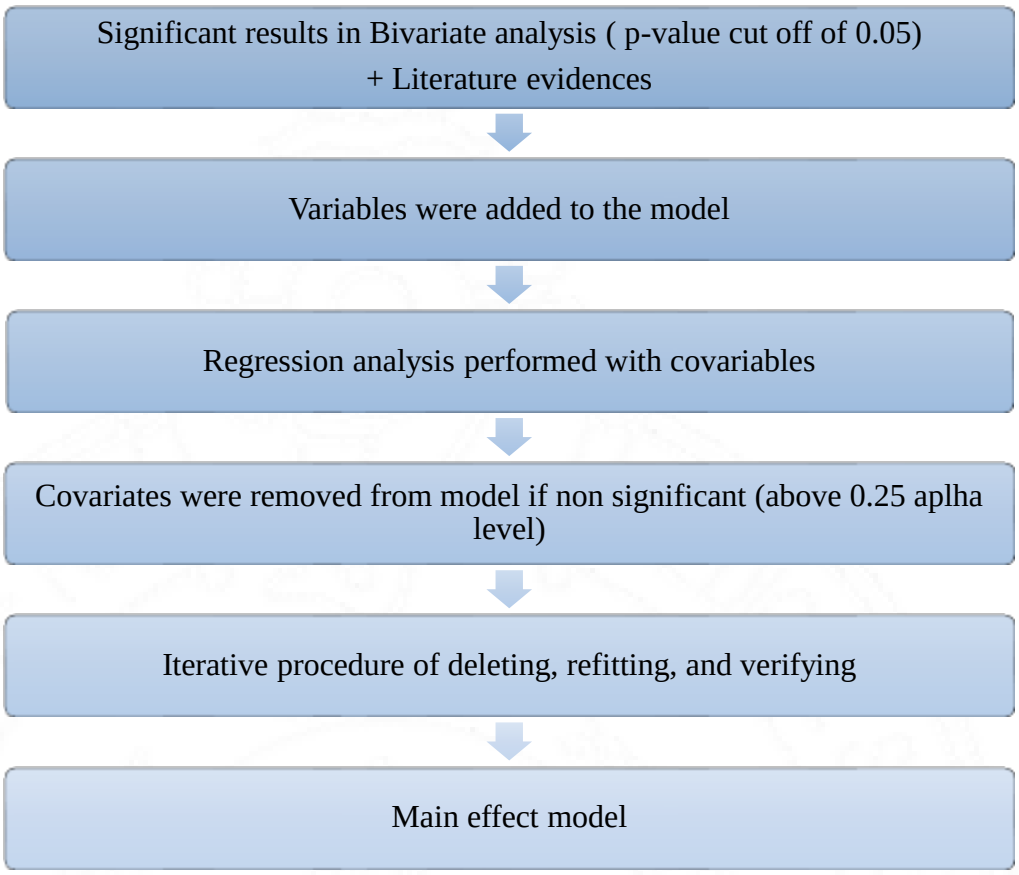


Figure 4.12: Steps in Binary logistic regression

The logistic regression was performed to investigate if 'Tobacco use pattern at the time of symptom recognition', 'Cancer stage', 'Reason for meeting HCP for current problem in oral cavity', 'Was worried about what the doctor might find out', 'Time to reach nearest healthcare facility' and 'Distance to nearest healthcare facility' are factors that predict the Patient interval. The outcome of interest was Patient interval 'Less than or equal to 90 days' or 'More than 90 days'. The Hosmer and Lemeshow goodness of fit was not significant ($\chi^2(8) = 4.806$, p=.778), indicating the model is correctly fitting. It helps to determine whether the model adequately describes the data. A significant value less than 0.05 indicates a poorly fitting model and the null hypothesis cannot be rejected. The independent variables 'Tobacco use pattern at the time of symptom recognition, Cancer stage, Reason for meeting HCP for current problem in the oral cavity, Was worried about what the doctor might find out and

Time to reach nearest healthcare facility' were contributing to the model, controlling for 'Distance to nearest healthcare facility'.

Based on the model, participants who finally consulted a doctor for the current problem in the oral cavity either due to 'pain' (OR, 8.300; 95% CI, 2.9 to 23.4) or 'discomfort to daily routine' (OR, 6.982; 95% CI, 2.5 to 19.3) had high chances of having patient interval more than 90 days in contrast to those consulted doctor due to 'insistence from family or friends. Patients presented in late stages (stage 3 and 4) were more likely to have patient interval more than 90 days (OR, 2.621; 95% CI, 1.3 to 5.2) over those reported in early stages (Stage 1 and 2)(Table 4.20).

Table 4.20: Summary of Binary Logistic Regression Analysis for Variables Predicting Patient interval

Variable	Patient interval n(%) ≤90 days	> 90 days	Adjusted Odds ratio (95% CI)	*p* value
Reason for meeting HCP for current problem in oral cavity				
Pain	36 (30)	62 (44)	**8.300(2.9-23.4)**	**<.001**
Discomfort to daily routine	45 (38)	73 (52)	**6.982(2.5-19.3)**	**<.001**
Insistence by family/friends	39 (33)	6 (4)	Reference	
Tobacco smoking status at the time of symptom recognition				
Current smoker	38 (32)	63 (45)	**2.518(1.3-4.7)**	**.005**
Former smoker	19 (16)	11 (8)	0.717(0.3-1.9)	.503
Never smoker	63 (53)	67 (48)	Reference	
Cancer stage				
Early (Stage 1&2)	60 (50)	23 (16)	Reference	
Late (Stage 3&4)	60 (50)	118 (84)	**2.621(1.3-5.2)**	**.006**
Was worried about what the doctor might find out				
Yes	23 (19)	64 (45)	**2.546(1.3-4.9)**	**.005**
No	97 (81)	77 (55)	Reference	
Time to reach nearest healthcare facility				
≤ 10 minutes	36 (30)	22 (16)	Reference	
11 – 30 minutes	72 (60)	83 (59)	1.443(0.6- 3.4)	.401
31 and above	12 (10)	36 (26)	**5.803(1.6-21.7)**	**.009**

Note: Control was 'Distance to nearest healthcare facility'(omitted from the table)

Omnibus Tests of Model Coefficients χ^2 = 59.26, df=20, p< .001 Likelihood ratio test :113.381

Goodness – of - fit test χ^2 = 4.806, df=8, p .778 Nagelkerke R Square :0.503

Overall percentage correct : 76.2%

Status of smoking at the time of symptom recognition does contribute to the model, with high chances of increased patient interval among 'current smokers' in contrast to 'never smokers' (OR, 2.518; 95% CI,1.3 to 4.7). Those who 'worried about what the doctor might find out in their mouth' were more likely to have patient intervals above 90 days, in comparison with those who did not worry (OR, 2.546; 95% CI, 1.3 to 4.9). Participants who have to travel more than 30 minutes to reach the healthcare facility were more likely to have patient intervals above 90 days, over those who can reach the hospital within 10 minutes (OR,5.803; 95% CI,1.6 to 21.7) (Table 4.20).

4.1.6: Factors associated with the diagnostic interval using Binary logistic regression

Further analysis of data was carried out to formulate a predictive model of the association between diagnostic interval and possible predictor variables. The outcome variable, the diagnostic interval was dichotomized into 'Less than or equal to 30 days' and 'More than 30 days' and binary logistic regression analysis was performed. Variables included in the regression model were those of known clinical importance and those who got a statistically significant relationship in Chi-square analysis ($p < .05$). To model the probability of diagnostic interval, the selected independent variables were used in various combinations, to get the main effect model by repeatedly deleting, refitting, and verifying. Several model specifications were tested to obtain the best fitting one.

An adequately fitting model, with Model coefficient [$\chi 2$] = 86.988(11), $p<.001$, -2 Log likelihood = 268.367and the Nagelkerke R Square = .381 was obtained (Table 4.21).

Table 4.21: Binary logistic regression analysis of predictors of Diagnostic interval

Variable	Frequency	Adjusted Odds ratio (95% CI)	*p* value
Age			
≤60yrs	136	**2.090(1.1-3.9)**	**.020**
>60yrs	125	Reference	
Caste			
Other backward class	167	Reference	
General class	47	**2.681(1.2-6.2)**	**.021**
Scheduled caste	19	1.412(0.4-4.5)	.558
Scheduled tribe	28	**3.85(1.3-11.1)**	**.012**
Number of HCPs consulted in the diagnostic pathway			
One	36	Reference	
Two	93	2.533(0.98-6.5)	.054
Three	78	**6.593(2.3-19.0)**	**.001**
Four & above	54	**4.743(1.5-15.5)**	**.010**
Advice by HCP			
Ignored symptom	81	**5.716(2.3-14.3)**	**.001**
Advised biopsy	102	0.700(0.4- 1.4)	.296
Referred to higher centre	78	Reference	
Monthly income			
≤ 5000 rupee	139	**2.681(1.2-6.2)**	**.021**
> 5000 rupee	122	Reference	

Note: Controls were 'Co- morbidities' and 'Marital status' and they were excluded from the table

There is more likelihood of getting diagnostic interval 'more than 30 days for those who aged less than or equal to 60 years (OR, 2.090; 95%CI 1.1 to 3.9). Also when compared to other backward classes, patients belonging to the General class (OR, 2.681; 95% CI 1.2 to 6.2) and scheduled tribe (OR, 3.85; 95% CI 1.3 to 11.1) are more likely to get a prolonged diagnostic interval. Those who had to meet three HCPs before making a definitive diagnosis were more likely to have 6.6 times high chances of prolonged diagnostic interval compared to those who met only one HCP. Compared to participants who were referred to a higher center for further evaluation, those who got their symptoms dismissed as minor by the consulting HCP were more likely to have a diagnostic interval of more than 30 days (OR 5.716, 95% CI 2.3 to 14.3). Those participants who had a monthly income of less than 5000 Indian rupees were more likely to have prolonged diagnostic intervals compared to those with a monthly income of more than 5000 Indian rupees.

4.2 Findings of in-depth interviews

4.2.1 Perspectives of oral cancer patients about their diagnostic journey

4.2.1.1 Introduction

In-depth interviews were conducted with oral cancer patients. Participants were asked about their initial symptoms, awareness about symptoms of oral cancer and pre-cancers, their health-seeking behavior, the attitude of their family and society towards them, and the challenges faced by them to access health care. The mean age of the participants was 55.75years. Out of the eight participants, three were women and two were scheduled tribes. The majority of the participants were daily wagers. Except for two, all others had completed their treatment and are on follow-up.

4.2.1.2 Economic aspects of patient and diagnostic intervals

Economic aspects are major influencers on the delay in diagnosis of oral cancer. In Kerala it is a common thing that there is only one earning member in a family. In the event of that earning member being diagnosed with cancer, it becomes worrisome. A Tribal woman aged 41 in village A, diagnosed with cancer - was a widow having a child of 13 years - said,

"I don't have money. If I don't go to work, my kid won't get anything to eat!! ".

The above statement echoes the concern about her family, especially about the child. The point of discussion was on the financial dependency of her dependents. It shows how financial dependency acts as a barrier to the timely seeking of care and treatment compliance. The occupation of the respondents also plays an important role in the diagnosis. Many of the patients were either daily wagers or working as laborers earning very little. The minimum income hampers them from visiting consultants and getting treated for their symptoms. On this issue a male participant mentioned,

"First and foremost thing is my job. If I don't go to work, I can't earn money. Government hospitals are not functioning during the afternoons and Sundays. For

consulting a doctor, I need to take a day off or approach a private hospital in town, and both are difficult for me"

Many of the participants work in the unorganized sector. The government provides health insurance coverage for those belonging to the low socioeconomic strata of society. People satisfying the eligibility criteria should enrol in such schemes. Many of them fail to enrol in government schemes as they miss the deadline for enrolment in such schemes due to their busy schedule. The only time they realize the importance of the schemes is when they fall sick. Many were even not aware of the benefits of such schemes.

As mentioned earlier, people were busy with their work and were not able to follow some of the medical advice due to lack of time. Many even migrated to other districts or states or Middle Eastern countries for employment. The above facts give a clear idea as to how the occupation hinders health-seeking and treatment adherence among the participants. A participant who had worked in a gulf country (Middle Eastern countries are locally referred to as 'gulf') recognized early symptoms when he was working there, and he did not get it treated due to exorbitant treatment costs abroad. He then waited for a vacation to visit his hometown in Kerala for treatment. This is a clear-cut example of how emigrants deal with their symptoms. They often prefer either to wait until they visit their hometown during vacation or delay their treatment. This is how migration for jobs leads to delay in diagnosis and treatment.

Another aspect that plays an important role is the cost of treatment in private hospitals. Many respondents mentioned that treatment charges were unaffordable. They were also not aware of any government scheme to support the treatment-related expenditure. There are government schemes to alleviate the financial burden of cancer patients. The Government of Kerala has a scheme called the "Cancer Suraksha Scheme" targeting children below 18 years. This is a free treatment scheme that is available for all irrespective of their socio-economic status. Karunya Benevolent fund and Sukrutham were the other two cancer treatment schemes of the Government of Kerala. Now, the government of Kerala merged all the existing treatment schemes with the Pradhan Mantri Jan Arogya Yojana (PMJAY) which is named 'Karunya

Arogya Suraksha Padhathi' (KASP). Under this scheme, beneficiary families will get Rupees Five Lakhs per year for secondary and tertiary care hospitalization. In the absence of other financial support, patients often sourced finance pledging gold, availing bank loans, or seeking assistance from friends and relatives. This also contributed to the postponement of medical consultation for some. People were also apprehensive about exorbitant investigation and treatment costs.

4.2.1.3 Assumptions about signs and symptoms of oral cancer

Assumptions about the signs and symptoms of oral cancer affect a patient's health-seeking behavior. Patients' interpretation of their bodily changes largely comes from their previous experiences, the experience shared by peers and others in the community, information circulated through print, audio-visual and social media. Symptoms are primarily bodily sensations interpreted as some deviant sensations based on their understanding of health and disease. This understanding is also influenced by socio-cultural practices pertaining to that community. Generally, patients consider their symptoms as trivial as long as their daily routine is not affected. They assume that their symptoms are not in any way associated with a serious oral condition and that it may resolve by itself. A middle-aged male participant recollected his experience of what he thought when he first noticed a change in his oral cavity …...

"*Initially, I noticed a small swelling on my gum and it was not painful. Then I thought it was some gum disease*". He continued justifying the fact that it was trivialized right from the beginning.

From this, it was evident that people ignore oral symptoms initially. So they do not seek professional care immediately. This ultimately adds to the patient interval among oral cancer patients. It is also important to note that periodic dental check-ups were not so common among the members of the community in Kerala. General awareness about the implications of various signs and symptoms associated with oral health is also very low. Patients often think of oral symptoms as harmless, self-limiting, and expected them to heal overtime.

"*May be a tooth-related injury that will heal by itself over time. Earlier also I had a wound from a broken tooth that lasted for a month and healed, I think"* - one of our participant's initial assessments about an ulcer in her oral cavity which on the later investigation was diagnosed to be oral cancer and that too in an advanced stage. The above statement endorsed the general belief that oral diseases are self-limiting in nature. It clearly shows that the optimism regarding self-resolving of the oral symptoms prolongs patient interval. Ulcers in the oral cavity were often overlooked and interpreted as common mouth ulcers. This generalization of oral ulcers pays off abysmally in the early oral cancer diagnosis. Lack of education is a barrier to acquiring the right information and knowledge about oral cancer from various sources. This further affects the ability to comprehend and verify the veracity of information received from other sources. In the present context, many of the participants with oral cancer were having only a minimum level of education, which was either below the secondary level of education or illiterates.

A woman who comes from a remote tribal village said "*I am illiterate. Who is going to look inside my mouth now and then? Even if I find something abnormal, I don't know how to comprehend!"*

The above statement clearly shows how the literacy level influences the knowledge on abnormalities and symptoms in the oral cavity. This proves the old saying in the local community 'The eyes cannot see what the mind does not know'. People were not able to distinguish between normal and abnormal in the oral cavity. Poor knowledge on oral cancer is not just contributed by literacy level alone. This might have been due to poor health promotion campaigns on the issue in the community.

In general, people attribute the abnormal findings or sensations in the oral cavity either with cheek bite or tongue bite or trauma from a toothbrush or increased quantity of lime consumed along with betel quid or higher intake of liquor and so on. This self-diagnosis of symptoms delays the presentation of the issue to a health professional and ultimately leads to the patient interval.

An elderly woman said *"Initially, I had some difficulty in consuming hot and spicy food. When I ate spicy food I was feeling like burning in my mouth. I thought this may be due to adding too much lime to the betel quid. So initially I ignored that."*

Patients with precancerous and cancerous oral lesions often report burning sensation in oral cavity. Prompt recognition of the lesions would shorten the delay in diagnosis and reporting. The above statement clearly explains how a participant attributed the symptom to her betel quid usage and as a respite reduced the betel quid consumption. This is an instance where a patient ignored the symptoms at first and did not consult the health professional on time. The decisions on different health choices for any family member were decided by all the members. The decisions on the options, the timing, and so on are all decided on consensus. This highlights the importance of awareness of various cancer signs and symptoms among the family members as well as the immediate social circle for quick diagnosis.

A tribal woman, who is a widow recollected *"When I was living with my husband, I told him about a wound in the oral cavity and he dismissed it as a trivial problem. This is common among all people."*

The statement highlights the influence of a family member on the health decision of a participant related to oral health. In general, the breadwinner of the family decides on it. In most of the cases, it used to be a male member of the family. The decisions made by the member of the family other than the person affected lead to delay in consultation for the patients. There are also instances where the family was responsible for hastening the diagnostic processes. For instance, a middle-aged male participant said *"My wife learned from a radio program that the white discolorations inside the mouth are dangerous. When I shared my condition, she immediately recalled the radio program and took me to a doctor. Initially, I resisted but she was adamant that I should consult the doctor.'*

The above statement is in agreement with the earlier point on the importance of educating all the family members regarding early diagnosis of cancer. In addition to the level of awareness, having exposure to similar events, for example, experiences of

a family member having cancer helps to recognize initial symptoms as a warning sign of oral cancer.

Many times the short-term relief experienced by the patients was misunderstood as a cure or no risk of further deterioration of the disease condition. Any misunderstanding about the betterment of disease condition during the initial stages of the diagnostic journey leads to a delay in diagnosis and ultimately it delays the treatment. In the event of symptoms subsiding before diagnostic investigations, the patients tend to refrain from further diagnosis. A similar instance was observed in the field.

A 50-year-old male farmer said, "*When I consulted a doctor, he had given me medicines and an ointment if my memory is correct. Following the doctor's advice, my pain subsided. I assumed that I was completely cured and I didn't visit the doctor again for follow-up".*

Bodily changes not eliciting pain from the beginning are often overlooked as mild. This was shared by a male participant aged 55, who relates harm with pain and discomfort and a state of normalcy with the absence of the symptoms.

"I first observed a small growth on my tongue. Then I felt it was harmless as it did not cause any pain or discomfort. So I did not give much attention to it as a symptom."

In the case of precancerous and early cancerous stages, pain is generally absent. When a person waits for pain or discomfort to manifest, it delays the diagnosis and treatment. This is how the absence of symptoms like pain and discomfort in the initial stages of oral cancer adds to the quagmire of patient interval.

4.2.1.4 Role of alternative medicine in cancer care

The participants reported seeking care from alternative systems of medicine. Home remedies were preferred among different options as an immediate relief when they recognize the symptoms. There were different alternative medicinal practices sought by the participants. It is common among the study population that home remedies were practiced for common ailments. For instance, for mouth ulcers, people used saline gargle (it is also prescribed by the physicians), buttermilk, and the local

application of turmeric extracts on the wound and so on. People believed that home remedies cure their disease. The practice of home remedies is a traditional practice that made the community as a whole trust their ancestral wisdom. In the event of failure following the home remedies, they either move to modern medicine or may seek alternate therapies.

A middle-aged male participant said *"Initially I applied a mixture of salt and pepper over the wound and got some relief. Later when the pain persisted, I went to a dental doctor to remove a loose tooth adjacent to the wound."*

Here, the participant shared how he first followed home remedies and got only temporary relief. Over the period he realized the symptom did not subside as expected. This is a case of the use of home remedies during the initial stage and the delay in reporting symptoms that prolonged the patient interval. Some of the communities practiced alternative and herbal medicines for such problems. Some of them even expressed their fear of modern medicinal practices.

A tribal woman said *"In my childhood days, I heard people saying that if someone is taken to a hospital means s/he is not going to come back alive. Now also we fear to get admitted in a hospital."* The apprehensions about seeking care from a modern medicine hospital is clearly expressed by the woman above. During the earlier days when hospitals and other health infrastructure were sparse, people were admitted to hospitals when they had no progress in the primary levels and it was considered as a last resort. This was after exploring all possible traditional treatment options. This lead to more probability of dying in the hospital setting as the mortality rates were high among those brought for emergency treatments to a hospital(Meacock*et al*., 2017). This was also interpreted as mistrust and fear of modern medicine. This is also an important aspect that contributes to the patient interval.

Among the tribal population, home remedies and herbal medicines were extensively practiced, and there existed practitioners for such practices. They were well-established practitioners who provide alternative medicine services to tribal and hill populations. Some well-established practitioners are known for their treatments and

attract patients from faraway regions for treatment. They also claim a cure for almost all diseases including cancers.

A male participant from a tribal area said *"In our area, everybody goes to a Vaidyar for all incurable diseases. He is very famous for cancer and many people from far-off places are coming for treatment. He treats 300 to 400 patients per day."*

The above statement highlights the successful practice and the trust they enjoy among the members of the community. People often get attracted to these practitioners through individual testimonies of a miraculous cure. Nowadays, even social media are increasingly used for promotions. One of our participants himself was a victim of such testimonies and false promises and received care for cancer. The wrong use of alternative treatments prolongs diagnostic interval and delays the treatment as these practitioners diagnose based on their past experiences.

4.2.1.5 Role of communication in early cancer diagnosis

Communication has an important role in healthcare-seeking and promoting early diagnosis. Interpersonal communication relevant to the health care seeking happens at the family/community level and hospital/health care provider level. People initially discuss any abnormal bodily sensations with other family members, especially with their spouses. Some prefer not to discuss with anyone and some others discuss with their colleagues and friends. This constitutes the first step of their diagnostic journey. The response or advice received from such acquaintances accelerates or decelerates further movements in the diagnostic journey (Figure 4.13).

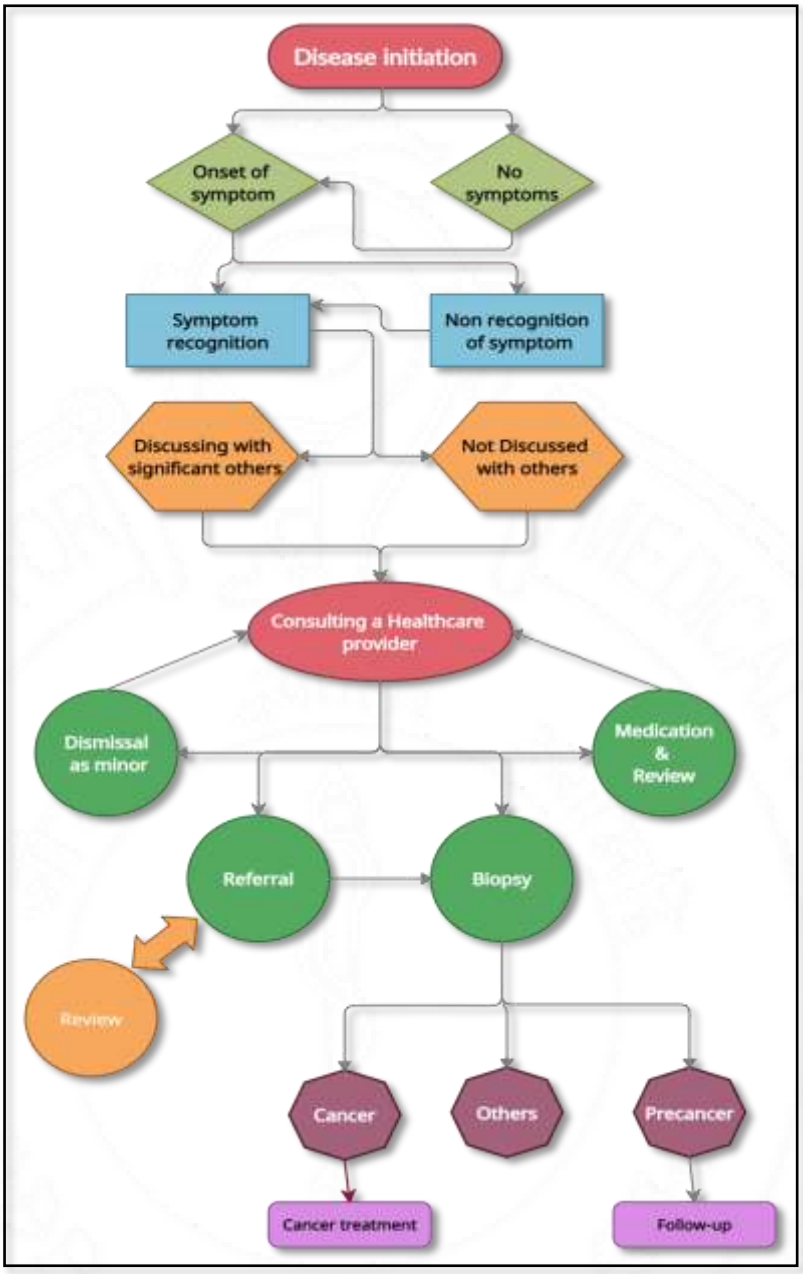


Figure 4.13: Process diagram of the diagnostic journey in oral cancer

An elderly woman aged 63, said *"I used to get mouth ulcers frequently. But the one I got recently was not healing and I was not able to eat properly. My husband noticed my discomfort. .Then I explained my situation. He immediately suggested some saline water gargling to address the pain. He didn't take it seriously in the beginning and it was true for myself too."*

The above statement clearly shows the spouse initiated communication initially. However, he did not recognize the problem. At the same time, it has become an excuse for the participant not to share the information with others and to accept it as a normal condition. Alternatively, if the spouse recognized the symptoms in the first instance, the diagnosis would have initiated on time.

One male participant (62yrs), said *"It was my son who insisted that I must consult a doctor for an ulcer on my inner cheek. I responded that he should buy some medicines from the medical shop to ease the pain but he declined to do so. My wife also agreed with my son and that made me consult a doctor in the end."*

This clearly shows the importance of how communication between spouses or other family members influences decisions on seeking care. Some people find it difficult to convey their problems to their health care providers. They may be afraid to visit the hospitals as they were not able to find appropriate words while communicating about their health concerns with the health providers who are usually busy due to patient load.

A tribal woman age 41 said, *"I am not educated. The doctors are all educated people, and many at times I feel embarrassed while talking to them".*

The above statement clearly shows the inhibitions patient had while communicating problems with the health care provider. This has in turn results in ambiguously sharing her problems with the healthcare provider. This resulted in a prolonged diagnostic interval.

This could also be due to the poor communication by the doctors to the patients. Many patients expressed their displeasure towards the doctors who many at times did not hear their problems or respond to their queries. Thus their worries and apprehensions were never addressed.

A male participant aged 50, said "*As I told you before when we visited the doctor, he gave some medicine and asked to come after a week time. He didn't inform me about the level of seriousness of the problem due to crowded OP timing at PHC. I could*

also acknowledge that there were so many people standing in the queue for consultation with him/her!!"

The participant further feels he would have acted promptly if he had received the right information at the right time. *"If s/he could have explained things in detail in the beginning, I would have reached the tertiary care center much earlier for treatment".*

The above statements highlight the importance of doctor-patient communication on diagnostic interval. Satisfactory doctor-patient communication helps the patient to make informed decisions about his or her conditions and thereby complete the diagnostic journey at a faster pace. Poor communication may lead to provider switching and poor adherence to follow-up or referral instructions.

4.2.1.6 Effect of tobacco and alcohol habits in diagnostic journey

The association of deleterious habits like tobacco, alcohol, and areca nut use with oral cancer is a well-established fact. This information was disseminated through different media campaigns among the community. These habits initiate the disease process in many oral cancer patients and the continuation of these habits delayed health care seeking due to delayed appraisal of symptom severity. Some participants couldn't quit their tobacco and alcohol habits even after recognizing the symptoms suggestive of oral cancer due to their high dependency on those products.

A male participant aged 60, recollects *"The doctor also asked me to stop chewing, but I failed to comply with that. I am doing this for the past 20 years. It's quite difficult. I couldn't even think of stopping the habit. I generally don't like to consult doctors as they always ask me to quit betel quid chewing after seeing those stains in my mouth."*

The above statement indicates the severe nicotine dependence of the participant and his inability to comply with the health advice he received from the health care setting. Participants' disapproval of repeated tobacco cessation advice from the health care setting indicates the need for establishing systematic tobacco cessation services in all health care facilities. Apart from addiction, it was also observed that tobacco and alcohol were used as symptom relievers. Few participants even increased the frequency or quantity of tobacco or alcohol use proportionate to their pain or

discomfort for relief. Symptom relief through the continued or increased use of tobacco and alcohol helped them to tide over the symptom in the initial phase but it also prolonged symptom presentation in a healthcare setting. Tobacco and alcohol use lead to increased patient interval. Betel quid or raw tobacco is used in some communities in Kerala for purposes like pain relief from a toothache, or as a mouth conditioner or freshener after a heavy non-vegetarian meal.

4.2.1.7 Healthcare-seeking practices in diagnostic journey

Health care-seeking practices such as the timely seeking of medical care and treatment adherence and follow-up instructions affect the diagnostic journey in oral cancer. Some people delay seeking care in the hope that their symptoms would get resolved over time. It is quite natural that people often observe their bodily changes for possible cues regarding its course. It is prudent to set a time frame for such observations or else will end up in delayed diagnosis.

A male participant aged 55, said "Initially I had an oral ulcer. *About 5 months later, the problem increased and become severe, and I was not able to eat. So I went to consult a doctor."*

The above statement suggests how symptom severity facilitates health-seeking. Unfortunately in oral cancer, severe symptoms appear only in late stages resulting in advanced stage at diagnosis and poor prognosis. Continuity of care is an important factor influencing diagnostic interval and is often overlooked. Provider switching by the patient as well as poor adherence to follow-up instructions were observed. This often complicates disease evaluation and burdens the already overstretched health system resulting in the prolonged diagnostic interval.

A male participant recollected "*I went to a dental doctor to remove that offending tooth. He gave me some medicines and asked me to come back after a week, but I couldn't. Later I met two other doctors for the same."*

The above statement clearly shows provider switching and poor follow-up adherence from the patient. Provider switching breaks the continuity of care and complicates the diagnostic journey. Some people fear medical procedures and hospitals. Fear of

procedure is a barrier to timely health-seeking. The mere suggestion of a surgical option worried one participant and as result, he postponed the follow-up consultation. Within the health system, those referral to 'higher centers' create fear among participants. One participant expressed his displeasure for seeking care from medical colleges. People prefer to get treated from an institution near to their home.

4.2.1.8 Support from society

Getting support from near and dear is an enabling factor for hastening the diagnostic journey. Participants emphasized how the support from their family and neighbourhood facilitated their diagnostic journey.

One male participant said *"Relatives and neighbours were very supportive. They supported my family after I lost my job, helped me financially and also through other means. My neighbour arranged a vehicle for my travel to the hospital. I am very lucky in that."*

The above statement clearly showed how the support from society facilitated patients' healthcare-seeking. On the other hand, the non-availability of support from relatives and neighbours prolongs the patients' diagnostic and treatment journey.

One participant said *"So, we could leave home only after sending children to school and have to reach home before they come back. My relatives were staying far off. There was no one nearby to support us."*

The above statement indicates how lack of support affects seeking care. They have very limited choices to make. This lack of support also affects their ability to select the healthcare facility as they need to return home before their child reaches home from school. Community leaders like elected representatives also supported the participants. Though the panchayath did not have provision for providing monetary support, they support by providing appropriate information, facilitating travel, and other logistics.

A female tribal participant aged 41, said *"after the demise of my husband, I lived a lonely life with my child. There was no one to support me as relatives were living in*

far off places. Our ward member helped to arrange a vehicle and provided some money from his pocket for treatment."

The above statement highlights the positive role played by representatives of the local self-governing institutions in facilitating cancer treatment and diagnosis. Though the support is largely non-financial, the impact it created in the diagnostic journey is unequivocal.

4.2.1.9 Summary

The family's financial dependence on the patient is a barrier to the timely seeking of health care and adherence to follow-up advice. People who work in the unorganized sector may postpone care seeking on concerns of job security and wage loss. Apprehensions about the cost of investigations, treatment, and hospital stays may dissuade people to defer medical consultations. Patient's self-appraisals and assumptions about their bodily changes influence the diagnostic journey. Trivialization of initial symptoms often leads to delayed help-seeking. Those symptoms which did not bother the patient were considered trivial. Awareness about signs and symptoms of oral cancer was minimal among the participants. People consider oral symptoms as self-limiting. There exist a practice of attributing symptoms suggestive of oral cancer to some known causes of trauma and ignoring the symptom. They consider those symptoms as self-limiting and delay care-seeking. Awareness about oral cancer symptoms is poor in the community. In some tribal and remote areas, such information was not reached. A media campaign targeting people with lesser education on the warning signs of oral cancer would reduce the patient interval among them. Cancer-related experience and symptom awareness should work positively to reduce patient interval. Individual's health-seeking decisions were often influenced by family or significant others. Support from the family and society enables timely seeking of care. Their health-related attitude and awareness affect patient and diagnostic intervals. Affinity for alternative medicine exists in the community. The use of any alternative treatment in the initial course of the diagnostic journey delays symptom presentation and increases patient interval. Communication plays an important role in health decision-making. For instance, communication in the

family, health setting, etc., contribute to this. Maintaining continuity of care is essential for achieving an early diagnosis of oral cancer.

4.2.2 Health Care Providers perspectives on early oral cancer diagnosis

4. 2.2.1 Introduction

In-depth interviews were conducted with health care providers involved in the diagnosis of oral cancer. The health care providers were asked about the frequency and pattern of oral cancers and pre-cancers in their routine clinical practice, adherence of patients towards follow-ups and management of oral cancers and pre-cancers, referral pattern and training requirements, and challenges for implementing early detection of oral cancer in clinical settings. All the interviewed health care providers had more than five years of experience in clinical practice. Health care providers interviewed include four primary care medical practitioners, two ENT surgeons, three Dental Surgeons, one Head and Neck Oncologist, and one General Medicine Specialist. Currently, all except one is working in the government sector but all of them had previous working experience in the private sector.

4. 2.2.2 Oral cancers and pre-cancers in routine clinical practice

The frequency of oral cancer cases seen by various practitioners interviewed in the study ranges from three to four cases per month to one case per year. The distinct variation in the frequency of oral cancer cases reported indicates geographic differences in the distribution of these cases as well as the pattern of reporting of these cases to various health care providers at different levels of care. Precancerous lesions were also reported in clinical practice of all participants but their frequency varied across specialties. Among all the ten participants, an ENT surgeon working in a district hospital reported the highest number of cases (three to four cases a month). In the health sector, cases from primary care were frequently referred to district hospitals. Similarly, an oral medicine specialist working in a government dental college reported that the maximum number of cases seen in a month was two. This clearly shows people's preference for tertiary care centres when they suspect

seriousness in their symptoms. A dental surgeon who worked in various community health centres in Kannur and Kasaragod districts recollects her exposure to precancerous lesions in practice,

"Precancerous case frequency in OPD depends on the population and the area. When I was working at Kasaragod, I used to get one case per week. But when I was transferred to the Kannur district, I got very few cases in my two and a half years of practice. It also depends on the availability of higher centres nearby. In Kannur, one private dental college was there near my hospital. Patients with symptomatic chronic lesions prefer to go to the dental college, a tertiary care centre."

All participants recollect diagnosing leukoplakia in their practice but dental surgeons and medical officers trained in early cancer detection were remembering diagnosis of other precancerous lesions like oral lichen planus and oral sub mucous fibrosis in their clinical practice. A medical practitioner working in a primary health centre in Kasaragod said

"There are many cases of leukoplakia. I used to give vitamin tablets. There is nothing else to do."

In the above statement, though the participant mentions leukoplakia, there is no mention of oral lichen planus, which is a frequent oral lesion reported among middle-aged females. The absence of a referral system for managing oral precancerous lesions and the lack of expertise of the provider in managing these lesions were also evident in the above statement. Leukoplakia is a white lesion associated with tobacco or alcohol use and it may progress to oral cancer in a later course of disease in some people. Oral lichen planus is also a type of white lesion seen in the oral cavity with some potential for malignant transformation. It is more commonly seen in middle-aged women and is not associated with habits. Oral sub mucous fibrosis is a precancerous condition that is associated with areca nut use. Erythroplakia is a red oral lesion with malignant potential. Correct identification and prompt management of these lesions will prevent the malignant transformation of these lesions. The practitioners in primary care should correctly identify these lesions and should initiate management or refer the patient to a higher centre for management.

4. 2.2.3 Adherence to medical advice and continuity of care

All the participants pointed out the lack of adherence to medical advice from the patient side for follow-up instructions of suspected oral precancerous lesions. Oral precancerous lesions need long-term follow-ups for identifying early malignant changes. Most of the precancerous lesions present as asymptomatic lesions. A participant said,

"*It is very difficult to convince the patients about the need for long-term follow-up for oral precancerous lesions. They usually take it lightly. Maybe because they are not recognising the symptoms. This may also be due to their inability to stop the use of tobacco, especially in aged patients. Youngsters with precancerous lesions usually comply with advice."*

In the above statement, the participant highlights his inability to convince the patient about the need for continuous follow-up. The patient's perception of symptom severity and seriousness was also suggested as a reason for their slack approach towards adherence to medical care and follow-up instructions. Similar concerns are raised by the majority of the participants.

"They either want the lesion to be cured immediately or else will wait for the lesion to become malignant. We cannot blame the patients. Most of these precancerous lesions are painless or have very mild symptoms. So they don't prioritize its management over other life issues. These lesions may take 10 to 15 years or more to become cancerous."

The above statement highlights the long preclinical phase of oral cancer cases which offer scope for early diagnosis. Regular follow-ups will help in the identification of early lesions and abstinence from tobacco and alcohol habits may help to prevent its cancerous transformation. HCPs emphasized the need for designing interventions for ensuring adherence to medical advice. An HCP working in a Taluk hospital mobilized

ASHA workers for ensuring follow-ups for precancerous lesions. Adherence to medical advice and continuity of care can be ensured by involving the grass-root level health workers. If ASHA workers were involved in the program, we could expect better compliance from the patient side as ASHA workers are known personally to them. Two participants described how the influence of immediate family members positively influences the health-seeking decisions of the patient. An ENT surgeon working at a sub-district hospital said

"Many patients report for consultation out of insistence from their family, especially from their spouse or children. Most of these patients were elderly and when they discuss with their children about oral problems, they bring them here. It is purely due to insistence from their family. In many cases, the patients themselves were very reluctant, I have observed that."

Apart from this insistence from the family, participants have also identified some other reasons for early diagnosis. According to a dental surgeon working at a sub-district hospital suggested previous experience with cancer patients and symptom severity appraisal by the patient as the other factors encouraging early diagnosis. He said

"Those who regularly reports for follow-up are those patients who knew about the seriousness of the condition or those who have familiarity with cancer patients. Maybe their friends or family members had cancer. But the majority of the patients report only when symptoms get worse. Some others may be experiencing pain or discomfort due to the lesion."

Knowledge about cancer either in terms of symptoms or witnessing a friend or a family member with cancer were regular to follow-up.

Lack of adherence to follow-up instructions might be due to the symptomatic improvement achieved during initial treatment and the absence of active intervention procedures in follow-up visits. An oral medicine specialist said

"When their distressing symptoms got relieved, they stop coming for follow-up reviews. They may be thinking that during these visits, doctors were just examining

the oral cavity and did not do any procedures or even advise to use the same medication. Then they might feel like there is no need to come every month and the medicines are costly too. "

Participants also highlighted the need for patient education to overcome this. A surgical oncologist working at a private hospital said

"*We need to increase our efforts for patient education. Doctors after one or two visits refer the patient to a higher center but there is neglect from the patient side for adhering to advice. It's the fear of cancer that delays diagnosis in many patients. Even those people having easy access to healthcare delay seeking care. One of my relatives ignored an oral ulcer for a long time and later presented in an advanced stage."*

4.2.2.4 Referral and training necessities in oral cancer diagnosis

The need for a structured referral system has emerged from the interviews with health care providers. The referral pattern followed by different practitioners varied considerably. Some participants refer cases based on their contacts with specialists. Some others refer the patient to the nearest cancer centers or medical colleges. An ENT surgeon working at a sub-district hospital said,

"Ideally, we should refer the patients to the next higher level in the health system, which is the district hospital. But no clear-cut guidelines are existing in the health service for the referral of oral cancer cases. I usually refer patients to Tertiary Cancer Centre or Medical College Hospital."

From primary care, patients with suspicious oral lesions were referred to Tertiary cancer centers, medical colleges, dental colleges, and district hospitals for further investigations and treatment. Although these centers were involved in the care of oral cancer patients, their capabilities in managing the disease differ. So an informed referral based on specific criteria will help in the optimal utilization of our public health resources. Moreover, any future referral system should also include diagnosis and follow-up of precancerous lesions.

Identification of various precancerous lesions needs training Most of the practitioners interviewed expressed their desire for training in oral cancer early detection. Missing precancerous lesions in clinical practice can be avoided if such training were provided to primary care providers. ENT surgeons, oral medicine specialists, dentists, and those medical practitioners who underwent training in cancer screening expressed confidence in diagnosing oral precancerous lesions but, only the oral medicine specialist expressed confidence in managing oral precancerous lesions. A medical practitioner working in a primary health center said

"We need special training in cancer early detection, especially for those who work as general practitioners. A general practitioner must know all of these. Most of the patients initially report at PHCs. Recently we had a training on Non-Communicable Disease. Cancer was also mentioned in that. But it did not cover cancer early detection sufficiently."

Some participants had attended cancer care training for primary care practitioners. They found these training were useful and expressed confidence in integrating cancer detection in primary care. A medical officer who completed short term training in basic cancer care at a tertiary cancer center said

"It was a great experience. We learned a lot about cancer screening. Now we could identify oral sub mucous fibrosis. Many things were new to us, especially the training on oral precancerous lesions. PHC doctors don't have much awareness about oral conditions. They are usually seen by dentists. We come across breast and cervical lesions in our practice and has some idea. I think such training should be given to all PHC doctors. At least a two-day training should be given to all. "

Commitment on the part of practitioners is also an important factor in the early diagnosis of oral cancer. Oral cancer opportunistic screening or follow-ups of oral precancerous lesions are additional responsibilities for practitioners who are already overburdened by crowded outpatient departments. They were racing against time to

finish their primary duty. So always performing oral cavity examinations for all patients may not be practical. A medical officer working at a PHC said

"To be frank with you, I don't get time for conducting oral cavity examination for all patients coming to OPD. It's done only for those who complain of oral problems. We are struggling to complete the regular OP load. We need more manpower for managing the regular cases in the OPD."

The above statement indicates the constraints faced by primary care practitioners in implementing oral cancer screening for all patients attending their OPD. Despite these unfavorable circumstances, One ENT surgeon and one dental surgeon working in primary care were doing oral cancer screening for all patients irrespective of their presenting problem.

4.2.2.5 Challenges and solutions for early oral cancer diagnosis from a provider perspective

According to the healthcare providers the challenges they face in early diagnosis of oral cancer in general were, shortage of time, poor infrastructure, and no training on the subject.

Early diagnosis of oral cancer cases among low-risk populations in general practice is a challenge. A surgical oncologist from a private hospital has opined with the above challenge. During the interview, he was mentioning,

"Nowadays oral cancer is seen in non-habitués also. So our strategy of targeting the high-risk population alone will not suffice and we should change it. These non-habitué cases are reported in the younger population. Neglect from the patient side is the biggest challenge."

Participants also discussed the ongoing COVID 19 situation and the challenges posed by it on oral cancer diagnosis. COVID situation also affected oral cancer screening and diagnosis. During the initial phases of lockdown, most of the clinics were shut down and there were no travel options to access care. During the period, practitioners including ENT surgeons and Dental surgeons working in health services were given

COVID duty resulting in manpower shortage for routine clinical activities in hospitals. Moreover, the general public was afraid of visiting the hospital for fear of contracting COVID. As slowly patients started appearing in the hospitals, the PPE kits were found to be interfering in the patient examination. The headlamp cannot be worn over the face shield and as a result, oral cavity examination was difficult to conduct for all patients. An ENT surgeon working at a district hospital said

"In my district hospital, there were no restrictions for patients or patient examination during the pandemic period. But in many primary health centers, services were restricted out of fear of COVID."

The COVID-related situation is changing and life is slowly returning to normal. These challenges can be addressed through the tailored health education program. A dental surgeon working at a community health centre said

"Awareness class for the common man is needed, I think. They must be informed regarding the disease, its nature, progression, available treatment options, and prognosis. If at all one has not attended such a class, there should be someone in the family or neighbourhood who can guide him in the right way."

4.2.2.6 Summary

Patients with oral cancer report initially to medical officers working in primary care levels or ENT surgeons and Dental surgeons working in secondary care institutions. Dental surgeons, ENT surgeons, and trained Medical officers were able to identify oral precancerous lesions in their clinical practice. Lack of training and absence of an established referral system affect the management of oral precancerous lesions in primary and secondary care levels. Poor adherence to follow-up instructions from the patient side also complicates precancerous lesion management and thereby missing the opportunity for early diagnosis. The patient's perception of symptom severity and seriousness was suggested as a reason for their non-adherence to follow-up instructions. Family member's insistence to seek care positively influences early diagnosis and adherence to medical advice. There exist a compelling need for patient education and practitioner training for 5symptom interpretation and early diagnosis.

The challenges for early diagnosis of oral cancer in the health setting include lack of time, lack of manpower, absence of referral system, lack of training, fear of treatment and treatment cost, and low penetration of health education programs in the high-risk population. The prevailing COVID 19 disease-related fear and public restrictions also posed a significant challenge to early diagnosis. During the first wave of COVID 19 infection, many private clinics and small hospitals were shut down and many hospitals were converted as COVID hospitals resulting in limited facilities for elective consultations. Moreover, patients were also afraid of visiting hospitals for fear of contracting Corona infections. Acute manpower shortages also existed for routine clinical services.

4.2.3 Community leader's perception of oral cancer

4.2.3.1 Introduction

In-depth interviews were conducted with community leaders for understanding their perceptions about oral cancer using an in-depth interview checklist. The community leaders were asked about general perceptions about oral cancer in the community, availability of facilities for cancer care, community-level support for cancer care, and the prevailing apprehensions about cancer in society. A total of five in-depth interviews were conducted. All the community leaders were having more than ten years of experience in community-level activities. They were leaders and active members of various non-governmental organizations, palliative care organizations, social service organizations, and political organizations. One out of the five members was a female. The mean age of the leaders was 55.4 years. The community leaders interviewed include the president of a grama panchayath who was also the leader of a political organization, panchayath standing committee chairperson who was also the leader of a political organization, director of a social service organization having members and activities in three districts, state-level president and district level president of two health-related organizations, and a retired professor who was the member of various socio-cultural and palliative organizations. These leaders conduct community-level activities in tribal, rural, and urban areas.

4.2.3.2 Community leader's perception about oral cancer occurrence

Perception about oral cancer occurrence varied among community leaders. Community leaders of urban areas believe that oral cancers were less in urban areas compared to other types of cancers. Community leaders of tribal and rural areas recognized there existed a higher incidence of oral cancer among their population. One of the leaders who coordinated activities in the tribal area for the last ten years said,

"Oral cancer is quite common than other cancers in tribal population. During our cancer early detection camp, we identified people with oral cancer. But for the general population, it is not that common."

The variation in the incidence of oral cancer in urban and rural areas was evident in the community leaders' perception of the problem. A community leader from a municipality area observed

"I think oral cancers are less compared to other cancers. Other cancers are more common in our community"

Oral cancer is more common among elderly people. The association of oral cancer with an increase in age was also reflected in the interviews. One community leader said

"Mostly in elderly people. I haven't seen a single case in children."

Oral cancers are commonly reported among people who belong to the low socioeconomic strata of the society and the extent of the disease in the community is known to those who participate in community-level interventions. A male community leader aged 64, and associated with palliative care recollected his experience with a community-based early cancer detection program.

"Years back, when we conducted a survey as part of a detection program, oral cancers were common. We did a house-to-house survey. Male volunteers performed oral cavity examinations during the house-to-house survey. We identified many oral cancers and precancers."

4.2.3.3 Community support services for cancer patients

Availability of community support services is an enabling factor in the diagnostic and treatment journey of cancer patients. Several stakeholders work in the community to contribute to the well-being of society. They include Local self-government institutions (LSGIs), non-governmental organizations (NGOs), political organizations, religious organizations, self-help groups (SHGs), and cause-specific public committees. The support, especially the financial support, extended by the LSGIs is meager compared to NGOs. Some of the community leaders opined that a greater role is played by NGOs rather than panchayath. Those community leaders from rural areas had a different perspective on this as they find a minimal role for both LSGIs and NGOs and its some public committees which mobilize fund for cancer treatment. This may be due to the modest presence of NGOs in rural areas. A community leader observed

"Supports are less from the panchayath side. There are many patients in our area but panchayath is not extending help more largely. They get help from other citizens and NGO organizations. The larger help is extended by these organizations rather than panchayath."

Some NGOs work specifically for cancer care through specific projects. They provide social support and rehabilitation support in addition to financial support for the needy population. Panchayath level support, though minimal, is focused on palliative care. Panchayath did not have provision for providing monetary support to all cancer patients for their treatment or follow-ups. Though no schemes or provisions exist, one panchayath had explored the feasibility of providing relief to cancer patients from the existing resources. A panchayath member said

"No such schemes exist in panchayath. The only scheme that can be extended to cancer patients is the president's relief fund. It is a fund made up of donations from the public. Mainly cancer patients get contributions from it. As the corpus amount is very less, beneficiaries usually get around rupees 2000 or so."

The majority of the community leaders felt the need for extending financial support for the cancer patients from the panchayath. Panchayath and other organizations should proactively work to ensure that all eligible people were included in the government treatment schemes and should also ensure the periodic renewal of the same. Many a time, people forget to renew their government health insurance cards and were unable to avail the benefits. These schemes take care of the treatment-related expenditures but some expenses are not covered under these schemes like pre-diagnostic interventions, post-treatment follow-ups, etc. If panchayath could come up with a financial scheme to support patients for meeting these expenses, which would help in early diagnosis and treatment adherence. Apart from these, patients also have to spend a lot of money for their travel and stay as treatment often lasts for months. All these period, they don't have an income. Usually, their family members accompany them to the treatment. So the entire family is devoid of income during that period. It creates a difficult situation for the family. As most oral cancer patients belong to lower socioeconomic strata, they don't have other income sources. This has to be addressed for achieving an early diagnosis. A community leader said

"I feel there should be a mechanism for getting financial aid for all poor patients for meeting their out-of-pocket expenditure, travel, and other logistic expenditure. It should also cover loss of income for the bystanders. Many of these bystanders are daily wagers with no other financial support. Otherwise, their treatment continuity may be affected due to non-availability of bystanders."

Some individuals do not seek support and keep it to themselves due to some reason. They do not want others to suffer for their cause. This attitude delays diagnosis or treatment. A community leader who functioned as the president of a panchayath recollected such an incident.

"Some people don't like to bother others. They don't even share their problems with family or friends. Attitude matters. A socially active person died of cancer in my panchayath. He actively participates in all our activities. It was a shock for all of us. We would have helped him to get good treatment. He didn't tell us about his problem

initially but consulted a naturopathy practitioner. It was too late when people came to know about that. He died few months after that."

This statement clearly shows how people's reluctance for accepting support from others affects their disease prognosis. Sharing and discussing problems with significant others will help in availing appropriate support for early diagnosis and treatment.

4.2.3.4 Availability of facilities for early detection and treatment

The existence of facilities for the diagnosis of cancer in the community is a necessity for achieving an early diagnosis. Facilities for cancer diagnosis are made available in the community as a part of cancer screening camps organized by the panchayath or an NGO once in a year or so. Early cancer detection services are generally not available at the primary care level. When people had to travel long distances for availing early diagnostic facilities, they may not go for follow-up in such instances and prolong diagnostic intervals. A community leader opined

"We need facilities for early diagnosis in our place. Many people hesitate to travel long for seeking medical help and they delay meeting doctor which will result in disease progression."

There is a perception among people that cancer diagnosis facilities exist only at specialized cancer care centers. This belief also delays diagnosis especially for oral cancer where early diagnosis can be achieved through simple visual examination of the oral cavity by trained primary health care providers. In some panchayath, there exists an early cancer detection clinic run by a trained nurse. These nurse-led early detection centers can be replicated in other PHCs and CHCs for enabling early diagnosis. The community leaders unanimously suggested that facilities for cancer diagnosis and treatment are inadequate and efforts for equitable distribution of these facilities are essential for early diagnosis. A community leader said

"Facilities are less. Most of the time, oral cancers are detected at a late stage. There is a need for decentralization of cancer treatment facilities."

4.2.3.5 Possible interventions for facilitating cancer early diagnosis in the community

Community leaders have identified possible interventions for achieving early diagnosis considering the local contest. Conducting awareness classes and cancer screening programs in the community at frequent intervals and setting up a regular facility for early detection of common cancers at the PHCs were suggested by community leaders as solutions for overcoming the delay in diagnosis. One community leader said

"We need to step up our efforts for early cancer detection. More awareness classes and screening camps need to be organized. These programs have to be conducted periodically. Ideally, every PHC should have a facility for the diagnosis of common cancers and there should be a mechanism for encouraging people to utilize the same."

Awareness programs and screening camps should targ*et al*l people irrespective of their age and gender and not just those at risk. So these interventions should be conducted at a variety of settings like places of work, places of fellowships, and meeting places of self-help groups like 'Kudumbashree'. A community leader who is a retired professor and active member of many social organizations said

"Programs must target all ages. All must know about cancer. Awareness programs were mostly attended by women. Male participation is a bare minimum. This should change. So awareness programs should be conducted in workplaces."

Training volunteers for community-based screening of oral cancer is possible and some community leaders recollected their experience in being part of such an initiative in the past. Such initiatives could reduce the burden on the health system and hasten the diagnostic journey. Though such programs were conducted once in a while, community leaders suggest such programs should be conducted regularly.

"Years back when we surveyed as part of a detection program, oral cancers were very frequent. We did house to house survey. Male volunteers performed oral cavity examinations during the house-to-house survey. We got many oral cancer

/precancerous lesions. We got thorough training in oral cancer screening in a session conducted by a professor from a TCC. We identified many leukoplakias. We had mobilized around 1000 patients for camp from a panchayath. "

The statement itself is a testimony on the effectiveness of training volunteers in oral cancer screening as he correctly mentions the name of oral precancerous lesion 'leukoplakia" which was taught to him some twenty years back. The statement also highlighted the power of community volunteers in mobilizing patients for early detection.

4.2.3.6 Prevailing apprehensions about Cancer in the community

Several apprehensions and misperceptions exist in the community about cancer. All these contribute to the diagnostic and treatment journey in cancer. People often become very upset when they confront cancer in their life. People fear cancer. This fear may be due to the misperception about the prognosis of cancer. Some people relate cancer to death. There exist a belief in society that cancer is incurable or it may recur later even if we treat it. These beliefs act as a deterrent for early diagnosis and treatment. Another reason for postponing cancer-related investigations or treatment is the perceived stigma associated with a cancer diagnosis. Because of this, people prefer to postpone diagnosis or treatment of cancer till they complete their family or social responsibility like the marriage of their children. A community leader said

"*About 50 to 60% people think that cancer is incurable. So they are afraid. Some people think a diagnosis of cancer might affect their daughter's marriage prospects and hence they may even hide their symptoms. They will wait for the marriage to get over. They also think cancer treatment will drain off family income. They prefer to avoid that.*

Some people fear cancer after seeing a terminally ill cancer patient. For them, cancer is synonymous with suffering. Side effects and difficulties of cancer treatment also contribute to cancer fear. Some people consider treatment costs as high and so they don't prefer undergoing treatment and may consult alternate treatment providers.

"*When people see patients in their terminal stages with all sufferings, they develop some ideas of the incurability of cancer. I have seen an oral cancer patient with maggots in the mouth. Such scenes haunt us for a long period."*

The sufferings associated with terminal stage disease creates lasting remarks in peoples mind. Some people quit their habits and lead responsible life to avoid cancer. Others may enter in a state of denial and delay seeking help. One community leader said

"Treatment cost is one factor. Many people admit that costs are high. Even those who receive treatment support schemes complain that out-of-pocket expenses, travel, and other insidious expenses are too high for them to meet. Thus I feel cancer treatment should be made free of charge. This will reduce fear. The most important factor that pulls back patients from cancer treatment is concern over treatment cost. Government should make cancer treatment completely free."

Among all fears, the fear of treatment cost acts as a major deterrent in seeking timely diagnosis and treatment. The majority of the community leaders suggest making all investigations and treatments related to cancer, free in government institutions. They feel that freeing people from the financial implications of cancer will enable early diagnosis. Even rich people struggle to manage cancer-related financial burdens.

4.2.3.7 Summary

Community leaders provide guidance and support to people for availing of health care services. They have a general understanding of various challenges and needs of society and are actively involved to find solutions. Community leaders working in tribal and remote areas recognize the increasing incidence of oral cancer in the community whereas those from urban areas consider it as a less frequent condition. Local Self-Governing Institutions (LSGIs) and Non-Governmental Organizations (NGOs) provide support for cancer patients. NGOs provide financial and other logistic support for needy patients. LSGIs have no provision for meeting the out-of-pocket expenditure incurred by the patient. The NGOs and LSGIs extend their support for the much-needed early diagnosis facilities by organizing population-based cancer

screening camps in the community. Generally, early diagnosis facilities for common cancers like oral, breast, and cervical cancers were not available in primary care. Some LSGIs, recognizing this, had established facilities for early detection in the primary health center with separate infrastructure and manpower. Replicating these nurse-led early cancer detection clinics in other LSGIs will help in achieving equitable distribution of facilities for the early diagnosis of common cancer in the state. Community leaders have the power to facilitate early diagnosis through motivation, awareness generation, and patient navigation. Apprehensions and misperceptions about cancer exist in the community. Fear of incurability, recurrence, suffering, treatment cost, and stigma associate with cancer act as major deterrents for seeking health care. Some people seek alternative treatment on concerns about treatment procedures and treatment costs. Lack of awareness about various government treatment schemes adds to patients' financial worries.

4.2.3.8 Recommendations from community leaders for achieving an early diagnosis of cancer

1. Awareness programs and screening programs should be conducted in the community at frequent intervals.
2. Regular facility for early diagnosis of common cancers should be set up at primary health centers
3. Awareness and screening programs should be conducted in a variety of settings including but not limited to, places of work and worship, and meeting places of self-help groups.
4. Awareness programs on early diagnosis should targ*et* all people irrespective of their age, gender and not just those at risk.
5. Manpower issues in early diagnosis may be addressed through training community volunteers in the early detection of oral cancers
6. Cancer screening and early diagnosis investigations should be made free of cost.
7. Mass campaigns should be undertaken for enrolling eligible people in various government treatment schemes.

8. Financial assistance should be provided for bystanders working in the unorganized sector for their wage loss.
9. Financial assistance should be provided to cancer patients' families for their subsistence on a case-to-case basis through LSGIs.

4.2.4 Health system administrator's perspectives on oral cancer

4.2.4.1 Introduction

In-depth interviews were conducted with health system administrators involved in cancer control in the state. Cancer control and prevention activities in the state are largely delivered through comprehensive cancer care centers in the public sector and curative services are provided through medical colleges and private hospitals. The Comprehensive Cancer Care Centres (CCCC) have dedicated departments for promoting early cancer detection. The Kerala Health services department, the National Health Mission, and the Local self-government institutions conducted various training and early detection programs with technical assistance from the CCCCs. In-depth interviews were conducted with the Director of a Comprehensive Cancer Centre, Deputy Director of Health Service, program manager of National Health Mission, and faculty members from Community oncology departments of various comprehensive cancer centers. Out of the six administrators interviewed, two were females and all of them were working in the public sector. The administrators were asked about specific initiatives and programs associated with oral cancer prevention, various policies, plans, and strategies for oral cancer control in the state, and challenges for implementing early diagnosis programs in oral cancer.

4.2.4.2 Specific initiatives and programs for oral cancer control

Kerala's health system is facing challenges from the increasing burden of non-communicable diseases(Muraleedharan and Chandak, 2021). There are many national programs for the prevention and control of non-communicable diseases and their risk factors. Of these, three national programs are of particular importance to the prevention and control of oral cancer. They include the National Tobacco Control Program (NTCP), National Oral Health Program (NOHP), and National Programme

for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS). The NTCP is initiated to control the main risk factor for oral cancer. NPCDCS is initiated to provide a coordinated approach for the prevention and control of major non-communicable diseases in the country. The NPCDCS program is very much into the prevention and control of diabetes and hypertension but its presence in the prevention and control of cancer is inconspicuous. A faculty from the community oncology department of a tertiary cancer center said *"I have no idea about any specific initiative under NPCDCS for early cancer detection".*The above statement shows the absence of early detection of cancer under NPCDCS or low visibility of such exercise even among those professionals who work in early cancer detection.When enquired about the role of NPCDCS in early cancer detection, an administrator working in the National Health Mission said

"We *have a state-specific non-communicable disease control program called 'AmruthamArogyam". Under this program, there are specific initiatives for different non-communicable diseases".*

The above statement shows the cancer-specific activities are included in the larger non-communicable disease control program in the state. The non-familiarity of such components among other stakeholders in cancer control indicates the need for better communication among different divisions under the health department. There were activities conducted under the National Oral Health Program. A health system administrator, who was a Deputy Director in the Kerala Health Services said,

"Under the 'Velicham' and 'Unarve' programs, we were able to identify around 15 oral cancers and 250 oral pre-cancers in Wayanad and Kollam districts. These camps were conducted with community support. "

The above statement clearly shows how national programs which are not directly linked to oral cancer control were used for early cancer diagnosis at the community level. The National Oral Health Program (NOHP) was launched to provide integrated, comprehensive oral health care through the existing health care facilities. Under NOHP, community-based oral health camps and other campaign events were conducted. 'Velicham' and 'Unarve', were two such activities targeting the tribal

population and elderly population respectively. These activities helped to identify oral cancers and precancers among the mentioned targeted populations. These activities were also utilized to disseminate awareness of oral cancer and its risk factors. The administrator emphasized the role of the community, especially some grass root level organizations, for ensuring sufficient participation of beneficiaries in the activities and suggested involving the community in such activities for better outcomes. These activities were conducted utilizing the manpower and infrastructure of the government health system in those areas. A health system administrator, who is a functionary of the National Health Mission at the state level said,

"We are in the process of implementing the health and wellness centers in Kerala. The training for the community health officers is in progress. We are proposing to screen all persons visiting the health and wellness centers for common cancers. "

Under the Ayushman Bharat-Health and wellness scheme, preventive, promotive, curative, and palliative services will be delivered through the health and wellness centers. It would also have components on early detection of common cancers including oral cancers. The health system administrator further explained the proposed activities of the 'Health and Wellness Centres' and 'Family Health Centres' in cancer control. They are planned in such a way to address the cancer care needs of society, particularly the early detection needs, to some extent. A new category of service providers called Community Health officers will perform these activities in the health and wellness centers. The Community Health Officers (CHO) are trained nurses, who will perform screening for common cancers at Health and Wellness Centres. They will conduct an oral visual examination of the oral cavity, clinical breast examination, and visual inspection of the cervix (VIA VILI). Apart from providing routine maternal and child health services, these centers will be transformed to provide various non-communicable disease prevention services.

The administrator functioning in the National Health Mission further described the ABHAYM initiative. The ABHAYM initiative is a step towards the decentralization of cancer management in Kerala. Under this initiative, assistant surgeons in the health services were trained in Comprehensive Cancer Management and posted in the

district or general hospitals. Day-care chemotherapy facilities were set up at these hospitals. At present, there are 24 hospitals across Kerala that have district cancer care facilities. A health system administrator who involved in the implementation of the ABHAYAM initiative said

"During the COVID lockdown period, we were able to provide cancer treatment through these district cancer care centers for those who had difficulties reaching RCC. Around 2000 chemotherapies were given during that period."

The above statement highlights the feasibility of decentralizing cancer care through training the existing manpower and thereby reducing the burden on comprehensive cancer centers. It is evident from the above statement that the availability of these centers helped in maintaining treatment continuity for many patients. Initiatives for the decentralization of cancer care are not new. Years back, Early Cancer Detection Centres (ECDC) were established in various districts. These centers were primarily tasked with the early detection of oral, breast, and cervical cancers. An administrator who heads the community oncology department of Comprehensive Cancer Care Centre in Kerala described a novel model for decentralized early cancer detection services.

"Ayurdeeptham project is an innovative model for decentralization of early cancer diagnosis. The District Medical Office along with National Health Mission and the Tertiary Cancer Centre conceived the Ayurdeeptham project. Under this project, early cancer detection clinics will be established in primary health centers with facilities for detecting oral, breast, and cervical cancers. A trained nurse under the supervision of a medical officer will conduct the screening. Similar clinics were also established with the participation of Non-Governmental Organisations in rural and difficult-to-reach areas as associate centers. "

The ECDC clinics and associate centers are nurse-led facilities for the early detection of common cancers. Though these initiatives address the basic issue of accessibility to early cancer diagnosis, sustainability and acceptance of these centers over the period will be crucial in replicating such models to other districts in the state.

4.2.4.3 Policies and Strategies for cancer control in Kerala

Kerala is one of the first states in India to have a 10-year action plan for cancer control as early as 1988 (Nair, 1988). Though oncology services were available at Medical colleges during that period, cancer care was delivered mainly through the Regional Cancer Centre, Trivandrum. From 1988 to 2018, facilities for cancer treatment were improved in medical colleges, two new Comprehensive Cancer Centres were established and many private hospitals were also started providing cancer treatment. Considering the new circumstances and the needs for cancer care in the state, the Kerala Cancer Control Strategy document with goals and targets to be achieved by the year 2030 was released in 2018. A health system administrator who is the Director of a Comprehensive Cancer Centre said,

"The new cancer care strategy document proposes for accessible and affordable cancer care facilities across the state. Kerala Cancer Care Grid is suggested as a possible mechanism to achieve the same. Both government and private cancer care institutions together will make the grid."

The inclusion of private institutions in the cancer care grid will improve service delivery. It acknowledges the role and potential of private institutions in addressing public health priorities and channelling their resources for the larger good of society. The inclusion of common cancer screening in the proposed Health and Wellness Centre will complement the cancer control strategy in the decentralization of cancer early diagnosis facilities. This will facilitate achieving the target of diagnosing more than 55% of oral cancer cases in the early stages by 2030.

4.2.4.4 Existing facilities for early oral cancer diagnosis

The health system infrastructure and facilities for oral cancer control in the state include the sub-centre to district hospitals under health services, medical and dental colleges under the medical education department, and comprehensive cancer centres under the health department (Table 4.22).

Table 4.22: Existing facilities for early oral cancer diagnosis in Kerala

(Adapted from Kerala Cancer Control Strategy 2018-30, Department of Health and Family Welfare, Government of Kerala)

Levels of institution		Existing Facility 2018	Proposed facilities 2020	Proposed facilities 2025	Proposed facilities 2030
Basic cancer prevention unit PHC CHC Taluk Hospital Selected Private Sectors	Health Promotion	_	++	++++	++++
	Early Diagnosis	_	_	++	++++
	Referral to higher centers	+	++	++	++++
	Treatment (Taluk Hospitals)	-	-	++	++
	Follow-up care	-	+	++	++++
	De-addiction clinics (Tobacco & Alcohol)	-	+	+++	++++
	Diagnostic services specific for oral cancer				
	Clinical examination	+	++++	++++	++++
	Visual inspection of oral cavity	_	++	++	++
Cancer treatment and care centers District Hospital & Selected Private hospitals In the grid	Early Diagnosis & Treatment	-	++	++++	++++
	Training of Health Care Providers	-	++	++++	++++
	Diagnostic services specific for oral cancer				
	Clinical examination	+	++++	++++	++++
	Visual inspection	-	++++	++++	++++
Oncology Units Medical College Hospital & Selected Private hospitals In the grid	Establishment of Oncology Units	+	++	+++	+++
	Capacity Building	+	++	+++	++++
	Facilitate Settings based approach for health promotion	+	++	++++	++++
Comprehensive Cancer Care Centre RCC MCC CCRC	Multidisciplinary care & Specialized services	+	++++	++++	++++
	Provide Leadership Role in Capacity Building	+	++++	++++	++++
	Development of Guidelines/ SOPS/ Referral Criteria	+	++	++++	++++

+ indicates 25%, ++ indicates 50%, +++ indicates 75% and ++++ indicates 100% of the centres will have the facility available and functioning on site

The medical colleges and dental colleges act as referral centres for patients referred from the periphery. Precancerous lesions were generally diagnosed and managed at Dental colleges. Medical colleges manage cancer patients. Medical and Dental colleges conduct occasional camps at the community level and facilitate opportunistic cancer screening. The comprehensive cancer centres have a dedicated department for conducting cancer screening camps and awareness programs in the community. These camps and awareness programs provide access to common cancer screening in the rural and hard-to-reach areas in the community. An administrator who is the head of the community oncology department of an institution said

"We conduct around 300 cancer awareness programs in a year. Most of these programs were conducted in rural areas with the support of LSGIs and local clubs. "

The institutions under the health services also occasionally conduct community-based cancer screening programs. A faculty working in the community oncology department said

"We get a lot of requests from local self-government institutions for conducting cancer detection camps. Sometimes we find it difficult to give dates for all."

The above statement clearly shows the dependence of LSGIs on tertiary cancer centers for implementing early cancer detection programs. Apart from Local self-government institutions, health departments and non-governmental organizations also depend on tertiary cancer centres for conducting community-based early cancer detection programs.

4.2.4.5 Challenges for early diagnosis of oral cancer

There exist a lot of challenges for early diagnosis of oral cancer in the community setting and health system setting. A faculty working in the community oncology department and having many years of experience in community-based cancer control programs said,

"People may not allow their oral cavity to be examined as per their inhibitions or belief. In tribal communities, people will not heed our advice for quitting the tobacco

habit even if we identify some precancerous lesions in their oral cavity. Imparting health education is difficult as betel quid chewing habit is deeply rooted in their traditions. For effecting change, we need to train someone from their community and the message has to be delivered through them."

The above statement indicates the resistance towards oral cavity examination prevailing in certain communities. The habits, especially betel quid chewing, are deep-rooted in their tradition and have social and cultural significance. This acts as a major impediment to impart health education on tobacco and oral cancer. A solution suggested for overcoming this challenge was to train someone from their community on the health hazards of tobacco and alcohol and impart awareness through him/her. Habit continuation and lack of symptom awareness constitute the most important factors for delayed symptom presentation in health care settings. An administrator who heads the community oncology department of a tertiary cancer centre said

"Most of the patients with oral cancers have deleterious habits. So they are least bothered about health care. Also, they belong to low socioeconomic strata. They also have low education levels. All these delay health-seeking."

Community programs for facilitating early diagnosis should serve the target population. Care should be taken to conduct such programs in areas where the beneficiary population is high. Such programs should be conducted at a time and place convenient to them. An administrator who is the head of the department in a tertiary cancer centre said

"When camps were conducted in urban residential areas, we don't get any cases. But the situation changes when we conduct the camp in coastal or tribal areas. We get oral cancers and pre-cancers there. So it's the area and type of people that matters."

Health education among the adolescent group is a challenge. Habit cessation is difficult as they often ignore the long-term health consequences of their habits. They also switch from one habit to another instead of quitting habits altogether. Participation in the community-based oral cancer early detection program is a cause for concern. Though this program is of particular importance for males with tobacco,

alcohol, or areca nut habits, their participation was minimal. A faculty who is working in the community oncology department said,

"Most of the time, the people attending the camps may not represent the beneficiary population. Women participate in these programs more than men. Men go for work and don't benefit from these camps generally. Those people with no symptoms attend camps more than those with symptoms. They are more motivated. They want to know whether they have any disease. Those without habits are more motivated for prompt health-seeking. Also, the absence of habits helps them to recognize symptoms early. This is why oral lichen planus cases are more commonly reported in hospitals than leukoplakia." The above statement clearly indicates the challenge posed by the poor health-seeking behaviour that existed in the high-risk population. Facilities and programs for early oral cancer detection were utilized by those at low risk for developing oral cancer. The lower representation of the high-risk population in screening camps and awareness programs was reported by all the administrators involved in the early detection of oral cancer. An administrator functioning in the directorate of health service in Kerala said,

"We are about to develop a comprehensive strategy for the referral of cancer patients identified at different levels of health care. This is mainly to avoid the rush in the tertiary care hospitals, and for that, we are strengthening our community, District, and sub-district hospitals."

The non-existence of an established referral system for the diagnosis and management of oral cancer is evident in the above statement. Implementation of a proper referral system will reduce the burden on tertiary care institutions and thereby permitting optimal use of available resources. Coordination among the health service department, medical education department, and comprehensive cancer care centres are necessary for implementing a comprehensive referral system for oral cancer diagnosis and management. The administrators also recognize the absence of a mechanism to ensure proper follow-up of oral precancerous lesions. An administrator functioning in the National Health Mission said,

"Many premalignant lesions, maybe a leukoplakia or other suspicious lesion, all need regular monitoring and follow-up. The patient may not comprehend this. At times, health workers consider this trivial and did not insist on follow-up. Now we have given instructions to keep a separate register for all precancerous lesions reporting in the institutions and to involve community-level workers for ensuring follow-ups."

The above statement reiterates the need for patient education and professional reorientation and training for the identification and effective management of oral precancerous lesions.

4.2.4.6 Summary

Measures specific for the prevention and control of cancer are limited. The national programs on oral health, NCD prevention, and tobacco control have the potential for including early oral cancer detection as one of its components. Interdepartmental coordination is essential for the smooth implementation of various cancer control programs. Initiatives for the decentralization of cancer treatment and early diagnosis like ABHAYAM and Ayurdeeptham should be implemented on a wider scale. The proposed 'Kerala cancer care grid', consisting of a network of private and public health institutions is a unique model for decentralization of cancer care and if successfully implemented, will revolutionize cancer care in the state. Early cancer detection and awareness programs are generally conducted by comprehensive cancer centers or other organizations with their technical support. The challenges for the implementation of early oral cancer diagnosis program include poor participation of the high-risk population in the community-based screening programs, lack of patients adherence to follow-up instructions, absence of an established referral system, poor symptom awareness of the patients, and absence of professional reorientation and training.

4.2.5: Summary diagram on Factors associated with diagnostic journey in Oral cancer based on qualitative study findings

The following individual, interpersonal, community, organizational, and policy factors have emerged from our in-depth interviews with oral cancer patients,

community leaders, healthcare providers, and health system administrators as contributing to the diagnostic journey in oral cancer. (**Figure 4.14)**

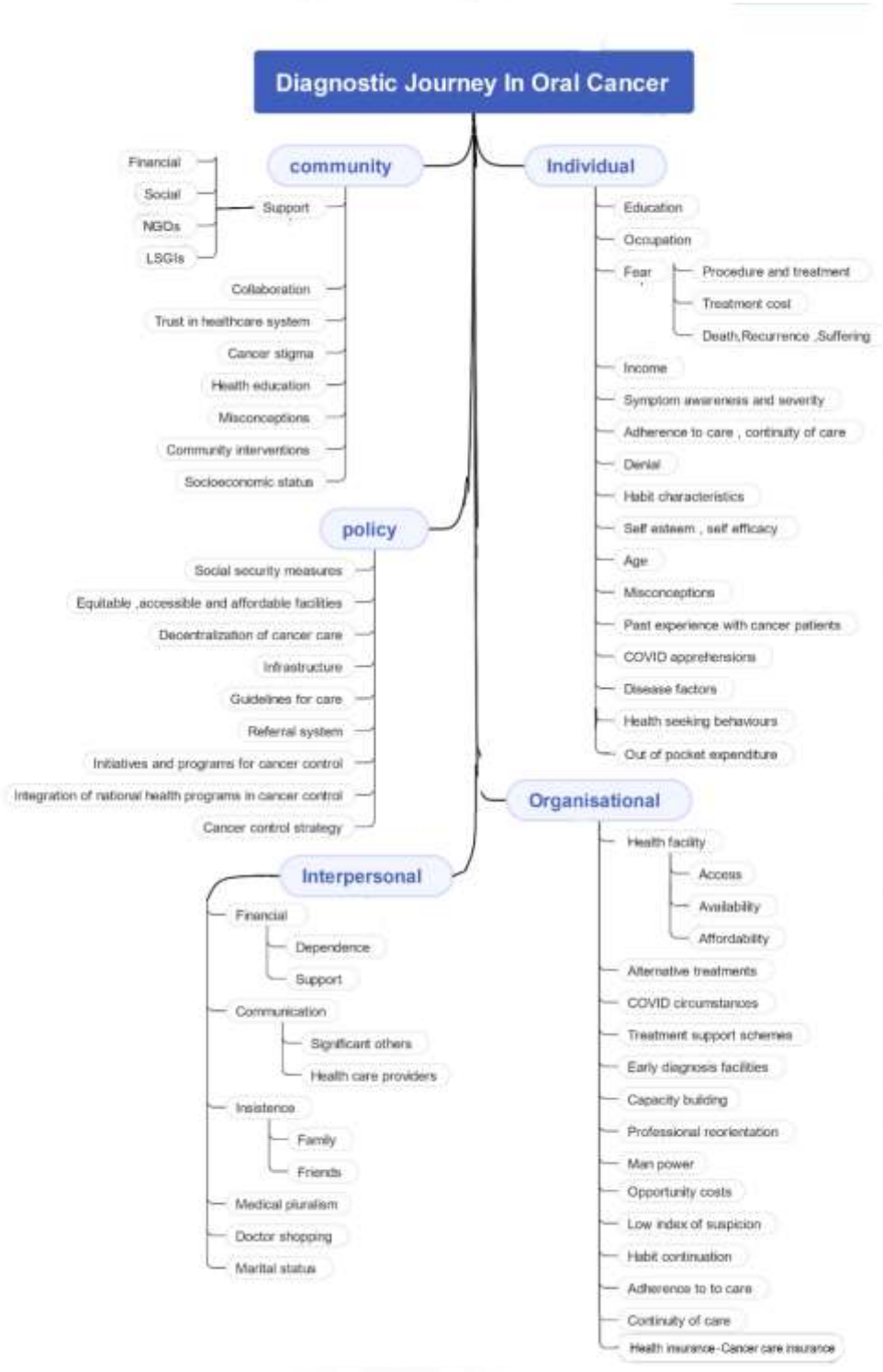


Figure 4.14: Factors associated with diagnostic journey in oral cancer

4.3 Policy analysis of Kerala Oral cancer initiatives: A document review

4.3.1 Introduction

A document review of various action plans, strategy documents, and health policy documents that discuss cancer control in the State of Kerala was done. Four documents were included in the review as described in the methodology section. The documents included are, Ten-Year Action Plan for Cancer Control in Kerala (1988), Kerala Cancer Control Strategy (2018), Draft Health Policy (2013), and Health Policy (2019). The above documents were analysed based on the policy document checklist to identify the key institutions and organizations involved in cancer/oral cancer prevention in the State and also to identify the roles and responsibilities of each institution in the cancer prevention program. The document was also assessed for identifying initiatives and measures taken for early oral cancer diagnosis as well as the proposed strategies and plans for oral cancer prevention. The findings of the analysis are presented in the following sections.

4.3.2 Characteristics of the documents

Year of the initiative: The ten-year action plan for cancer control was published in 1988. Kerala was the first state in India to have such a plan for cancer control in the state in line with the national cancer control program. The second strategy document was published in 2018, thirty years after the first document. The draft health policy document of Kerala was published in 2013 and the first health policy document of Kerala was published in 2019.

Stated goals and objectives: The objective of the ten-year action plan document was to implement the national cancer control program in Kerala. The main objectives of the national cancer control program were the primary prevention of cancer, especially tobacco-related cancers, early diagnosis and treatment of cancer of the uterine cervix, and lastly distribution and extension of services through Regional Cancer Centres, Medical and Dental colleges. The stated goal of the cancer control strategy document of 2018 was to reduce the burden of common cancers and enhance the quality of life

of cancer patients in Kerala through the Kerala Cancer Grid and Universal Health Coverage. The draft health policy of 2013 was prepared to guide the government in achieving the targets set under the 12th five-year plan. The 12th plan envisages achieving universal health coverage for all citizens. Health policy 2019 was prepared with the long-term objective of establishing a universal, free and comprehensive healthcare system. It aims to strengthen the primary health centres and also to modernize the public health system.

Governance: As per the Ten-year action plan, the governance and oversight of the national cancer control program in the state were vested with the state cancer control board. The state cancer control board was formed under the chairmanship of the Chief Minister and it included the minister of health as vice-chairperson. The members included elected representatives, Government secretaries, and directors of various departments. Representatives from central government ministries, national research institutions were also included. The Director of the Regional Cancer Center, Thiruvananthapuram was the member secretary. The 2018 cancer control strategy document also proposed setting up a multidisciplinary State Cancer Control Board with multi-stakeholder involvement for the coordination and implementation of the cancer strategy. The health policy documents did not mention any governance strategy for cancer control in the state.

4.3.3 Key institutions/organizations/departments involved in cancer control /oral cancer control

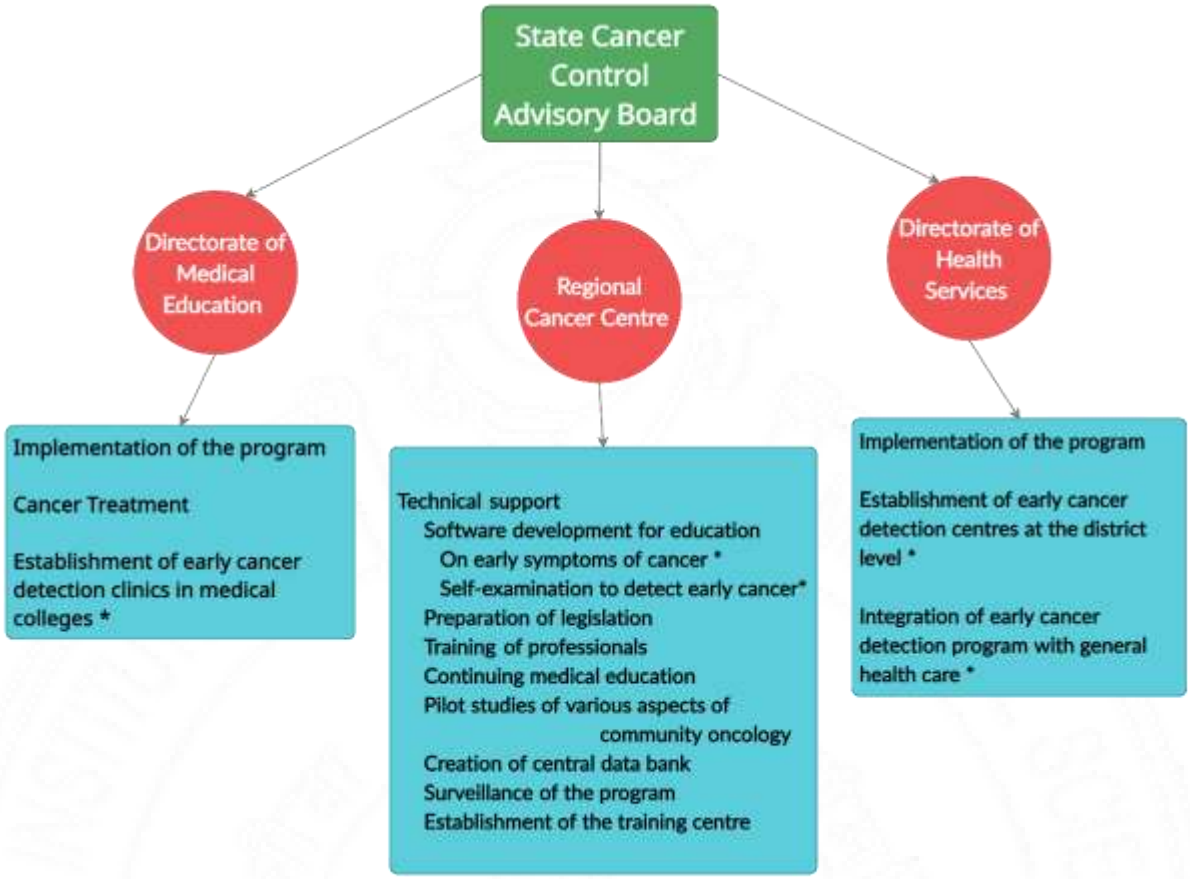
Regional Cancer Centre (RCC) at Trivandrum and Radiotherapy departments in major government medical colleges were the key institutions providing cancer treatment in the State in 1988. Many new institutions have emerged for cancer care in private and government sectors over the next 30 years. Two new comprehensive cancer centers, Malabar Cancer Centre (MCC) at Thalassery and Cochin Cancer Centre and Research Centre(CCRC) at Ernakulum, were established in the public sector during this period. Oncology wings in some government medical colleges were developed as Tertiary cancer centers. Several institutions in the private sector were also started providing oncological services. The need and necessity to coordinate the cancer control

activities at the state and district level were highlighted in the reviewed documents and suggested for the formation of a State Cancer Control Board (SCCB) and district committees to oversee the implementation of the cancer control strategies.The1988 Action Plan document advocated for the participation of the general community in implementing the recommendations of the NCCP. This was suggested as a strategy to ensure public acceptance of the cancer prevention programs but the document did not mention any association or partnership with the private sector for cancer control. This may be due to the inconspicuous role of private players in cancer care during the 1980s.

The 2018 cancer control strategy document advocates for the involvement of private cancer care institutions in attaining the cancer control goals specified in the document. The 2018 Cancer Control Strategy document proposes to form the Kerala cancer control grid. RCC, MCC, CCRC, medical colleges, district hospitals, and private sector hospitals will form part of the grid. The grid is stated to provide people equitable, accessible, and affordable facilities for early cancer detection and treatment within 50 kilometers vicinity from their residences. The draft health policy of 2013 proposed to set up early cancer detection facility and follow-up chemotherapy facility at district hospitals. The idea of early cancer detection centres in every district was first suggested in the 1988 Action plan document. The health policy of 2019 also proposed to establish cancer treatment facilities in all medical colleges and to develop similar facilities in district hospitals of those districts where government medical colleges did not exist.

4.3.4 Functions/ responsibilities of different actors involved in the cancer control/oral cancer control

The cancer control policy of 1988 had specifically described the functions and responsibilities of different players involved in the cancer control program. The three core service providers involved in the program were RCC, Directorate of Medical Education (DME) Government of Kerala, and Directorate of Health Services (DHS) Government of Kerala(Figure 4.15).

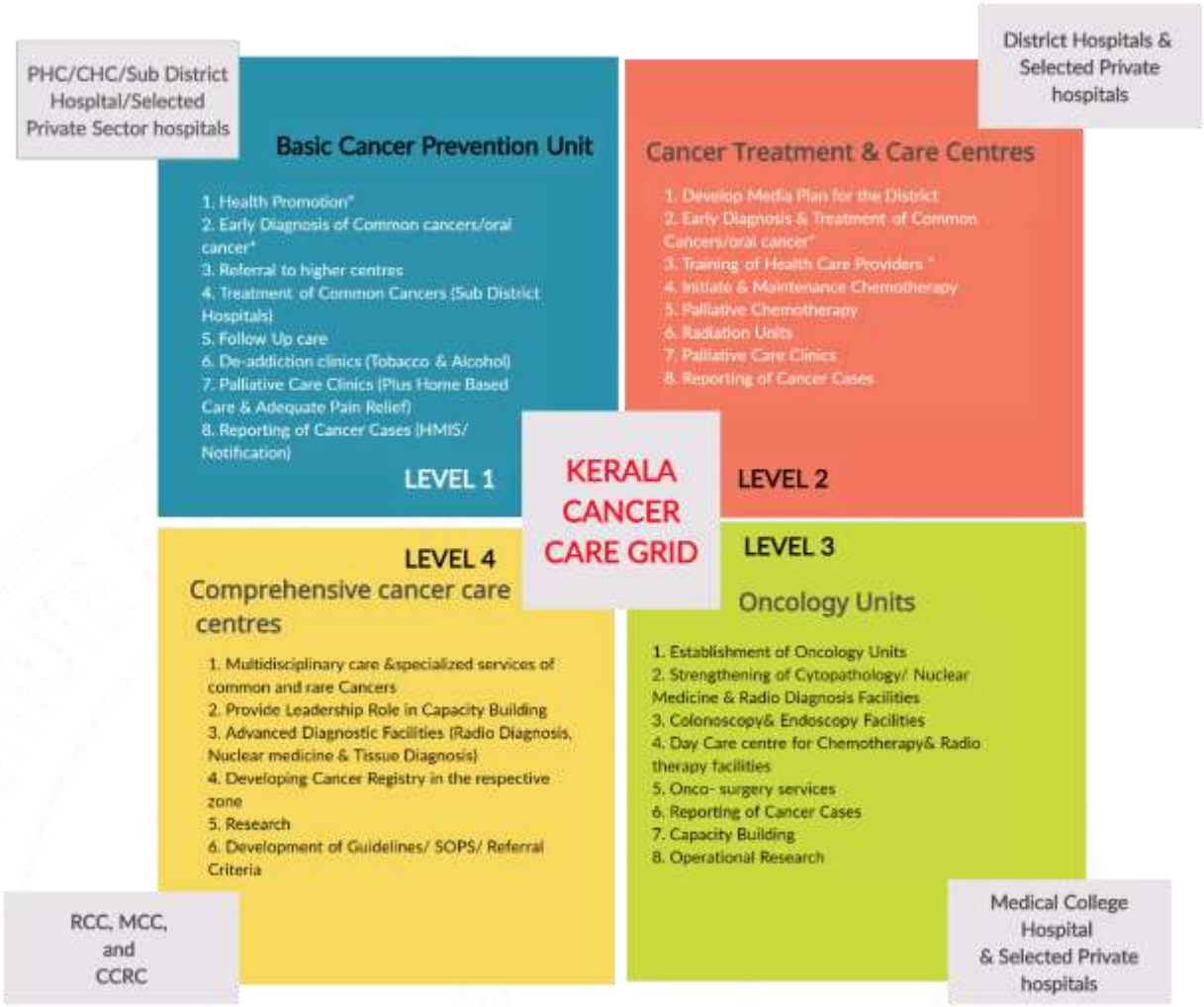


*Relevance for oral cancer early diagnosis

Figure 4.15: Structure and function of cancer control in Kerala suggested in the Ten-year action plan of 1988

DHS and DME were assigned with program implementation, whereas RCC provided the technical support for the program. Appropriation and allotting of funds to the participating institutions was the responsibility of the State Cancer Control Advisory Board of Kerala. The utilization of these funds was entrusted with district-level committees.

In the 2018 cancer control document, the SCCB is responsible for operationalizing the different elements of the strategic plan. It also has to mobilize the necessary resources. The cancer control and prevention goals set in the 2018 document will be achieved through the Kerala Cancer Care Grid(KCCG). KCCG is proposed as a network of health facilities offering cancer care services(Figure 4.16).



***Relevance for oral cancer early diagnosis**

Figure 4.16: Structure and function of the proposed Kerala Cancer Care Grid

These institutions will be categorized according to their cancer care facilities and capacities. Apart from Government institutions, private institutions can also join the Grid. The Kerala Cancer Care Grid put forth a novel concept of equitable distribution of cancer care services with the participation of private institutions. The cancer care grid will also address the geographical inequality in accessing care. This unique model, if implemented successfully, will revolutionize cancer detection and treatment in Kerala. The health policy documents of 2013 and 2019 did not explicitly mention the functions and responsibilities of different players involved in cancer care.

4.3.5 Mention on referral guidelines and diagnostic protocols

Appropriate referral guidelines are necessary for speedy diagnosis and treatment. The 1988 Action Plan provided referral guidance for those cancers that can be detected by a trained health worker. When a health worker comes across a person with suspected symptoms of Cancer during screening, should refer to the PHC medical officer, and subsequently, the PHC medical officer should refer them if they are confirmed with some suspicious symptoms to the respective district early cancer detection centers. However, the document failed to recognize the need for referral of precancerous oral lesions and the procedures to ensure proper follow-up and management of those lesions. The documents also ignored the need for initiating tobacco and alcohol cessation programs in medical, dental colleges, and other secondary and tertiary care centres.

The Cancer Control Strategy document of 2018explicitly recognized the absence of a referral system and suggested training primary care providers and doctors of all systems of medicine working in secondary and tertiary levels of healthcare in identifying early warning signs and symptoms of cancer and also for appropriate referral. The document suggested establishing a referral pathway for cancer through the Kerala Cancer Control Grid. The grid comprises hospitals categorized according to the type and level of cancer care services. The comprehensive cancer care centers (RCC, MCC, and CCRC) were entrusted to prepare the referral guidelines. If properly implemented, Referral guidelines will reduce the burden on tertiary care institutions and will ensure judicious and optimal use of existing cancer care facilities at various levels of the health care system. Capacity-building training and sensitization programs for health workers including doctors and infrastructure augmentation should precede implementation of cancer referral guidelines. The following excerpts from the 2018 cancer control strategy document indicate the need for health workers' training for the identification of signs and symptoms of cancer.

"As Cancer is still considered to be a highly specialized condition and primary care physicians don't seem to be confident in dealing with these conditions".

For the successful implementation of any referral system, the general public should be familiar with the referral process. One of the objectives of the draft health policy of 2013 was to develop referral networks managed by primary care providers. The 2019 health policy advocates for implementing a strict referral system for accessing sub-district and district hospitals and medical college hospitals. The document further suggested developing protocols and guidelines for implementing referral systems in health services. All the four reviewed documents recognized and recommended implementing a referral system but not yet been materialized.

4.3.6 Discussion on Early diagnosis of cancer

The 1988 Action plan document proposed to popularise the early detection of cancers like oral cancer that can be detected through a simple physical examination. It suggested educational and legislative measures to promote early detection and the establishment of a proper referral system. The document also suggested training for a large group of workers on early detection at the community level. This was suggested considering the paucity of trained hands in health services to manage screening activities. The 1988 Action plan document noted that

"No Government, however rich, will be able to mobilize a sufficient number of doctors for early detection".

The above excerpt shows the impracticability of mobilizing doctors and other resources for organized cancer detection programs.

"Any program aimed at inducting doctors for early cancer detection can be quite expensive and rather wasteful as experience has demonstrated that the ordinary health worker can perform this activity equally well, of course in specific sites".

The above excerpt from the 1988 Action plan document suggests training community volunteers in cancer detection. Moreover, community ownership of the program may ensure its sustainability. Community-based detection programs need a backup of diagnostic infrastructure. Without such facilities, the program would fail. So, the document suggested ensuring accessibility to cancer diagnostic facilities across Kerala. In this regard, the establishment of early cancer detection centers at the

district level would help in achieving the goal of early diagnosis. The document further suggests establishing dedicated early cancer detection centers with separate staff and infrastructure.

The 2018 Cancer Strategy document proposed early detection of common cancers in PHCs, CHCs, and Taluk hospitals. The document has given due importance to improving the cancer-related knowledge of health professionals and the general population. It proposes to include early detection and diagnosis of cancer in the Medical curriculum and cancer health education in the school curriculum. Public health education campaigns were also planned to promote self-examination of the oral cavity. The 2018 cancer strategy document recognized that oral cancer was amenable for early detection due to the presence of precancerous lesions and tests for early detection were available. The document made it clear that the focus of our cancer control activities should be early diagnosis and not population-based cancer screening. The document further notes that

"*At present Kerala should focus on early diagnosis and not on population-based screening, which is resource-intensive and current infrastructure including qualified manpower is inadequate to meet the demands of an organized screening program".*

The 1988 Action plan document suggested a professional reorientation program for appropriate referral of common cancers. While the 2018 Cancer Strategy document suggested in-service training for primary care practitioners for early detection of cancers. The detection was done by identifying through a simple physical examination with specific reference to cancers of the oral cavity. This will facilitate the early diagnosis and treatment of oral cancer. The 2013 draft health policy document proposed to enhance the dental treatment facility at district hospitals by providing oral cancer detection facilities. The document also proposed to establish early cancer detection facilities at the district level. The 2019 health policy document also noted the importance of early diagnosis in mortality reduction but did not elaborate on the strategies for achieving the same. It recognized the necessity of early detection of breast cancer and cervical cancer but didn't mention oral cancer.

4.3.7 Stated goals and objectives about oral cancer control

The stated objectives of the 1988 Action Plan document related to cancer/oral cancer control include generating awareness about tobacco and cancer in the community, training people in early cancer detection activities, setting up dedicated and accessible cancer diagnostic services, and incorporation of cancer detection, diagnosis, and treatment in the medical curriculum. The first two objectives were about community-level activities and the rest were about provider-side capacity building.

The 2018 Cancer strategy document puts integrated cancer prevention through people's participation and strengthening of the health care delivery system as its objectives. The document further provides strategies to achieve the above objectives. The first objective can be achieved through risk mitigation strategies and improving cancer literacy. The second objective can be achieved through Kerala Cancer Grid. It will ensure equitable and accessible facilities for early cancer detection and treatment. The targets specific to oral cancer to be achieved before 2030 include reduction of incidence of oral cancer to less than 15%, improve 5-year oral cancer survival to 60%, more than 55% of oral cancer should be diagnosed early, more than 80% of the population should be aware of warning signs of cancer, and more than 90% of oral cancer patients should complete their treatment within a year from the date of diagnosis. Though the document advocates for early diagnosis, the period to be considered as "early" is not defined in the document. However, for achieving these targets, the cancer control strategy relies heavily on the proposed Kerala Cancer Care Grid. The proposed Kerala Cancer Care Grid is a network of health care institutions whose control is vested in different government directorates and private bodies. Thus the formation of the grid itself is a challenge. So a strong administrative and political will is necessary for the formation and initial functioning of the Grid.

4.3.8 Proposed measures /strategies for oral cancer control

The following activities were suggested under the 1988 Action plan related to oral cancer control. They include preparation of awareness materials on early symptoms and self-examination, proper enforcement of tobacco control laws, the establishment

of early cancer detection centers, and the establishment of oncology units in Medical colleges with facilities for treatment and early detection.

The 2018 Cancer strategy document suggested upgrading the existing oncology services in medical colleges by establishing oncology wings. It also suggested addressing the geographical inequality in cancer care across the state. There are districts in the state with no facility for cancer treatment. The document further suggested integrating various national health programs with similar objectives for achieving comprehensive cancer control. The proposed Kerala Cancer Care Grid will ensure access to diagnosis, treatment, and survivorship care without delay. The 2018 Cancer strategy document is a pragmatic step towards equitable distribution of cancer care across the state with the participation of the private sector and general public.

The 2013 health policy document suggests decentralization of cancer care by equipping secondary level institutions in health services. It suggests setting up an early cancer/oral cancer detection facility at the district level. The 2019 health policy document advocates for improving treatment facilities in all districts. It did not mention oral cancer.

4.3.9 Resources allocated –infrastructure and man power-for cancer control

The Action plan of 1988 and the Cancer strategy of 2018 suggested utilizing the existing infrastructure of the health service department for implementing the primary and secondary prevention programs. The cancer strategy document of 2018 proposed for partnership with private institutions providing oncological services in the state. The above documents also advocated for strengthening the cancer treatment facilities at medical colleges. The Action plan of 1988 had allocated 76.4% of total program expenditure for strengthening the cancer treatment facilities in medical colleges. The directorate of health service, which coordinates the early cancer detection program was given 7.2% of the total program expenditure. It clearly shows that the 1988 Action plan had allocated nearly three fourth of its proposed budget for strengthening the oncology units in Medical colleges. The lower share of funds for early diagnosis activities can be justified as the establishment of adequate treatment and diagnostic facilities is a prerequisite for initiating any screening /early detection program. It is

futile to initiate any early detection program if we don't have sufficient facilities for providing timely treatment.

The 2018 cancer strategy document did not elaborate on the financial aspect of executing the strategy as the document is primarily prepared to guide the government in cancer care. Both the documents had tasked the state Cancer Control Boards to raise the necessary resources for executing these strategies. Governments over the past 30 years had substantially invested in developing cancer treatment facilities in the public sector. Apart from the Regional Cancer Centre and Malabar Cancer Centre, six government medical colleges and the general hospital in Ernakulum have started providing comprehensive cancer treatment. Over time, private institutions were also started providing cancer treatment. Despite this, Districts like Palakkad, Wayanad, Idukki, and Malappuram were not having any tertiary cancer care centres. So the document rightly discusses the inequity in the distribution of cancer diagnostic and treatment facilities in Kerala. The proposal of the Kerala Cancer Care Grid came as a response to this disparity. The document suggested forecasting the human resource and infrastructural requirements for the state and to create sufficient manpower for cancer care.

The 2018 cancer control strategy document says *"Develop capacity in the state for producing an adequate number of specialists in various aspects of cancer management. Train primary care providers and doctors at secondary and tertiary care providers in all streams to identify and refer for confirmation symptoms of cancers in their practice*".

The above excerpt from the 2018 cancer control document suggests training practitioners from all streams in the early identification of signs and symptoms of common cancers and their referral. This suggestion, if implemented, will increase the early cancer diagnosis facilities in the community. Kerala Cancer Care Grid is no panacea to all problems associated with cancer control, but it offers some solutions to few critical issues like shortage of manpower and inequity in the distribution of cancer care services. Through the Grid, a lot of cancer care activities like early detection, diagnosis, management of early lesions, follow-ups, palliative treatments,

etc. can be entrusted to primary and secondary care institutions. This will relieve the burden on comprehensive cancer care institutions and their highly skilled manpower can concentrate on tertiary care. It highlights the need for increasing the post-graduate seats in oncology-related specialties and super specialties. The 2019 health policy document also suggested increasing specialty and super specialty seats in medical colleges.

4.3.10 Context of discussion on oral cancer

In all the reviewed documents, oral cancer is discussed mainly in the context of early detection. Other contexts for discussion on oral cancer include discussions on common cancers, cancer incidence in males, training health workers in cancer screening and early detection, health education, and discussion about risk factors like tobacco and alcohol use.

The 2018 cancer strategy document says *"Primary care practitioners in public services will be reoriented by in-service training initiatives to provide oral visual inspection among symptomatic people and in users of tobacco or alcohol or both and refer those with suspicious lesions to facilitate early diagnosis and prompt treatment of oral cancers"*. The draft health policy of 2013 discusses oral cancer in the section about "oral health". The 2019 health policy document did not mention oral cancer.

4.3.11 Administrative /technical content

The cancer-specific strategy documents of 1988 and 2018suggest the formation of a state board for cancer control. The State Cancer Control Board will oversee the implementation of the project. The 2018 cancer strategy document also suggests forming a multi-disciplinary technical Advisory group under State Cancer Control Board to monitor and implement the activities proposed in the program. A district-level committee is also proposed in both documents to oversee the implementation of the program in the districts with community participation. Under the ten-year action plan of 1988, district-level committees consists of popular and technical members could decide on utilization funds for the program. The administrative structure of the program is clearer in the 1988 document whereas the 2018 cancer control strategy

document lacks that clarity. This is more of a vision document where further administrative and operational plans are left to the government to decide.

4.3.12 Extent of participation

The ten-year action plan of 1988 entrusted the directorate of medical education with cancer therapy-related activities and the directorate of health services with early detection activities. The regional cancer centre was instructed to provide training and other technical supports for the program. These three agencies had to work in close coordination for the implementation of the Action plan. The cancer control strategy document of 2018 focuses on the proposed Kerala Cancer Care Grid for the implementation of its strategies. The document had specified the extent of participation of every institution in the Grid. For that purpose, all participating institutions were categorized into four levels based on the extent of oncological services they provide. Level one is Basic Cancer Prevention Unit and level four is the Comprehensive Cancer Care Centres. Both government and private institutions were included.

4.3.13 Summary

Kerala was the first State in India to prepare a policy document for cancer control as early as 1988. The cancer control plan outlined in that document provided more emphasis for developing basic cancer treatment facilities by strengthening the government institutions. It also recognized the importance of primary and secondary prevention and planned programs for executing the same with community participation. The second strategy document on cancer control was prepared in 2018, thirty years after the release of the first document. By the time of the second strategy document, cancer care was no longer a service provided by the government sector alone. Though many private institutions started providing cancer care, access and affordability issues remained as a concern. The new Cancer strategy document outlined a pragmatic strategy for equitable cancer prevention and control in the state. The Kerala Cancer Care Grid proposed in the document is a unique concept to address the geographical inequality in access to cancer care. The strategy provides a comprehensive approach covering all aspects of cancer care including early diagnosis.

It set specific targets for risk reduction and early diagnosis of common cancers including oral cavity cancers but did not explicate the strategy for achieving the same. The Health policy documents were also given due importance for cancer early diagnosis. The 2018 cancer strategy document identified interdepartmental coordination and partnership with private sector institutions and community organizations as crucial for achieving cancer control goals. Successful operationalization of the strategy outlined in the 2018 Cancer Strategy document will result in equitable, accessible, and affordable cancer care for all citizens in the state.

DISCUSSION

Chapter 5

Discussion

Oral cancer ranks second among all cancers in India (Ferlay J *et al*., 2020a). Most of the oral cancer patients are diagnosed at late stages leading to increased treatment costs and poor outcomes(Coelho, 2012). Delayed presentation of symptoms as well as the delay in diagnosis often results in advanced stage at diagnosis, leading to disease progression and ultimately resulting in poor prognosis (Coelho, 2012). Information about the magnitude of these time events in the diagnostic journey of oral cancer is scanty in the existing literature, especially from the South Central Asian countries. Similarly, research on factors contributing to these periods is limited and often restricted to socio-demographic characteristics (Philip and Kannan, 2019). Inconsistencies in the methodology and reporting of existing early diagnosis research led to the development of the Aarhus statement to guide early cancer research (Weller *et al*., 2012). The absence of validated tools for measuring the various time points in the diagnostic journey of oral cancer further constrained early oral cancer diagnosis research.

In the present study, validated tools were developed to measure the patient interval and diagnostic interval in oral cancer and also to identify various factors contributing to these intervals. Using the newly developed tool patient interval and diagnostic interval were measured in days and used median and interquartile range to describe the summary statistics. We found that 'The compelling reason behind initial consultation with a health care provider', 'Tobacco smoking status at the time of symptom recognition', 'Cancer stage', 'Worry about what the doctor might find out, and the 'Time to reach nearest healthcare facility were significant predictors for the patient interval in oral cancer. The predictors for diagnostic interval include 'Monthly income', 'Type of advice provided by the health care provider', Number of healthcare providers consulted in the diagnostic journey', 'Age of the participant', and 'Caste'.

A sequential explanatory design(Ivankova*et al*., 2006) was used for conducting the study as the research problem demands a comprehensive evaluation of the complex behavioral and social aspects associated with the diagnostic journey of oral cancer. This design facilitated a greater understanding of the oral cancer patient's diagnostic journey as findings from the qualitative part helped in explaining the results of the primary quantitative study. It also brought in aspects of patient interval and diagnostic interval from an individual, community, and system perspective. The sequential explanatory design was also used in other cancer-related studies exploring patient behaviors in cancer screening (Jain *et al*., 2016), and diagnostic delay (Ganesan *et al*., 2020). Though sequential explanatory designs provided a comprehensive understanding of the research problem, researchers generally refrain from choosing this study design owing to the long duration necessary for completing such studies (Ivankova *et al*., 2006).

The lack of a validated tool for identifying the exact duration of patient and diagnostic interval in oral cancer necessitated the development and validation of the data collection tools. The only validated tool for measurement of patient-reported time to diagnosis in cancer was developed by Neal *et al*(Neal *et al*., 2014). However, this tool did not include oral cavity cancers. Developing a tool for oral cavity cancers was challenging due to the presence of multiple signs and symptoms that may suggest oral cancer. To include all the possible signs and symptoms reported by the patient during their initial consultation with a health care provider, we contacted health providers who serve as the first point of contact for oral cavity-related symptoms. Retrieving the initial date of symptom recognition from the patient was another challenge as they generally provide an estimate only(Neal *et al*., 2008). To rectify this, a protocol was developed by Neal *et al* to calculate the 'pseudo exact' dates from the 'estimated dates' provided by the patient. Neal *et al* also provided a validation protocol for validating the 'pseudo exact dates'(Neal *et al*., 2014). These protocols were adapted to match the local context and used in our study. The tool along with the protocols helped to identify and validate various time points in the diagnostic journey of oral cancer.

The diagnostic journey of oral cancer patients begins from the time they recognize an abnormal bodily change or sensation in the oral cavity. The 'General model of total patient delay' proposed by Andersen *et al* is a useful model for early diagnostic researchers to explain the various time points and events in the diagnostic journey of cancer(Walter *et al*., 2012). Andersen's model of total patient delay consisted of a series of possible delays to final treatment. They included appraisal delay, illness delay, behavioral delay, scheduling delay, and treatment delay(Walter *et al*., 2012). Walter *et al* further refined the Andersen model and proposed 'Model pathways to Treatment'. The refined model replaced the word 'delay' with 'interval' to describe the periods. It also excluded the 'illness delay', 'behavioral delay', 'scheduling delay' and added 'help-seeking interval' and 'diagnostic interval'(Walter *et al*., 2012). The use of the word "delay" in the patient delay or diagnostic delay amounts to blaming the patient or the provider. World Health Organisation's Guide to Early Diagnosis combined 'appraisal interval' and 'help-seeking interval' as 'Patient Interval'(World Health Organization, 2017). Patient factors, health care provider and system factors, disease factors, financial, logistic, and sociocultural factors influenced diagnostic journey in cancer(Walter *et al*., 2012; World Health Organization, 2017). The conceptual framework for the present study is derived from Walter's refinement of the Andersen Model of Total Patient Delay and the World Health Organisation's guide to Early Cancer Diagnosis. The 'Aarhus statement' on early diagnosis research clearly stated the need for a theoretical framework for early diagnosis studies for ensuring quality and enabling comparison across studies(Weller *et al*., 2012). This study was designed and reported following the 'Aarhus statement'. The beginning and endpoints of 'patient interval' and 'diagnostic interval' were clearly defined before the initiation of data collection (Weller *et al*., 2012).

5.1: General characteristics of the study population

5.1.1: Socio-demographic factors

At the outset, the present study findings confirm the fact that oral cancer is more common among higher age groups. The mean age of the participants was 60.77 ± 12.3 years. A multi-country study on oral cancer reported the mean age of their participants

as 58.37±15.77 years (Dhanuthai *et al*., 2018) but some studies report mean age as high as 76 years (Goldenberg *et al*., 2014). The male-female ratio observed in the present study of 2.4:1 was similar to that observed in a previous study (Dhanuthai *et al*., 2018). The socio-demographic and economic profile of the study participants is in line with the observations from the previous studies (Ganesan *et al*., 2020; Warnakulasuriya, 2009b). Awareness about oral cancer was less among people belonging to low socioeconomic status and sometimes an inverse relationship was also observed(Azimi *et al*., 2020). When the findings on religion and caste affiliation of the study population were compared with that of the latest census data of Kerala, a higher representation of scheduled tribes was found in the study population (10.7%) as against the census data (1.45%)(Government of India, 2011b). A higher prevalence of risk factors and precancerous lesions among the tribal population were reported in other studies from Kerala. Increased incidence of oral precancerous lesions was reported in certain tribal populations in Kerala(Palliyal, 2018). This may be due to the high prevalence of tobacco habits among the tribal population in Kerala(Janakiram*et al*., 2016). In-depth interviews with community leaders reported a higher incidence of oral cancer among the tribal population compared to the general population. Moreover, the tribal community in India lags behind the rest of the population on several social, developmental, and health indicators(Narain, 2019).

5.1.2: Habit related factors

Although the prevalence of smoking and smokeless tobacco in Kerala is well below the national average as per the latest Global Adult Tobacco Survey held in 2016-17(Ramanarayanan and Rajeev, 2020), the prevalence of these habits in the study population was much higher than the national average. In this study, the assessment was made as to how self-appraisal of symptoms suggestive of cancer affected the tobacco and alcohol habits of participants. Symptom recognition made some quit the habit or reduce the frequency of tobacco and alcohol consumption; others have either continued or increased their consumption. More than three-fifths of the current smokers and about half of the pan masala users have either quit or reduced frequency of consumption whereas others either increased or continued the habit. The continuation of habit was more pronounced among betel quid and alcohol users. More

than three fourth of alcohol users either continued or increased their alcohol use. From the qualitative analysis of patient interviews, it was observed that some patients continued or increased the frequency of their habit for temporary relief from their symptoms, especially discomfort or pain. Most of them reported pain relief when the quantity of alcohol consumed was increased. A higher proportion of alcohol users and betel quid chewers increased their habit frequency after symptom recognition than smokers and pan masala users in this study.

5.1.3: Health seeking behavior

The general health-seeking behavior observed from the study participants reflected limited utilization of services. Participants in the study availed health care facilities generally for acute or serious conditions. This pattern is true for general dental care also. The qualitative findings suggest financial dependency of the family on the participant was a barrier to seeking care and adherence to treatment. Many of the participants were daily wagers working in unorganized sectors. Concerns about job security and wage loss deterred them from seeking care during working hours or taking leave for availing healthcare. Even though private hospitals function even outside the general working hours of government primary care institutions, financial and accessibility issues prevent them from availing these services. A study that evaluated the health care utilization in India based on the National Sample Survey data, observed a strong association between socioeconomic status and health care utilization with higher utilization among those belonging to high socio-economic strata(Banerjee and Chowdhury, 2020). Underutilisation of dental care services was reported in a study from Andhra Pradesh. Acute conditions like dental pain prompted more than two-third of the participants to seek dental services(Nagarjuna *et al*., 2016).

In this study, more than three-fifths of the participants either used self-remedies or over-the-counter medicines before consulting any health care provider. A study from Germany reported a very high prevalence (80%) of home remedies in their study population. On average,22 different home remedies were used per person (Parisius *et al*., 2014).

5.1.4: Presence of comorbidity

More than one-third of the study participants were having chronic diseases such as hypertension, diabetes, chronic respiratory diseases, and cardiovascular diseases. A large state-wide community-based cross-sectional study on the prevalence of non-communicable diseases in Kerala had found raised blood pressure and fasting blood glucose among 30.4% and 19.2% of their participants respectively(Sarma *et al*., 2019). The 'surveillance effect' due to the frequent contact with the health system resulting in early diagnosis and thereby early stage at diagnosis was not observed in a large cohort study consisting of patients with cancers of different sites(Gurney *et al*., 2015).

5.1.5: Access to health care

Information regarding the distance, duration of travel, and transportation available to the health facility will give some idea about access to health care. In this study, more than one-third of the participants were living farther than three kilometers from the health facility and nearly one-fifth of participants took more than 30 minutes to reach the first point of contact in the health system. More than one-third of the participants had to depend on a combination of public and private vehicles to reach the health facility. A systematic literature search on the transportation barriers to health care access observed that inadequate transportation facilities acted as a deterrent for healthcare access, particularly for people of low socioeconomic status(Syed *et al*., 2013). Though the distance to the health facility was a barrier for health care utilization, its impact was relative to the health status and resources of the patient, and the urgency and complexity of services needed(Buzza*et al*., 2011). A systematic review on the impact of travel time or distance to the health facility on health outcomes could not rule out the observation that traveling farther from health facilities resulted in poor health outcomes(Kelly *et al*., 2016).

5.1.6: Site of oral cancer

In the present study, the most common site of cancer in the oral cavity was buccal mucosa (ICD Code -C06) followed by the anterior two-thirds of the tongue (ICD

Code- C02). In southeast Asia, buccal mucosa constitutes the most frequent site of oral cancer and in other parts of the world, cancer of the tongue was more common(Sankaranarayanan *et al*., 2015). Oral cancer is defined and described differently in various studies making comparisons and interpretations across studies difficult(Tapia and Goldberg, 2011). A literature review had identified 17 different definitions for oral cancer(Tapia and Goldberg, 2011). This variation was partly because of the different anatomical sites described for oral cancer in various studies. To overcome this methodological issue in oral cancer research, we used the ICD code for identifying various anatomical sites in the oral cavity. For defining oral cancer, we included ICD codes C00 to C06 (WHO, 2016). This definition of oral cancer is as per the definition for lip, oral cavity cancer used in the IARC global cancer observatory, which provides reliable estimates of the region and country-specific cancer statistics (Ferlay J *et al*., 2020a).

5.1.7: Cancer stage at diagnosis

More than two-thirds of the participants in the present study reported their disease at an advanced stage at the time of diagnosis. A study from Sri Lanka reported an advanced stage at reporting among nearly three-fifths of their study participants (Alahapperuma and Fernando, 2017). Nearly three fourth of the participants in a study from Poland also reported advanced stage at diagnosis, which was higher than what is observed in this study(Rutkowska*et al*., 2020). A study from Canada had found that a higher number of patients from deprived neighborhoods reported advanced stage at diagnosis compared to those from the affluent neighborhoods(Auluck *et al*., 2016). We couldn't find any such association in this study as no such categorization of the place of residence exists in our area.

5.1.8: Initial symptom recognized by the patient

The most frequent initial symptom reported by our participants was a non-healing ulcer with pain followed by tooth mobility. Studies from the United Kingdom also reported non-healing ulcers as the most common symptom initially observed by oral cancer patients(Crossman *et al*., 2016; Rogers *et al*., 2011). Nearly half of our study participants considered usual mouth ulcers or traumatic ulcers from known causes as

their initial oral symptoms. Interestingly, more than half of the participants considered their initial symptom as minor and expected it to heal by itself. A study from Poland also reported that more than one-third of the participants considered their symptoms as a minor condition and did not consult a health care practitioner(Rutkowska*et al*., 2020). Symptoms in the oral cavity were seldom ascribed to oral cancer and were generally considered trivial(Scott *et al*., 2006). Qualitative findings also reported misinterpretation of signs and symptoms of oral cancer by patients which lead to delayed help-seeking for the same. Generally, those symptoms which did not affect their daily routine were considered by people as trivial.

5.1.9: Social relationships

Social relationships like family, friends, peers influence help-seeking behavior(Low *et al*., 2016). In the present study, more than two-thirds of the participants discussed their oral problems with significant others before finally meeting a health care provider. Nearly half of them discussed with their spouses and another one-third discussed with their immediate family members. Moreover, the discussion interval was short for those who discussed with their daughters or spouses. A systematic review on influences of cancer symptom knowledge, beliefs, and barriers on cancer symptom presentation identified 'disclosure of symptom to a family member' or a friend' as the most common facilitator of symptom presentation(McCutchan*et al*., 2015). Qualitative findings from the present study also endorse the above observation. The level at which the significant others aware of the oral cancer symptoms and their opinion towards where to seek care influenced patients' health-seeking decisions. Family and friends of more than three-fifth of the participants facilitated symptom presentation. A study from the United Kingdom reported the favorable role of encouragement from friends and family in seeking care for symptoms suggestive of cancer(Whitaker *et al*., 2015).

5.1.10: Barriers to seeking help

Patients' barriers to medical help-seeking were assessed and found that "diseases if any would get resolved by themselves" was the most common barrier endorsed by the participants. A study from the UK reported the barrier "I didn't realize that the

problem or symptom was serious" as the most common barrier reported among their study participants(Crossman *et al*., 2016). The findings from our qualitative study further elaborated the above observations on the trivialization of initial symptoms. There exist a general belief among people that oral symptoms are self-limiting in nature. Oral ulcers are often overlooked as common mouth ulcers. Lack of symptom awareness on oral cancer among the general public leads to misinterpretation of oral symptoms. Another study reported barriers such as "Found it difficult to get an appointment with a particular doctor", "difficulty getting an appointment at a convenient time", and "Did not want to be seen as somebody who makes a fuss", as the most frequently endorsed barriers for help-seeking (Moffat *et al*., 2016). Women were more likely to endorse emotional barriers like "Found it embarrassing talking to the doctor about symptoms"(Waller *et al*., 2009). In our study, females were more likely to endorse the practical barriers 'Did not have money to consult a doctor or visit a hospital, 'Did not have a person to accompany me during hospital visits' and service-related barrier "Prefer alternative medicines than modern medicine', and males were more likely to endorse the practical barrier 'Too busy to make time to go to the doctor'. The gender differences in the endorsement of barriers observed in the studies indicate the need for gender specific strategies for overcoming barriers to help seeking. Gender differences observed in the study were mostly practical barriers whereas the one reported from a UK based study were emotional barriers indicating the role of financial and access related factors in help seeking in our country. In depth interviews with the community leaders highlighted the fear of treatment cost as a major deterrent to help seeking. A study(Azad *et al*., 2020) from Central Malawi, a low middle income country, observed that women were less likely to find additional financial funding for their healthcare costs from the family or society than men. The gender disparity on health care utilisation is contributed by the attitude of the society that underestimate the health of women over men(Azad *et al*., 2020).

5.1.11: Health care provider first consulted

The first health care professional consulted by the patients for discussing the symptoms suggestive of oral cancer in the study included general medical practitioners, dental surgeons, ENT surgeons, and general surgeons. The type of HCP

first consulted in the diagnostic journey of oral cancer varies from country to country. In UK, Finland, and Poland, general practitioners were more frequently consulted than dentists whereas in Japan dentists were more frequently consulted than general practitioners (Grafton-Clarke *et al*., 2019; Rogers *et al*., 2007; Rutkowska *et al*., 2020).

5.1.12: Initial response from HCPs

In this study, health care providers advised biopsy or referral to higher centers during the initial consultations for more than two-thirds of the participants. A similar initial response pattern was observed in a study from Poland where referral, biopsy, and antibiotic prescriptions were the three most frequent initial responses received by patients with symptoms suggestive of oral cancer (Rutkowska *et al*., 2020). The study further reported that most of the patients who first reported at a general medical practitioner were either referred to other doctors or given medicines for their symptoms whereas biopsies were performed by Oral surgeons (62%) followed by Laryngologist(23%) and Dentist (13.5%)(Rutkowska*et al*., 2020). The above observations highlight the difference in initial response by different practitioners and also provide an idea about routes to diagnosis. In our qualitative findings, poor doctor-patient communication and dismissal of initial symptoms by the health care providers were identified as a barrier for early diagnosis.

5.1.13: Routes to diagnosis

The number of health care practitioners consulted by the patients during their diagnostic journey varied considerably. The average consultations made in the diagnostic journey of participants in this study was about three. Very few patients could complete their diagnostic journey by consulting a single health care provider. Nearly two-thirds of our study participants had to consult two to three practitioners to complete their diagnostic journey. In Australia, the mean primary care consultation was 2.7 (range 1-6) whereas, in Thailand, it was 4.7 (range 2-50) (Grafton-Clarke *et al*., 2019). Lack of established referral patterns in the Kerala health system resulted in multiple doctor consultations. In this study, the patient's journey towards oral cancer diagnosis was not linear and not following a vertical model. Previous studies have

also observed that the pathways to the cancer diagnosis are neither straightforward nor linear(Weller *et al*., 2012). Although cancer, early diagnostic services are provided through comprehensive cancer care centers in Kerala, the community leaders urged for increasing such activities in the community. They also pointed out the inadequacy of such early diagnostic facilities in the society. Qualitative findings suggested provider switching, lack of adherence to provider's advice, loss to follow up, and the referral advice from the previous HCP as the probable reasons for multiple consultations in the diagnostic journey. The absence of an established referral system and lack of professional reorientation and training for primary care providers identified from the qualitative findings also complicates the routes to diagnosis in oral cancer. The document review identified the lack of referral pathways in oral cancer care. Implementation of a referral system similar to the one recommended by the National Institute for Health and Care Excellence (NICE), UK will reduce multiple consultations in the diagnostic journey(Yeung, 2015). The details of the NICE guideline are given in Table 5.1.

Table 5.1: The NICE guideline for recognition and referral of oral cancer (Yeung, 2015)

Sl No	The NICE guideline for recognition and referral of oral cancer
1	Consider a suspected cancer pathway referral (for an appointment within two weeks) for oral cancer in people with either: • Unexplained ulceration in the oral cavity lasting for more than 3 weeks • A persistent and unexplained lump in the neck.
2	Consider an urgent referral (for an appointment within 2 weeks) for assessment for possible oral cancer by a dentist in people who have either • A lump on the lip or in the oral cavity • A red or red and white patch in the oral cavity consistent with erythroplakia or erythroleukoplakia.
3	Consider a suspected cancer pathway referral by the dentist (for an appointment within 2 weeks) for oral cancer in people when assessed by a dentist as having either: • A lump on the lip or in the oral cavity consistent with oral cancer • A red or red and white patch in the oral cavity consistent with erythroplakia or erythroleukoplakia.

5.2: Patient interval in oral cancer

Different studies have used different summary measures like mean, median, or proportion to report patient interval (Weller *et al*., 2012). Median is more frequently used as it is unaffected by extreme values (Centelles *et al*., 2012). The median patient interval of 92 days reported in our study is in agreement with a similar observation from a regional cancer center in northeast India(Baishya*et al*., 2015) but there are reports of median patient interval ranging from 35 days (Jovanovic *et al*., 1992) to 123 days(Peacock *et al*., 2008) in other studies. The pioneering research on delay in cancer diagnosis suggested three months as an acceptable delay in cancer(Pack and Gallo, 1938). A study from a tertiary care hospital in north India had reported patient intervals of more than 90 days in 60% of their study participants (Akram *et al*., 2014)whereas, in this study, 54% of the study population had patient interval more than 90 days.

A study among oral and oropharyngeal cancer patients in Sri Lanka reported a patient interval of more than three months in 19% of participants of their study participants(Alahapperuma and Fernando, 2017), which is much less than what is observed in the present study. This finding from Sri Lanka is of particular importance to Kerala as both regions have comparable health care systems and good social and health indicators(Bhutta*et al*., 2004). Despite these, a higher proportion of increased patient intervals observed in this study indicate an urgent need for reviewing our strategies for the early diagnosis of oral cancer. Sri Lanka provides free health care services including specialty care like cardiology and oncology to all its citizens(Amarasinghe *et al*., 2019). Qualitative interviews with oral cancer patients in the present study observed financial dependency and fear of treatment costs as potential barriers for early diagnosis of oral cancer. Community leaders also highlighted the role of financial factors in the delayed disease presentation. They suggested making cancer treatment free for all for facilitating early oral cancer diagnosis. In a study(Nair *et al*., 2013) conducted at the government tertiary cancer hospitals in Kerala, Rajasthan, Maharashtra, Mizoram and West Bengal, patients from Kerala and Maharashtra reported the highest indirect and opportunity costs for cancer

care. The study further reported that more than one-fourth of the study participants delayed their decision on treatment for financial concerns (Nair *et al*., 2013).

5.3: Factors associated with the patient interval in oral cancer

5.3.1: Socio-demographic factors

Various socio-demographic characteristics were analyzed for identifying possible association with patient interval. As observed in one of the previous studies reported from India, socio-demographic characteristics were not found to be associated with patient interval(Kumar *et al*., 2001) in our study as well, except 'type of house'. Though the relationship between age and occurrence of oral cancer was a well-established association, no relationship between age and patient interval in our samples could be found. The previous studies on patient interval had given contradicting results on socio-demographic factors that contribute to the prolonged patient interval. Socio-demographic variables like age, socioeconomic status, and place of residence were associated with the patient interval in a study from India (Akram *et al*., 2014) whereas the place of residence(Baishya*et al*., 2015), and age (Alahapperuma and Fernando, 2017)were not associated with the patient interval in other studies. A study that assessed the influence of low socioeconomic status and delays in presentation of oral cancer couldn't find any association(Rogers *et al*., 2007) although deprivation was associated with the incidence of oral cancer(Madani *et al*., 2010). The 'type of house' in which the patient lived was the only socio-demographic characteristic found to be significantly associated with the patient interval in this study. A study from south India reported a higher prevalence of tobacco smoking among those who live in semi-pucca-type houses in comparison to those living in pucca-type houses (Vinothkumar *et al*., 2020). Less affluent households often have poor housing conditions and that may affect health outcomes (Braubach and Savelsberg, 2009). This finding supports our observation that a higher proportion of patients with a patient interval of more than 90 days had semi-pucca-type houses and were 'ever tobacco users', unlike those who live in the pucca houses.

5.3.2: Habit-related factors

In binary logistic regression analysis, tobacco smoking status at the time of symptom recognition was identified as a significant predictor for the patient interval. A study from China reported that current smokers were more likely to delay seeking treatment for more than 21 days compared to never smokers and former smokers(Zhang *et al*., 2019). Findings from qualitative interviews also suggest high nicotine dependency act as a barrier for timely health-seeking. Smokers' reluctance for help-seeking compared to non-smokers for symptoms suggestive of lung cancer was reported in a study from the United Kingdom (Friedemann Smith *et al*., 2016). These observations further validate our findings.

We also identified an association between betel quid or pan masala use status after symptom recognition with patient interval. Those who increased or continued their betel quid or pan masala use after symptom interpretation were more likely to have increased patient interval than those who decreased or stopped these habits after symptom recognition. A similar pattern was also observed with alcohol use although but not on statistical terms. Our qualitative findings suggest that patients may continue or increase their habit frequency after symptom initiation to get relief from those symptoms. This helped them to overcome the discomfort or pain from the lesions.

5.3.3: Healthcare-related factors

Healthcare-related factors like the pattern of medical consultation, pattern of dental consultation, first response to a general health problem, previous experience with cancer patients, travel options, duration, and distance to health care facility were found to be associated with patient interval. Findings on the pattern of health-seeking such as home-remedy, self-medication, and consulting traditional healers were found to delay symptom presentation in a previous study from a developing country (Azhar and Doss, 2018). The present study found that those who were reluctant to visit medical/dental facilities were more likely to have increased patient intervals than those who undergo regular medical /dental consultations. A previous study had reported that high-risk people such as tobacco and alcohol users seldom visit a dentist

or dental screening program (Brouha *et al*., 2005; Peacock *et al*., 2008). In binary logistic regression analysis, travel duration to health facilities was found to be a significant predictor for the patient interval. Those who had to travel more than 30 minutes to the health facility were more likely to have increased patient interval than those who could reach within 10 minutes. A study from Sri Lanka identified that the cost of travel contributed to the patient interval(Alahapperuma and Fernando, 2017). A systematic review on the relationship of travel distance and travel duration on health outcomes in global north countries had found that the majority of the included studies report worse health outcomes among those who lived farther from the health facility(Kelly *et al*., 2016). The above findings highlight the role of access to the health facility in determining patient interval in oral cancer. Decentralization of cancer care including early diagnosis was stated in the cancer strategy document published in 2018. A mechanism called 'Kerala Cancer Care Grid' was also suggested for implementing the same.

5.3.4: Financial factors

Nearly three-fifths of the patients who were the breadwinners of their family were found to have increased patient interval but the association was not statistically significant. Similarly, more than three-fifths of the participants having debt was also noted to have increased patient interval. Our qualitative analysis has identified the financial dependency of the family on the patient as a deterrent to the timely seeking of care. Patients, as well as community leaders, highlighted the role of financial factors in healthcare-related decision-making.

5.3.5: Barriers to medical help-seeking

In our study, emotional barriers like "Found it embarrassing talking to the doctor about symptoms", "Was worried about what tests they might want to do "and "Was worried about what the doctor might find out", were found to be significantly associated with patient interval. In a study conducted among ethnic minority groups in England, "worry about what doctor might find out" was the most frequently endorsed barrier to seek medical help(Waller *et al*., 2009). In our binary logistic regression analysis, the barrier "worry about what the doctor might find out" was identified as a

significant predictor for the patient interval. Practical barriers like “Was too busy to make time to go to the doctor”, “Had too many other things to worry about”, “Did not have a person to accompany me during hospital visits/consultations”, and “Did not have money to consult a doctor/visit a hospital” were associated with the patient interval in our study. Service-related barriers like “Comfortable in discussing symptoms with a nurse than a doctor”, and “Prefer alternative medicines than modern medicine” were significantly associated with patient interval. The association of barriers to help-seeking with the patient interval in oral cancer was not explored in the existing literature. The preference for alternative medicine in certain communities has emerged in our qualitative analysis of patient and community leaders’ interviews. Practical barriers like financial concerns and the absence of family support were also identified as barriers for help-seeking in our qualitative analysis.

5.3.6: Initial response to oral symptoms

In our study, more than four-fifth of participants either ignored or tried local remedies as a first response to their initial oral problem. The study reported a higher chance of having patient intervals less than 90 days among those who consulted an HCP as a first response to their initial oral problem compared to others. Similar findings were also reported from the United Kingdom where nearly half of the oral cancer patients considered their symptoms as not serious and another one-third tried local remedies instead of seeking professional help(Rogers *et al.*, 2011). Patients may attribute symptoms suggestive of cancer to other disease conditions (Scott *et al.*, 2007). Trivialisation of initial oral symptoms was also identified in our qualitative analysis. A preference for home remedies and herbal medicines was observed in the period immediately after symptom identification. This preference varied from person to person. Home remedies were also used for temporary relief from symptoms.

5.3.7: Disclosure of symptoms with significant others

Disclosure of symptoms suggestive of oral cancer with significant others before consulting a health care provider is associated with patient interval. The association of social and family support in reducing patient interval in cancer patients was reported in a previous study(Pedersen *et al.*, 2011). We found that sharing symptoms with

friends or family after symptom recognition accelerated the diagnostic journey and decreased the patient interval. However, a notable proportion of participants with oral cancer had failed to discuss their symptoms with significant others. The study findings by Rogers *et al* support this observation(Rogers *et al*., 2011). The importance of interpersonal communication within the family for symptom interpretation and health-seeking decision-making has emerged in our qualitative analysis. Some people discussed their symptoms with their spouse while others with other family members or friends. For them, this discussion constitutes the first step in their diagnostic journey. The understanding and attitude of people around them influenced their health-seeking behavior. Advice from significant others may lead to a reappraisal of the symptom(Scott *et al*., 2007).

5.3.8: Reason for meeting HCP

For more than four-fifths of the study participants, the compelling reason for meeting a health care provider for their oral symptoms was pain or discomfort. In binary logistic regression analysis, the reason for meeting a health care provider was found to be a significant predictor for the patient interval. Those who consulted an HCP due to pain from the lesion were eight times more likely to have a patient interval of more than 90 days than those who consulted an HCP out of insistence from their family or friends. The role of social support in shortening patient intervals was reported in a previous study that supports this finding(Pedersen *et al*., 2011). Moreover, our qualitative findings also support the role of the family in hastening the diagnostic journey. Health care providers, while sharing their experience in early oral cancer diagnosis, recollected instances of family support facilitating early diagnosis.

5.3.9: Cancer stage

The present study identified the oral cancer stage as a significant predictor for the patient interval. Those who reported in late stages were more likely to have patient intervals more than 90 days. A Finnish study on patient delay among oropharyngeal cancer patients also reported the association of cancer stage with patient interval. (Nieminen *et al*., 2020) . Oral cancer in the initial stages may be asymptomatic or have symptoms that appear to be less severe or alarming and hence people ignore

them. The pain or discomfort usually presents in the late stages. Hence those who consult a doctor only when they have persistent pain or discomfort were more likely to have increased patient interval.

The stage of cancer is an important predictor for prognosis and survival in oral cancer(Thavaroo*et al*., 2019). The cancer stage indicates the extent of disease spread in the body. In the present study, more than two-thirds of the participants reported in advanced stages at diagnosis. A study from Brazil reported advanced-stage disease in more than four-fifth of study participants(Le Campion *et al*., 2017). Late-stage diagnosis of oral cancer is a global phenomenon. Early-stage oral cancers are highly curable with low morbidity and reduced treatment cost (Güneri and Epstein, 2014). The primary goal of any early diagnosis intervention is to identify cancer in its early stages.

5.4: Diagnostic interval in oral cancer

The median diagnostic interval reported in our study was 35 days and the proportion of participants having increased diagnostic interval more than 30 days was nearly three-fifth. Existing literature suggests diagnostic interval of more than one month can lead to an advanced stage of cancer presentation and poor survival rates(Allison *et al*., 1998b; Fortin *et al*., 2002). The duration of the median diagnostic interval, as well as the proportion of participants having increased diagnostic interval, varies considerably across studies. The median diagnostic interval of 21 days(Rogers *et al*., 2007), 30days(Ganesan *et al*., 2020) and 86 days (Esmaelbeigi *et al*., 2014)were reported in studies from UK, India, and Iran respectively. The term professional delay is used instead of diagnostic interval in some studies (Rogers *et al*., 2007; Stefanuto *et al*., 2014). A study from Canada reported 35.1% of participants with diagnostic intervals of more than 30 days which is much lower than what is observed in this study. Some of the outlier values in the diagnostic intervals were reported by participants in this study, who had initial symptoms suggestive of oral precancerous lesions like leukoplakia. This was however not based on any histopathological or clinical evaluation reports. A population-based study on oral precancerous lesions conducted in Kerala reported malignant changes in four percentage of leukoplakia cases over a

ten-year follow-up period(Gupta *et al*., 1980). Some of these lesions may persist for years without any change and some others may regress over time. Prolonged diagnostic interval in patients with the premalignant lesion can be attributed to the natural history of malignant transformations(Wang *et al*., 2018). In our qualitative interviews, health care practitioners reported poor compliance with follow-up instruction among those patients with oral precancerous lesions. This negligence is largely due to the asymptomatic or mildly symptomatic nature of these precancerous lesions. The patient generally trivializes those conditions which did not elicit persistent pain or discomfort. Any break in the continuity of care will lead to a delay in diagnosis.

5.5: Factors associated with diagnostic interval

5.5.1: Socio-demographic factors

In our binary logistic regression analysis, it was found that those participants aged less than or equal to 60 years were more likely to have prolonged diagnostic intervals than others. A similar observation was reported in a study from Iran where a higher chance of having prolonged diagnostic interval was seen in participants aged between 35 to 60 years (Jafari *et al*., 2013). In our qualitative interview with oral cancer patients, participants cited financial dependency as a barrier for medical care-seeking, as most of them work in the unorganized sector with no job security and social welfare measures. This may be a reason for increased diagnostic interval among those aged less than or equal to 60 years as they have to work to support their family.

Although socioeconomic status is an independent predictor of survival and stage at diagnosis in oral cancer(Aulucke*t al*., 2016), very few socio-demographic and economic factors like caste, marital status, and monthly family income were found to influence diagnostic interval in this study. Compared to married people, those who were ‘single’ were more likely to report a diagnostic interval of more than 30 days. This could be attributed to the support given to the married person by their spouse and family. Previous studies on delay in diagnosis of breast cancer had reported a significant association between diagnostic interval and marital status(Foroozani*et al*., 2020; Olarewaju *et al*., 2019). In binary logistic regression analysis, monthly income

less than 5000 Indian rupees was found to be a significant predictor for having a diagnostic interval of more than 30 days.

Another predictor for prolonged diagnostic interval observed in this study was caste. Those belonging to the general class and scheduled tribes were more likely to have increased diagnostic interval than those belonging to other backward classes. A previous study on the treatment-seeking behavior of the tribal population in India reported poor healthcare utilization among tribal people (Raushan and Acharya, 2018). The higher diagnostic interval observed in general caste people may be due to the low suspicion of oral cancer among those belonging to higher socioeconomic strata as oral cancer is more common among those belonging to lower socioeconomic strata(Conway *et al*., 2008; Warnakulasuriya, 2009b). However, further studies are necessary to validate this observation.

5.5.2: Health care provider first consulted

In our study population majority of participants (62%) first met either a medical doctor or dental surgeon for their symptoms related to the current problem. A study by Crossman *et al* in the UK stated that 57% of patients consulted general medical practitioners and 32% spoke to their Dentists first(Crossman *et al*., 2016). The medical practitioners can do a lot more in facilitating early oral cancer diagnosis as people more frequently visit a medical practitioner than a dental practitioner though the latter is well equipped for detecting oral cancers (Crossman *et al*., 2016). This suggests the need for including oral cavity examination as part of the general examination for facilitating early oral cancer diagnosis. In this study, those participants who first consulted a general medical or dental practitioner had shorter diagnostic intervals than those who first consulted an alternative medicine practitioner. Ayurveda, Yoga and Naturopathy, Unani, Siddha, Sowa-Rigpa, and Homeopathy are the alternative system of medicines recognized by the Government of India(Rudra *et al*., 2017). Based on a nationally representative survey, 6.9% of all outpatient services were provided by recognized alternative medicine practitioners in India and their utilization is particularly high in Kerala(Rudra *et al*., 2017). This indicates the need for training alternative medicine practitioners in the early diagnosis

of oral cancer. This will expand the early oral cancer diagnosis facilities in the community.

5.5.3: Initial advice from health care providers

The opinion or advice provided by the practitioner first met by the patient in the diagnostic journey will affect the diagnostic interval. We found the low index of suspicion and reluctance for referral for specialist consultation or investigation as factors responsible for the increased diagnostic interval. Our binary logistic regression analysis identified the dismissal of initial symptoms as minor by the HCP as a significant predictor for the prolonged diagnostic interval. A study from the United Kingdom on general practitioners' initial response to oral cancer symptoms highlighted the need for streamlining the oral cancer diagnostic pathway to minimize diagnostic delay as one-fourth of the participants didn't receive appropriate instructions for further management from the primary care(Crossman *et al*., 2016). The health care providers in the first point of contact in the health system should be adequately trained to identify initial signs and symptoms of oral cancer. HCPs, especially general medical practitioners, suggested the need for training in oral cancer diagnosis in qualitative interviews. In a study from the UK, only 15% of the medical practitioners and 37% of dental surgeons considered themselves confident in identifying oral premalignant and malignant lesions(Macpherson *et al*., 2003).

5.5.4: Routes to diagnosis

The number of pre-diagnostic consultations and activities undertaken by the patient in their diagnostic journey affects the diagnostic interval. The number of times HCPs were consulted before diagnosis in our study ranged from 1 to 10 with an average of 2.7 HCPs per patient. In our binary logistic regression, consulting three or more HCPs in the diagnostic journey was found to be a significant predictor for having prolonged diagnostic intervals. A systematic review observed that oral cancer patients on average had to make three consultations before referral to a specialist(Grafton-Clarke *et al*., 2019). Macpherson *et al* studied the referral pattern of primary health care professionals in oral cancer diagnosis and observed that more than half of the medical and dental HCPs re-evaluated their patients before referring them to higher

centers(Macpherson *et al*., 2003). In this study, those patients who first consulted a dental surgeon had lesser HCP consultations in their diagnostic journey. In a previous study, 23% of medical practitioners and 48% of dental surgeons expressed confidence in their ability to decide on urgent referrals for oral lesions(Macpherson *et al*., 2003). Another reason for multiple routes to diagnosis was the absence of an established referral system and the inadequacy of early diagnostic facilities in the periphery.

5.5.5: Diagnostic interval and stage at diagnosis

In our study cancer stage at the time of diagnosis was not significantly associated with diagnostic interval. This may be because symptom severity associated with late-stage disease may expedite diagnostic procedures(Groome *et al*., 2019). Clinically large tumors will alert the clinician to initiate emergency referral or investigation leading to diagnosis within the acceptable time frame. A study from the Netherlands on oral cancer reported short diagnostic intervals for large tumors compared to small tumors(Brouha *et al*., 2007).

5.6: Strengths and limitations

There are many strengths in the present study. The first and foremost strength was adapting a sequential explanatory design for the study. This design facilitated in explaining the findings of the primary quantitative data with the qualitative data. Secondly, the present study used validated tools for estimating the various time points in the diagnostic journey of oral cancer. The study used the protocol for calculating 'pseudo exact dates' from the 'estimated dates' developed by Neal *et al*. The protocol was modified to adapt it to the local context(Neal *et al*., 2014). The 'pseudo exact dates' were validated using the validation protocol developed by Neal *et al*(Neal *et al*., 2014). The symptom interpretation process in oral cancer is often very complex as a multitude of signs and symptoms may represent oral cancer, at times they are also associated with other minor oral illnesses. Considering this, our study developed a checklist of all possible symptoms of oral cancer to assist patients to recollect the initial symptoms. The principal investigator, a dentist by training and having ten years of experience in early diagnosis of oral cancer, conducted in-person interviews with

all participants. This study was designed as per the guidelines of the Aarhus statement for early cancer research, which distinguished it from the existing published literature.

The outcomes of the study were derived from the patient-reported data. There may be a possibility of having recall bias in reporting events. The duration of the patient interval and the diagnostic interval may not be without the recall bias. Hence, the results should be read with caution. However, efforts were made to reduce the effect of recall bias in determining study outcomes. Several measures were adopted for reducing it. Firstly, it was minimized based on using validated data collection tools. Information on time events in the diagnostic journey was collected in a face-to-face interview by the principal investigator himself using a validated interview schedule. The dates provided by the patients were cross-checked with the referral letters and histopathology reports. The Neal *et al* protocols for calculating and validating the pseudo exact dates from the estimated dates were used for triangulation and validation of data(Neal *et al*., 2014). Data were collected within three months of diagnosis to minimize the recall bias(Alahapperuma and Fernando, 2017). Another limitation of the study was the possibility of social desirability bias as patients may prefer to report earlier dates than the actual date of symptom recognition. In this study, questions were framed in such a way that patient did not feel any discomfort or guilt in answering the question. Moreover, participant anonymity and confidentiality were assured before the data collection. The study was conducted at a tertiary cancer center and that may affect the generalizability of the study findings. However, this institution was the only comprehensive cancer center in the northern part of Kerala and provides subsidized treatment to patients through various government treatment schemes. A previous study from Kerala had reported that the income level of the patient was a determinant of treatment-seeking from private institutions(Dinesh *et al*., 2020). Oral cancer patients generally belong to the low socioeconomic strata of the population(Warnakulasuriya, 2009b), which restricts their choice of cancer treatment to government institutions. Most of the studies in early diagnosis were conducted in hospital settings as cancer needs specialized care, people diagnosed with cancer report to a specialized center for treatment.

SUMMARY AND CONCLUSION

Chapter 6

Summary and Conclusion

This is one of the first study from Kerala which examined patient and diagnostic interval in oral cancer and its determinants. The present study was conducted in conformity with the Aarhus statement for early diagnosis research. One of the contributions of the present study is developing and validating a tool to measure patient and diagnostic interval in the diagnostic journey of oral cancer. The study reported prolonged patient interval in more than half of the participants indicating flaws in the current secondary prevention strategies. The patient interval observed in the study is similar to studies conducted in other parts of India and found higher compared to studies from Europe. Similar to patient interval, a higher proportion of participants reported increased diagnostic interval in the present study. This suggests the need for a better health system response to oral cancer early diagnosis in our state.

Factors which affected patient interval in the present study are behavioural factors, illness conditions, accessibility of services, personal characteristics, social stratifications and economic conditions. The known risk factors for oral cancer, tobacco and areca nut use, also associated with patient interval. Another aspect that has emerged as an important one was the financial stability of the participants which was critical in reducing the interval. The above factors along with lack of knowledge and awareness about the disease contributed to the delayed presentation of the condition. The usage of home remedies and other systems delayed seeking care for symptoms suggestive of oral cancer, particularly among the tribal population.

The recognition of symptoms suggestive of oral cancer did not have much effect on the habits such as tobacco and alcohol. There are still many who either continued at the same level of consumption or increased after symptom recognition. This is common among both tribal and other populations. There were also instances where the participants trying to defend the usage by saying the usage helped them to forget or mask the pain.

Majority of participants belonging to low socioeconomic strata make them difficult to skip their work for visiting health personnel. Even if they visit, the expenses in addition to the loss of pay add to their financial burden. Even the existing schemes do not fully cover the expenses makes them difficult to go for treatment.

In Kerala which is known for good development indicators still has problems such as transportation. This makes patients not seek care due to distance and the non-availability of transportation.

A common problem in cancer care is the delay in recognition of symptoms and late presentation. Even the present study found there is a delay in presentation to the primary care. Many times they may end up trivializing the symptoms as just an ulcer or so. That adds to the delay in seeking care initially.

People were also having apprehensions to visit a health facility as the initial investigations may uncover serious conditions such as oral cancer.

Sharing health concerns with significant others and their health-related knowledge and attitude contribute to patient and diagnostic interval duration. The positive role played by friends and family has helped in early diagnosis in many. That friend or a member of the family who recognized the importance of the symptoms and advised to go for further consultation helped in the early diagnosis of oral cancer. Otherwise, people report to the healthcare provider only when they experience increased pain or discomfort which many at times were unbearable.

Like the patient interval, the diagnostic interval for oral cancer was also higher due to factors such as social and economic factors, type of health care provider initially contacted, the initial advice received from a health care provider and the number of health care providers consulted.

Even today in Kerala, there is no proper referral system from primary care to a higher level for oral cancer. People tend to visit an average of three healthcare providers before they receive a definitive diagnosis. Lack of knowledge on recognizing the oral cancer symptoms by many of the primary care providers leads to increased diagnostic

delay. Dental surgeons are not available at the primary care level in the Kerala health system.

To conclude, there exists an increased patient and diagnostic interval in the diagnostic journey of oral cancer patients which require immediate attention. The present study highlights the importance of socio-economic factors that contributes to cancer care with specific reference to oral cancer. If the problems faced by the patients due to the socio-economic and other system-related issues are addressed, it will reduce the length of diagnostic journey in oral cancer.

Recommendations

There should be a system to collect information on patient interval and diagnostic interval routinely in the health system as part of the cancer registry initiative. The implementation of the proposed Kerala Cancer care Grid will facilitate early cancer diagnosis. Initiatives should be taken to implement stringent restrictions on the use of tobacco and alcohol. All primary healthcare providers and dental surgeons should be trained in tobacco and alcohol cessation. Health education on oral cancer symptom awareness and early diagnosis should be disseminated in the community. It is important to create oral cancer awareness among family members of all high-risk populations as they will play the role of opinion leaders in the family. Special efforts should be made to address the oral health issues among the tribal population as they are at high risk compared to the general population. Health care facilities in primary care should have extended working hours so that people could avail these services after their regular work. The Health system should be strengthened at the primary care level by incorporating referral guidelines and in-service training for early diagnosis of oral cancer for all primary care practitioners including practitioners of AYUSH and other systems of medicine.

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ANNEXURE

DOI:10.31557/APJCP.2021.22.10.3143
Patient Interval and Associated Factors in Oral Cancer

RESEARCH ARTICLE

Editorial Process: Submission:03/11/2021 Acceptance:10/26/2021

Patient Interval and Associated Factors in the Diagnostic Journey of Oral Cancer: A Hospital-Based Cross-Sectional Study from Kerala, India

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Abstract

Background: The incidence of oral cancer is increasing in south-central Asia. Though it can be detected early, most cases were reported in late stages, resulting in a poor prognosis. Reducing the patient interval will facilitate early diagnosis and better disease survival. The paucity of research on the patient interval in oral cancer has limited our ability to design and evaluate programs for early diagnosis. **Methods:** The study was conducted to identify the duration of patient interval and associated factors in oral cancer. Patients with oral cancer reporting at a tertiary cancer center during the study period were interviewed using validated data collection tools. The 'Aarhus statement' guidelines were followed in designing and reporting the study. **Results:** Among the 261 participants, 54% reported a patient interval of more than 90 days. The median (IQR) patient interval was 92 (38-168) days. In the multivariate binary logistic regression model, those who approached healthcare facilities due to pain (OR, 8.3, 95% CI, 2.9 to 23.4) were more likely to have a patient interval of more than 90 days over those who came due to insistence by family. Smoking status (Current smoker vs. never smoker) at the time of diagnosis (OR, 2.518, 95% CI, 1.3 to 4.7), Stage of cancer (late vs. early) of participants (OR, 2.62, 95% CI, 1.3 to 5.2), and time of travel (>30 minutes vs. ≤ 10 minutes) to health care facility (OR 5.8, 95% CI, 1.6 to 21.7) were the other significant predictors for the patient interval of more than 90 days. **Conclusion:** Patient interval in oral cancer can be reduced by improving symptom awareness, abstinence from tobacco use, and facilitating access to health care facilities. The double burden of tobacco use in oral cancer, as it increases the risk of disease occurrence and delays symptom presentation, needs serious policy considerations in the context of cancer prevention.

Keywords: Delay in presentation- Patient delay- Early diagnosis- Symptom awareness- Aarhus statement

Asian Pac J Cancer Prev, **22 (10)**, 3143-3149

Introduction

Oral cancer is the 16th most common cancer in the world with 3,77,713 cases reported in the year 2020. Of these, 84% were from Asia and Europe (Sung et al., 2021). It is the second most common cancer in India and this contributes to more than one-third (36%) of total oral cancer incidence in the world (Ferlay et al., 2020). An analysis of the data from 29 cancer registries in India reported a general uptrend in the incidence of oral cancer (Sharma et al., 2018). The risk factors for oral cancer are well known and desisting from those habits is a time-tested primary prevention strategy. Several favorable factors exist for its early diagnosis. The ease of access to the oral cavity for physical examination is one among them (Shrestha and Maharjan, 2020). Dental and medical primary care providers and trained health workers can identify oral cancer through oral visual examination. At times, many are preceded by precancerous lesions that can be detected and managed to prevent them from progressing to oral cancer (Sankaranarayanan et al., 2015). Despite all these favorable factors, oral cancer is continuously been reported and diagnosed in late stages leading to poor treatment outcomes (Güneri and Epstein, 2014).

An important factor associated with an advanced stage at diagnosis is the patient delay (Alahapperuma and Fernando, 2017). Early diagnosis has a significant impact on the disease outcome and survival (World Health Organization, 2017). The five-year survival rate of early-stage oral cancer is around 80%, while that of late-stage disease is nearly 20%. Moreover, 50% of oral cancer cases are presented in very late stages. So emphasis should be given to early diagnosis to improve survival rates (van der Waal, 2013). If a patient takes more than three months to meet a health care professional after recognizing a symptom suggestive of cancer is considered as undue delay (Pack and Gallo, 1938). Several circumstances and factors are responsible for this delayed presentation (Philip and Kannan, 2019). It is inappropriate to blame the patient for the same. Considering this, the World

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Health Organization (WHO) has suggested using the term "Patient interval" instead of "Patient delay" (World Health Organization, 2017). Though studies were conducted to measure this interval and to know about the contributing factors, they did not have uniformity in their approaches and definitions making comparisons across such studies difficult. Considering this, a consensus workshop of early cancer researchers was convened and developed "Aarhus statement" consisting of definitions and recommendations for early cancer diagnosis research (Weller et al., 2012). There is a paucity of early cancer diagnosis research studies that focus on oral cancer (Philip and Kannan, 2019). This creates a serious knowledge gap for guiding further research as well as for planning interventions to address the delay in reporting symptoms suggestive of oral cancer. Moreover, region-specific data on the magnitude of patient interval and associated factors are necessary for planning tailored programs. The objective of the present study was to identify the duration of patient interval and its contributing factors among the oral cancer patients reporting at a tertiary cancer center in Kerala, India.

Materials and Methods

Methodology

This hospital-based cross-sectional study was conducted using validated tools for measuring patient interval and identifying contributing factors. The estimated dates of events provided by patients were used for calculating pseudo exact dates with the help of a protocol developed by Neal (2014). We followed the guidelines given in the Aarhus Statement for designing the study (Weller et al., 2012). The study was conducted at a tertiary care hospital in Northern Kerala from December 2019 to August 2020. Each consecutive oral cancer patient who reported at the institution during the study period and who met the eligibility criteria and consented to enrol was included in the study until the required sample size was reached. The newly registered patients with malignant neoplasm of the oral cavity (ICD code C00 to C06) were included in the study. Patients having a recurrence, patients with other cancers, patients who were diagnosed through routine cancer surveillance programs, patients who had completed treatment and registered only for follow up and patients who were not willing to participate in the study were excluded. Details about sample size, sample selection, variables, data sources, data collection methods were given elsewhere (Philip and Kannan, 2019).

The study received approval from the institutional Ethics Committee and Technical Advisory Committee of the institution where the principal investigator is a research scholar (SCT/IEC/1388/JUNE-2019). Ethics committee approval was also obtained from the institution where the study was conducted (1617/IRB-IEC/13/MCC/13-05-2019/5). We took every effort to minimize recall bias in our study. We corroborated the information provided by the participants with their medical records and referral letters. We used validated instruments for data collection and a protocol was used for validating the estimated dates provided by the participants. The main dependent variable in the study, patient interval, was measured in days. Participants were then categorized into two groups based on the duration of the patient interval. The first group consists of participants having a patient interval less than or equal to 90 days. The second group includes those participants having a patient interval of more than 90 days. This categorization was based on the arbitrary definition of undue delay as more than three months (Andersen et al., 2009). Moreover, a patient interval of more than three months was associated with lower survival rates (Richards et al., 1999). The study by Akram (2014) also considered a patient interval of more than three months as a delayed presentation.

The collected data was cleaned, rechecked, and prepared for analysis. Univariate analysis was performed to describe the data and to identify important covariates that could affect the patient interval. Continuous variables which are normally distributed were summarized using mean (standard deviation) and non-normally distributed ones were reported by median (Interquartile range). Patient interval data are usually positively skewed and reported with the median (Dobson et al., 2014). Categorical variables were analyzed using contingency tables. Chi-square statistics or Fisher's exact test, when appropriate, were used to test the significance of relationships. Also, we collapsed those categories with low cell counts for a sensible analysis and meaningful result.

Variables that had a significant relationship with patient interval and variables of known importance in the existing literature were planned to include in the binary logistic regression analysis for getting a model of the relationship between them and the patient interval. First, logistic regression was done with the single covariate of interest, for selecting the most influencing variables that are to be included in the final model. All selected independent variables (with $p < 0.25$) were added in the binary regression model in various combinations to get a best-fitting model.

Results

Data from 261 oral cancer patients reported at a tertiary cancer center in Kerala were collected and analyzed. The mean age of the participants was 60.76 years (SD=12.27). The male-to-female ratio was 2.4:1. Half of the participants were aged between 53 and 70 years. The mean age of female participants (64.45±10.86) was higher than that of males (59.25±12.56) and the difference was statistically significant (p=0.002). The majority of the participants (94.3%) had education up to the high school level and were daily wagers (64.4%) or farmers (13.8%). The median (Inter Quartile Range) patient interval was 92 (37.50-167.50) days [males-92(44.50-158.00), females- 90 (31.25-179.50) days]. The proportion of participants with patient interval duration equal to or less than 90 days was 46% and those with duration more than 90 days was 54%.

The association of patient interval with socio-demographic and habit-related factors was analyzed (Table 1. Selected Socio-Demographic and Habit Related Factors Associated with the Patient interval in Oral Cancer Patients). After recognizing the cancer-related symptoms,

Table 1. Selected Socio-Demographic and Habit Related Factors Associated with the Patient interval in Oral Cancer Patients (n= 261)

Variable	≤ 90 days n (%)	> 90 days n (%)	Total n (%)	Chi-square p value
Age				
Below 60 yrs	63 (52.5)	73 (51.8)	136 (52.1)	0.907
Above 60 yrs	57 (47.5)	68 (48.2)	125 (47.9)	
Sex				
Female	39 (32.5)	37 (26.2)	76 (29.1)	0.267
Male	81 (67.5)	104 (73.8)	185 (70.9)	
Caste				
General class	25 (20.8)	22 (15.6)	47 (18.0)	
Other Backward class	72 (60.0)	95 (67.4)	167 (64.0)	0.435
Scheduled Caste	11 (9. 2)	8 (5. 7)	19 (7. 3)	
Scheduled Tribe	12 (10.0)	16 (11.3)	28 (10.7)	
House type				
Pucca	68 (56.7)	58 (41.1)	126 (48.3)	.012*
Semi pucca/Kutcha	52 (43.3)	83 (58.9)	135 (51.7)	
Tobacco smoking				
Current smoker	38 (31.7)	63 (44.7)	101 (38.7)	
Former smoker	19 (15.8)	11 (7. 8)	30 (11.5)	.033*
Never smoker	63 (52.5)	67 (47.5)	130 (49.8)	
Betel quid chewing				
Current user	56 (46.7)	70 (49.6)	126 (48.3)	
Former- user	9 (7.5)	13 (9.2)	22 (8. 4)	0.713
Non- user	55 (45.8)	58 (41.1)	113 (43.3)	
Alcohol usage				
Current user	51 (42.5)	70 (49.6)	121 (46.4)	
Former- user	5 (4.2)	6 (4.3)	11 (4.2)	0.496
Non –user	64 (53.3)	65 (46.1)	129 (49.4)	
Total	120 (46.0)	141 (54.0)	261 (100)	

*, p value less than 0.05

60.8% (n=62) of smokers, 46% (n=58) of betel quid users, 56.5% (n=13) of pan masala users, and 22.8% (n=28) of alcohol users either reduced or stopped their habits. It was observed that, those participants who continued or increased their habit of chewing tobacco after symptom identification were more likely to have a patient interval of more than 90 days compared to those who decreased or quit the habit (OR, 2.76 95% CI, 1.3 to 5.7). Compared to persons without any habits, those with habits had higher chances of getting a patient interval of more than 90 days (OR, 2.74; 95% CI, 1.1 to 6.6).

Financial factors such as, "availability of government or private insurance", "having another earning member in the family", "dependence on others for meeting their financial needs", and "having financial liabilities" were not significantly associated with the patient interval.

Information on participants' health-related practices (Table 2: Association of various factors with patient interval in oral cancer patients) and the barriers towards help-seeking were collected (Table 3: Endorsement of barriers to help-seeking and Patient interval in oral cancer patients).

Discussion interval is the time taken by the participant for discussing the problems in their oral cavity with someone in the family or among his or her social circle, before meeting a health care professional. Among the participants (n=261), 69% discussed their oral problems, with a median (Interquartile range) discussion interval of 14 (7-30) days. Persons with whom these participants first discussed their symptoms were spouses (45%), sons (18.3%), daughters (12.2%), or friends (10%). Participants with a discussion interval of more than 30 days were more likely to have a patient interval of more than 90 days (OR, 7.85; 95% CI, 4.03 to 15.29) compared to those with less than 30 days of discussion interval.

A binary logistic regression was performed to analyze the factors that predict the patient interval. The patient interval of "more than 90 days" and "less than or equal to 90 days" were the outcomes. A final model was obtained with non-significant Hosmer and Lemeshow goodness of fit (χ^2 (8) = 4.977, p=.760), indicating that the model adequately describes the data. The predictor variables identified were "Reason for meeting HCP for current problem in the oral cavity", "Distance to the nearest

Table 2. Association of Various Factors with Patient Interval in Oral Cancer Patients (n= 261)

Variables	≤ 90 days n (%)	> 90 days n (%)	Unadjusted OR (95% CI)
Access and Pattern of Healthcare related factors			
Pattern of medical consultation			
Health screening at intervals	37 (30.8)	21 (14.9)	Reference
Medical consultation for illness	53 (44.2)	50 (35.5)	1.662 (0.9-3.2)
Urgent medical care only	30 (25.0)	70 (49.6)	4.111 (2.1-8.2)
Pattern of dental consultation			
Dental screening at intervals	10 (8.3)	4 (2.8)	Reference
Dental consultation for illness	54 (45.0)	31 (22.0)	1.435 (0.4-4.9)
Urgent dental care only	56 (46.7)	106 (75.20)	4.732 (1.4-15.8)
First response to general health problem			
Consult physician /health-worker	57 (56.4)	24 (24.0)	Reference
Home remedy/Herbal medicines	27 (26.7)	44 (44.0)	3.870(2.0-7.6)
Medicines from store	17 (16.8)	32 (32.0)	4.471(2.1-9.5)
Previous experience with cancer			
Yes	39 (32.2)	24 (17.0)	Reference
No	81 (66.9)	117 (83.0)	2.377(1.3-4.3)
Travel options to nearest healthcare facility			
Single vehicle transport	89 (74.2)	83 (58.9)	Reference
Multiple vehicle transport	31 (25.8)	58 (41.1)	2.006(1.2-3.4)
Distance to nearest healthcare facility			
≤ 3 kilometres	58 (48.3)	41 (29.1)	Reference
Above 3 kilometres	62 (51.7)	100(70. 9)	2.282(1.4-3.8)
Time to reach nearest healthcare facility			
≤ 10 minutes	36 (30.0)	22 (15.6)	Reference
11 – 30 minutes	72 (60.0)	83 (58.9)	1.886 (1.0- 3.5)
31 minutes and above	12 (10.0)	36 (25.5)	4.909(2.1-11.4)
Current problem in oral cavity			
Discussed present problem in oral cavity with someone before meeting HCP			
Yes	99 (82.5)	81 (57.4)	Reference
No	21 (17.5)	60 (42.6)	3.492 (1.96-6.2)
Reason for meeting HCP for current problem in oral cavity			
Pain	36 (30.0)	62 (44.0)	11.19 (4.3-29.0)
Discomfort to daily routine	45 (37.5)	73 (51.8)	10.54 (4.1- 26.9)
Insistence by family/friends	39 (32.5)	6 (4. 3)	Reference
Cancer stage			
Early (Stage 1&2)	60 (50.0)	23 (16.3)	Reference
Late (Stage 3&4)	60 (50.0)	118 (83.7)	5.130 (2.9-9.1)
First response to the current problem in oral cavity			
Ignored the symptoms	54 (45.0)	80 (56.7)	Reference
Tried local remedies	27 (22.5)	53 (37.6)	1.325 (0.7-2.4)
Consulted Doctor	39 (32.5)	8 (5.7)	0.138 (0.06-0.32)

OR, Odds ratio; HCP, Healthcare Personnel

healthcare facility", "Cancer stage", "worry about what the doctor might find out", and "Tobacco smoking status at the time of symptom recognition" (Table 4: Summary of Binary Logistic Regression Analysis for Variables Predicting Patient interval).

Discussion

To our knowledge, this is the first study on the patient interval in oral cancer from Kerala, India designed and conducted as per the Aarhus statement. Early diagnosis reduces morbidity and mortality associated with oral

Table 3. Endorsement of Barriers to Help-Seeking and Patient Interval in Oral Cancer Patients (n= 261)

Variable	≤ 90 days n (%)	> 90 days n (%)	OR (95%CI)
Found it embarrassing talking to the doctor about symptoms			
Yes	21 (17.5)	46 (32.6)	2.283(1.3-4.1)
No	99 (82.5)	95 (67.4)	Reference
Was too busy to make time to go to the doctor			
Yes	40 (33.3)	68 (48.2)	1.863(1.1-3.1)
No	80 (66.7)	73 (51.8)	Reference
Had too many other things to worry about			
Yes	49 (40.8)	82 (58.2)	2.014 (1.2-3.3)
No	71 (59.2)	59 (41.8)	Reference
Was worried about what tests they might want to do			
Yes	29 (24.2)	70 (49.6)	3.094 (1.8-5.3)
No	91 (75.8)	71 (50.4)	Reference
Did not have a person to accompany me during hospital visits/consultations			
Yes	20 (16.7)	44 (31.2)	2.268 (1.2-4.1)
No	100 (83.3)	97 (68.8)	Reference
Did not have money to consult a doctor/visit a hospital			
Yes	23 (19.2)	47 (33.3)	2.109 (1.2-3.7)
No	97 (80.8)	94 (66.7)	Reference
Was worried about what the doctor might find out			
Yes	23 (19.2)	64 (45.4)	3.505 (2.0-6.2)
No	97 (80.8)	77 (54.6)	Reference
Comfortable in discussing symptoms with a nurse than a doctor			
Yes	32 (26.7)	55 (39.0)	1.759 (1.03-3.0)
No	88 (73.3)	86 (61.0)	Reference
Prefer alternative medicines than modern medicine			
Yes	17 (14.2)	42 (29.8)	2.570 (1.4-4.8)
No	103 (85.8)	99 (70.2)	Reference

Table 4. Summary of Binary Logistic Regression Analysis for Variables Predicting Patient interval

Variable	Patient interval n (%) ≤90 days	Patient interval n (%) > 90 days	Adjusted Odds ratio (95% CI)
Reason for meeting HCP for current problem in oral cavity			
Pain	36 (30)	62 (44)	8.300 (2.9-23.4)
Discomfort to daily routine	45 (38)	73 (52)	6.982 (2.5-19.3)
Insistence by family/friends	39 (33)	6 (4)	Reference
Tobacco smoking status at the time of symptom recognition			
Current smoker	38 (32)	63 (45)	2.518 (1.3-4.7)
Former smoker	19 (16)	11 (8)	0.717 (0.3-1.9)
Never smoker	63 (53)	67 (48)	Reference
Cancer stage			
Early (Stage 1&2)	60 (50)	23 (16)	Reference
Late (Stage 3&4)	60 (50)	118 (84)	2.621(1.3-5.2)
Was worried about what the doctor might find out			
Yes	23 (19)	64 (45)	2.546 (1.3-4.9)
No	97 (81)	77 (55)	Reference
Time to reach nearest healthcare facility			
≤ 10 minutes	36 (30)	22 (16)	Reference
11 – 30 minutes	72 (60)	83 (59)	1.443 (0.6- 3.4)
31 and above	12 (10)	36 (26)	5.803 (1.6-21.7)

Note: Control was 'Distance to nearest healthcare facility'(omitted from the table)

cancer (van der Waal, 2013). The time took by the patients for self-referral when they notice those symptoms suggestive of cancer is a key factor in the diagnostic pathway. The median patient interval of 92 days reported in our study is in agreement with a similar observation from a regional cancer center in northeast India (Baishya et al., 2015), but there are reports of median patient interval ranging from 35 days (Jovanovic et al., 1992) to 123 days (Peacock et al., 2008) in other studies. A study from a tertiary care hospital in north India had reported increased patient interval in 60%of their study participants (Akram et al., 2014) whereas, in our study, this proportion was 54%. These findings point to the higher prevalence of increased patient interval in our study population.

We took every effort to conduct and report our study in concurrence with "Aarhus statement" (Weller et al., 2012). The beginning and endpoints of patient interval duration were clearly defined before the initiation of data collection using a validated instrument (Philip and Kannan, 2019). At the outset, the present study findings confirm the fact that oral cancer is a disease of the elderly. Studies from some western countries had reported mean age as high as 76 years (Goldenberg et al., 2014). This is true with oral precancerous lesions also (Pindborg, 1978). Though the relationship between age and occurrence of oral cancer is well established, we couldn't identify any such relationship between age and patient interval. The previous studies on patient interval had given contradicting results on socio-demographic factors that contribute to the prolonged patient interval (Philip and Kannan, 2019). The lack of association of other socio-demographic factors with patient interval may be due to the known relationship between oral cancer and low socioeconomic status (Madani et al., 2010).

The type of house in which the patient lived was the only socio-demographic factor found to be significantly associated with the patient interval in our study. A study from south India reports a higher prevalence of tobacco smoking among those who live in semi-pucca-type houses in comparison to those living in pucca-type houses (Vinothkumar et al., 2020). Less affluent households often have poor housing conditions and that may affect health outcomes (Braubach and Savelsberg, 2009). This finding supports our observation that a higher proportion of participants with the patient interval of more than 90 days had semi-pucca-type houses and were ever tobacco users unlike those with the pucca house.

Factors linked to the pattern of health-seeking like self-remedy, self-medication, and consulting traditional healers were found to delay symptom presentation in a study from a developing country (Azhar and Doss,

2018). We also had similar observations in our study. Those who were reluctant to visit medical/dental facilities were at higher risk of having increased patient interval. High-risk people seldom visit a dentist or dental screening programs (Peacock et al., 2008). In our study, only 5.4% of participants reported a history of dental screening. Access to the health facility was an important determinant of patient interval duration. A study from Sri Lanka identified the cost of travel as a factor associated with patient interval (Alahapperuma and Fernando, 2017). A systematic review on the relationship of travel distance and travel duration on health outcomes in global north countries had found that the majority of the included studies report worse health outcomes among those who lived farther from the health facility (Kelly et al., 2016). In our study, we examined those disease factors that were directly linked to the current disease and found the stage of disease as a significant predictor of increased patient interval. A Finnish study on patient delay among oropharyngeal cancer patients also reported the association of cancer stage with patient interval (Nieminen et al., 2020). The stage of cancer is an important predictor for prognosis and survival in oral cancer (Thavarool et al., 2019). Thus any reduction in the patient interval duration will help to add quality years to the patient's life. Oral cancer in the initial stages may be asymptomatic or have symptoms that appear to be less severe or alarming and hence people ignore them. The pain usually presents in the late stages. Hence those who meet a doctor only when they have persistent pain or discomfort had increased patient interval.

We found that sharing symptoms with friends or family and taking them into confidence will reduce the patient interval. Discussing symptoms with family or friends may act as a trigger for presenting symptoms suggestive of cancer immediately to a health care provider. It is of concern that a notable proportion (31%) of participants with oral cancer had failed to discuss their symptoms. The study by Rogers et al., (2011) supports this observation. This indicates the need for providing cancer symptom awareness education in families and workplaces, especially in high-risk communities. In our study, 82% of participants either ignored their symptoms or tried local remedies resulting in the postponement of medical consultation and prolongation of patient interval. In one study, nearly half of the oral cancer patients considered their symptoms as not serious and another one-third tried local remedies instead of seeking professional help. These findings provide scope for interventions that focus on oral cancer symptom awareness education. These interventions should highlight the importance of early presentation for better prognosis and survival. The triggering reason for meeting the HCPs was mainly symptom-related discomfort or pain (83%) and a higher proportion of these participants were in advanced stages in comparison with those reported due to insistence by friends or family and this association was statistically significant. This suggests that people should not wait for oral symptoms to get aggravated for reporting. Symptoms generally get aggravated in late stages. Care should be taken to report any symptoms, however mild it may be to a health care provider irrespective of its perceived severity.

In conclusion, health education on symptom appraisal and familiarisation of health care facilities in the context of cancer detection may improve symptom reporting at the primary care level. Most of the oral cancer patients are working in the unorganized sector where provisions for availing medical care were non-existent. Work site-based health education and early diagnosis interventions should be planned and provisions for periodic free health check-ups should be made mandatory. The double burden of tobacco use in oral cancer, as it increases the risk of disease occurrence and delays symptom presentation, needs serious policy considerations in the context of cancer prevention. Man, being a social animal, is influenced by the people around him. Sharing health-related concerns with the people around him may speed up the diagnostic journey. People at high risk of developing oral cancer should be given health education on the warning signs and curability of early-stage oral cancer. Although oral cancer is one of the few cancers that have the ideal characteristics suitable for early detection, most of the cases are reported in advanced stages. One of the solutions for reducing late-stage reporting is to decrease the patient interval. The patient interval can be shortened by addressing the relevant individual, interpersonal and organizational factors like symptom awareness, habit patterns, health-seeking and help-seeking attitudes, family and social support, and accessibility and availability of health care facilities.

Author Contribution Statement

Conceptualization: PMP, SK; Design: PMP, SK; Literature search: PMP; Data acquisition: PMP; Data analysis: PMP, SK; Manuscript preparation: PMP; Manuscript editing: PMP, SK; Manuscript review: SK.

Acknowledgments

We would like to thank Dr. Satheesan B, Director, Malabar Cancer Centre, and Dr. Neethu AP, Head of Department, Department of Community Oncology, Malabar Cancer Centre for their unwavering support for the study. We would also like to thank Dr.Sankara Sarma P, Professor, Achutha Menon Centre for Health Science Studies, SreeChitraTirunal Institute for Medical Sciences and Technology, Dr. Jayakrishnan R, Associate Professor, Regional Cancer Centre, Trivandrum, and Dr. Jissa V T, scientist C, Achutha Menon Centre for Health Science Studies, Sree ChitraTirunal Institute for Medical Sciences and Technology for comments that greatly improved the manuscript. We thank Dr. Dimla Denny C, Senior Resident, Government Dental College, Thrissur for her valuable inputs for the manuscript preparation.

Funding Statement

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

The first author is a Ph.D. scholar at Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology,

Trivandrum, Kerala, India (An institution of national importance under the government of India) and the study is part of his Ph.D. thesis work.

Ethics committee approval

Institutional ethics committee approval was obtained before the conduct of the study from the The institutional ethics committee of the Malabar Cancer Centre (1617/IRB-IEC/13/MCC/13-05-2019/5) and the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCT/IEC/1388/JUNE-2019).

Availability of data

All datasets leading to the results of the study are available with the corresponding author on reasonable request

Conflict of interest

The authors of this paper declare no conflict of interest

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Original Article

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Quick Response Code:

Website: www.jehp.net

DOI: 10.4103/jehp.jehp_145_18

Community-based interventions for health promotion and disease prevention in noncommunicable diseases: A narrative review

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Abstract:

PURPOSE: Noncommunicable disease (NCD) prevention is emerging as a public health priority in developing countries. For better health outcome in these countries, it is necessary to understand the different community-based interventions developed and implemented across the world.

OBJECTIVE: The objective of the current review is to identify the best strategies used in community-based health intervention (CBHI) programs across the world.

MATERIALS AND METHODS: For review, we searched in PubMed and Google Scholar with the keywords "community based," "health interventions," "health promotions," "primary prevention," chronic diseases," "lifestyle-related diseases," and "NCD." Data were extracted using predesigned data extraction form. CBHI studies detailing their intervention strategies only were included in the review.

RESULTS: Out of 35 articles reviewed, 14 (40%) were randomized control trials, while 18 (51.4%) were quasi-experimental design. Individual level ($n = 14$), group level ($n = 5$), community level ($n = 6$), and policy level ($n = 4$) intervention strategies were identified. Twenty-three (64%) studies were based on interventions for 1 year and above. Twenty-eight (80%) studies were intervened among specific populations such as Latinos and so on.

CONCLUSION: Successful programs advocate for a package or a chain of interventions than a single intervention. The type of interventions at different levels, namely individual, group, community, and policy levels vary across studies, but individual, and group level interventions are more frequently used.

Keywords:

Community interventions, disease prevention, health promotion, noncommunicable disease

Introduction

It is a common practice in the developed countries to have community-based health interventions (CBHI) in noncommunicable disease (NCD) prevention.[1] However, developing countries prioritize these resources for communicable disease prevention and maternal and child health.[2] In the recent past, developing countries experience epidemiological transition.[3] Increase in the share of NCDs in total disease burden compelled the policy makers and researchers to focus on NCD problem. Classic experiments such as North Karelia project have demonstrated the feasibility of interventions at the community level and with a specific focus in preventing NCD and with a specific focus on the cardiovascular diseases.[4] The Ottawa charter for health promotion makes it apparent that favorable political, economic, social, cultural, environmental, behavioral, and biological factors influence and shape health.[5] North Karelia project over the years has demonstrated how

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Received: 23-05-2018
Accepted: 04-08-2018

How to cite this article: Philip PM, Kannan S, Parambil NA. Community-based interventions for health promotion and disease prevention in noncommunicable diseases: A narrative review. J Edu Health Promot 2018;7:141.

social and behavioral science concepts were applied for health promotion.[4,6] Similar programs such as Stanford Three Community Study, Stanford Five-City Project, Minnesota Heart Health Program, and Pawtucket Heart Health Program were carried out in the United States of America for cardiovascular disease prevention.[1] Tobacco use, physical inactivity, unhealthy diet, and harmful use of alcohol are the common risk factors for NCDs such as hypertension, cardiovascular disease, and cancer.[7] Thus, the focus has shifted from cardiovascular disease prevention to NCD prevention due to the similarity in risk factors. Programs initiated by the World Health Organization (WHO) then served as templates for program planning and implementation at different regions. Interhealth, countrywide integrated NCD intervention program, and CARMEN were WHO promoted programs for NCD prevention.[1] Community-based programs are based on the fact that human behavior is molded through the interactions occurring in the social environment.[8] As a result, these programs use community-focused public health approach and primary prevention strategy for modifying factors influencing community health.[9] Furthermore, a community is described and interpreted in different ways. A community is "a group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings."[10] The word community used in CBHI may be interpreted in accordance with the role it plays in that intervention. It may be the "setting," "target," "resource," or the "agent."[11,12] CBHIs recognize community as a unit of identity and builds on the strengths and resources within the community. It encourages the involvement of all participants in all phases of research. It endorses co-learning and blends knowledge and action for the collective gain of all participants.[13] Many models and theories guide the planning and implementation of community-based health interventions.[14,15]

The objective of the current review is to identify the best strategies used in community-based health intervention programs across the world.

Materials and Methods

A systematic literature search and narrative synthesis[16] was performed on studies published in the English language from January 2004 to July 2016. Original studies published in peer-reviewed scientific journals having full-text availability were included in this review. No restrictions were made on the article search process on the basis of the type of study, type of intervention, or type of participants. Articles on community-based health intervention programs detailing their intervention strategy were included in this study. Commentaries and hospital-based studies were excluded from the study.

Literature search strategy

Articles listed in electronic databases PubMed and Google Scholar were searched using the following keywords. "community based," "health interventions," "health promotions," "primary prevention," "chronic diseases," "lifestyle-related diseases," "cardiovascular diseases," "diabetes," "hypertension," "obesity," "tobacco," "cancer," and "community-based interventions." The keywords were combined using the Boolean operations "OR" and "AND." Two reviewers independently screened the title and abstract of the identified articles to confirm the eligibility. Disagreements if any were resolved through discussion and when required, a third reviewer was consulted. Duplicate articles were removed using Zotero reference management software, and the result was cross-checked manually.

Data extraction process

Data extraction forms were prepared through expert consultation and were verified and filled by the first reviewer. The experts were from the field of epidemiology, biostatistics, and community oncology. Two reviewers independently extracted data. The completed forms were cross-checked for accuracy by the third reviewer and differences were resolved through mutual discussion among reviewers. The extracted data included the author details, country, title, and year of publication, objectives, outcome, intervention area, study design, target population, intervention model or theory, intervention strategy, and intervention duration.

Results

Figure 1 shows the process of selecting 35 articles included in the review. A meta-analysis was not possible due to the heterogeneity of the included studies. Table 1 shows the characteristics of articles from 14 countries included in the review**.** Qualitative research designs were less commonly used.[17-20] Table 2 summarizes the key findings from the current review. Articles report various theories and models used for intervention development and implementation [Table 3: Theories and models identified in the review] and some studies used multiple theories for their intervention program development. Community-based participatory research (CBPR) was the most commonly used model.[17,21-27] The reviewed articles reported a number of intervention strategies. Even though many of those interventions are commonly used in community health programs,[20-22,25,26,28-38] few innovative ones were also reported[17,19,22,23,33,39-43] [Table 4]. The focus of interventions was individual, group, community, and policy levels [Table 5].

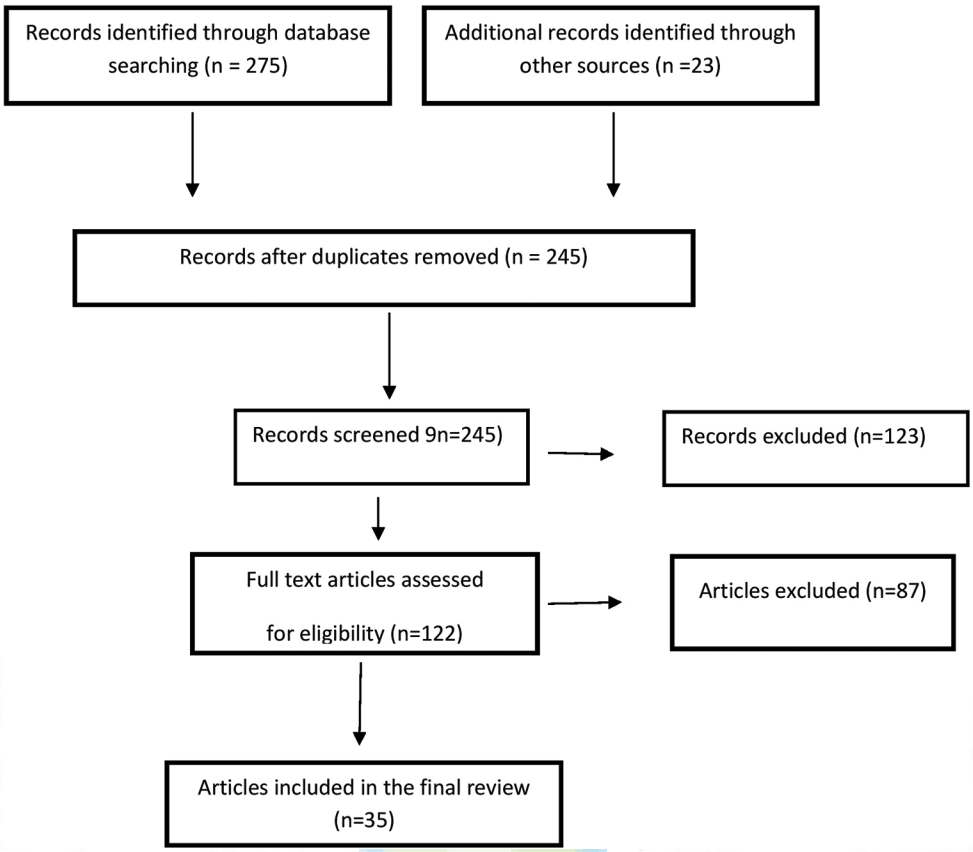

Figure 1: Flowchart depicting the article selection process

Table 1: Characteristics of included studies

No	Author and year	Country	Study design	Model/method	Health issue	Study population
1	Chen *et al*., 2015	Taiwan	Quasi-experimental	-	Suicide prevention	General population
2	Ono *et al*., 2008	Japan	Quasi-experimental	Social support	Suicide prevention	General population
3	Langford *et al*., 2014	USA	Program	Health belief model, stress and coping, social support	Cancer prevention	Lay community men (African American)
4	Blumenthal *et al*., 2010	USA	RCT	CBPR, social ecological theory, social cognitive theory	Cancer prevention, colorectal	369 African American people
5	Blumenthal *et al*., 2005	USA	Multicomponent community intervention trial/quasi-experimental	CBPR, health belief model, community organization, social marketing	Cancer prevention	African American community
6	Hiatt *et al*., 2008	USA	Quasi-experimental (2*2 factorial design)	-	Cancer screening	Multi ethnic underserved women
7	Park *et al*., 2011	South Korea	Quasi-experimental	HBM, TTM, PRECEDE -PROCEDE	Cancer prevention	Women in community
8	Emery *et al*., 2014	Australia	RCT (2*2 factorial)	Community engagement models	Cancer prevention	Rural population
9	Westfall *et al*., 2013	USA	Quasi-experimental	CBPR	Cancer prevention	Rural community
10	Aragones *et al*., 2015	USA	Quasi-experimental	-	Cancer prevention	69 Mexican Americans
11	Williams *et al*., 2013	USA	RCT	CBPR, kin keepers model	Cancer prevention	Black, Latina, Arab women

Contd...

Table 1: Contd...

No	Author and year	Country	Study design	Model/method	Health issue	Study population
12	Shiramizu *et al*., 2012	USA	Qualitative	CBPR	Cancer prevention	HIV infected native population
13	Jayakrishnan *et al*., 2013	India	RCT	-	Tobacco control	Rural current daily smoking men
14	Muramoto *et al*., 2014	USA	RCT	SCT	Tobacco	Health influencers
15	Mishra *et al*., 2014	India	Program pre-post		Tobacco	Women
16	Levinson *et al*., 2015	USA	RCT	Motivation interviewing	Tobacco	Smokers among parents
17	Bhagabaty *et al*., 2015	India	Quasi-experimental	-	Tobacco	Tobacco users in the community
18	Sarrafzadegan *et al*., 2009	Iran	Quasi-experimental	-	Cardiovascular	General population
19	Fornari *et al*., 2013	Brazil	RCT	-	Cardiovascular	School children , parents
20	Austin and Claiborne, 2011	USA	PROGRAM	CBPR	Diabetes	African American community
21	Vojta *et al*., 2013	USA	Quasi-experimental	-	Diabetes	Prediabetic people
22	Katula *et al*., 2010, 2013	USA	RCT	-	Diabetes	300 obese and overweight people
23	Parikh *et al*., 2010	USA	RCT	CBPR	Diabetes	Prediabetic
24	Colagiuri *et al*., 2010 Vita *et al*., 2016	Australia	Quasi-experimental	SCT	Diabetes	People aged at high-risk of developing type 2 diabetes
25	Lu *et al*., 2015	China	RCT Three different interventions	-	Hypertension	Diagnosed hypertensive, age between 40 and 75
26	Zoellner *et al*., 2011	USA	Quasi-experimental phase followed by RCT	CBPR, social support, and motivational interviewing	Hypertension	African Americans
27	Thankappan *et al*., 2013	India	Quasi-experimental	-	Hypertension	General population
28	Land *et al*., 2014	Australia	Quasi-experimental	Communication for behavioral Impact framework	Hypertension/ salt reduction	General population
29	Perry *et al*., 2015	USA	Program	Care group approach	MCH	Women
30	Tripathy *et al*., 2016	India	RCT	Participatory learning and action	MCH	Women aged 15–49 years
31	Yassin *et al*., 2013	Ethiopia	Quasi-experimental	-	TB	General population
32	Eastmen *et al*., 2006	USA	PROGRAM	Social learning theory, health belief model, theory of reasoned action	Sexual education	Parents of sixth to tenth graders
33	Johnson *et al*., 2008	USA	RCT	TTM	Weight management	Obese adults
34	Woelk *et al*., 2016	Swaziland, Uganda, and Zimbabwe	RCT	-	HIV	General population
35	Morisky *et al*., 2004	Philippines	Longitudinal crossover design	Participatory action research	HIV	High-risk male heterosexual populations (6 arms)

RCT=Randomized control trial, CBPR=Community-based participatory research

Community-based interventions in cancer prevention

The objectives of these intervention programs were to increase cancer-related knowledge, reduce the time to diagnosis, improve screening rate, decrease risk behaviors, and correct cancer-related myths.[19,21,22,24-26,28,30,33,34] CBPR model was used in five articles. Peer leaders, general practitioners, patient navigators, community health workers (CHWs), kin keepers, and lay health workers led interventions were the persons delivering the intervention in five articles. The "Kin keeper" intervention is a CBPR study that relies on the teamwork and natural contact that exist among women in families.[26] The trained CHWs select clients from their usual practice and suggest each client gather other women in the family for a group education session

Table 2: Summary of key findings from the review

Number	Focus of review	*n*
1	Health issue/disease	
1.1	Cancer prevention	10
1.2	Tobacco control	5
1.3	Cardiovascular disease prevention	2
1.4	Diabetes prevention	5
1.5	Hypertension prevention	4
1.6	Maternal and child health	2
1.7	HIV prevention	2
1.8	Suicide prevention	2
1.9	Others	3
2	Study designs	
2.1	Randomized controlled trials	14
2.2	Quasi-experimental designs	17
2.3	Qualitative methods	4
3	Target population	
3.1	General population	7
3.2	Specific population	28
4	Intervention models and theories	
4.1	Community participatory models	15
4.2	Health promotion theories	12
4.3	Communication and counseling models	6
4.4	Other models	3
5	Intervention duration	
5.1	<1 year	12
5.2	1 year	6
5.3	>1 year	17

Table 3: Theories and models identified in the review

Community participatory models	Health promotion theories	Communication and counseling models
Community organization model community engagement model social support model, participatory learning and action	Trans-theoretical model	Kin keepers model
Participatory action research Community based participatory research	Social learning theory	Patient navigation model Motivational interviewing
	Theory of reasoned action	Communication for behavioral impact framework
	Social cognitive theory	Care group approach
	Health belief model	
	Social-ecological theory	

at their houses.[26] Men's fellowship breakfasts, panel discussions, health fairs, and education sessions were also used as intervention strategies. Tobacco control is an integral part of any cancer or other NCD prevention programs.

Community-based interventions in tobacco control

Three studies used a randomized control trial (RCT) design[35,38,39] and the remaining two were intervention studies with no control.[37,44] The study population included rural men current smokers on a daily basis,[38] women[44] and parents.[35] "Smoking solution guides" were used in community-based cessation programs. They help and persuade the participants to utilize the existing tobacco cessation facilities in the health system.[35] "Health influencers" (HIs) were a set of people having varied levels of relationship and social distance with the tobacco users. A "health influencer" may be a friend, relative, subordinate, colleague, companion, service provider, or even a stranger. Here, these "health influencers" were given training in tobacco cessation strategies to persuade the tobacco user to give up the habit.[39]

Community-based interventions in cardiovascular, diabetes, and hypertension prevention

Isfahan Healthy Heart Program is a lifestyle intervention program from Iran which demonstrated the effectiveness of such programs in the developing country.[45] In this project, the intervention was channeled through 10 distinct projects targeting worksites, nongovernmental organizations and specific populations such as women, children, health professionals and high-risk groups. The assessment of smoking behaviors, diet, and physical activity was done at baseline and every year for 4 years. Key intervention strategies include public education through mass media, community participation and education, legislation and policy development. Significant changes were observed in dietary habits but no such changes observed in smoking behaviors.[45] Children first study is a school-based cardiovascular prevention program from Brazil. In this 10 months' prospective study, 6–10-year-old school children and their parents were randomized to intervention and control group.[46] Intervention group children received weekly 1 h age-appropriate class on cardiovascular prevention by a specially constituted health team. The policy level intervention was illustrated in the dietary salt intake reduction program. Policy level (public advocacy and salt substitution), community level (community mobilization), and individual level interventions (food switch smartphone application[41]) were reported in the reviewed articles. Except one,[17] all other studies reported intervention duration of 1 year or more. The target population in diabetes prevention programs where people at risk of developing diabetes.[23,31,47,48]

Community-based interventions in other health issues

Care group approach[20] and participatory learning and action model[32] were the two interesting intervention model reported from maternal and child health studies. In a care group approach, the volunteers share messages with the mothers of the households to promote important health behaviors and to use key health services. The care groups demonstrate a cost-effective model with an augmented effect for reaching out the community.

Table 4: Summary of Intervention strategies used in community health interventions

Individual level			Group level	Community level	Policy level	Person delivering the intervention
Personal education and counseling	**Self- learning printed materials**	**Phone and web-based**				
Counseling (*n*=2) One to one education (*n*=6) Individualized reports (*n*=1) Pedometer monitoring (*n*=1) Motivational interviewing (*n*=1)	Pamphlets and leaflets (*n*=8) Booklets (*n*=4) Posters (*n*=2)	Phone calls (*n*=2) Text messaging (*n*=1) Web based training (*n*=1) Mobile application (*n*=1) Mailing (*n*=2)	Panel discussions (*n*=1) Group exercises (*n*=1) Workshops (*n*=3) Group education (*n*=11) Cooking demonstration (*n*=1)	Awareness campaign (*n*=4) Health fairs (*n*=1) Mass media (*n*=1) Network meeting (*n*=1) Video films (*n*=1) Community mobilization (*n*=1)	Public advocacy (*n*=2) Salt substitution (*n*=1) Access restriction (*n*=1) Legislation (*n*=1)	CHWs (*n*=3) Health providers (*n*=5) Lay health worker (*n*=9) Patient navigators (*n*=1) Medical social worker (*n*=2) Health influencers (*n*=1) Peer counselors (*n*=1)

CHW=Community health worker

Table 5: Levels of intervention

Serial no author	Individual level	Group level	Community level	Policy level	Culturally sensitive
1. Chen *et al*., 2015	-	-	-	Access restriction (charcoal)	-
2. Ono *et al*., 2008, 2013	1. Counseling	-	1. Network meetings 2. Public awareness campaigns 3. High-risk screening 4. Outreach	-	-
3. Langford *et al*., 2014	-	1. Panel discussions 2. Small group exercises 3. Cooking demonstrations	1. Fellowship breakfasts 2. Health fairs	-	Yes Ethnic
4. Blumenthal *et al*., 2010	1. One-on-One education 2. Out-of-pocket expenses 3. Pamphlets	1. Group education 2. CHW	-	-	-
5. Blumenthal *et al*., 2005	1. Fliers 2. Posters 3. Booklets	1. Education sessions 2. Clinicians	1. Partnership with church 2. Health fairs 3. Mass media 4. Professional help		Yes Ethnic
6. Hiatt *et al*., 2008	1. One to one education	1. Group education 2. Lay health worker 3. Clinic provider	-	-	-
7. Park *et al*., 2011	1.Posters 2.Leaflets 3. Mailing 4. Phone calls	1. Group education	1. Street promotion	-	-
8. Emery *et al*., 2014	-	1. GP intervention	1. Awareness campaign	-	Yes Rural
9. Westfall *et al*., 2013	-	-	1. Awareness campaign	-	Yes rural
10.Aragones *et al*., 2015	1. Text messaging 2. One to one education 3. Booklet	1. Lay health worker	-	-	-
11.Williams *et al*., 2013	-	1. CHWs 2. Group education	-	--	-
12. Shiramizu *et al*., 2012	-	1. Community sessions 2. Patient navigators	-	-	Yes, Ethnic

Contd...

Table 5: Contd...

Serial no author	Individual level	Group level	Community level	Policy level	Culturally sensitive
13.Jayakrishnan *et al*., 2013	1. Leaflet 2. Booklets	1. Group counseling 2. medical social worker	1.Medical camps	--	-
14. Muramoto *et al*., 2014	1. Personal training 2. Mailed material 3. Web-based training	1. Health influencers	-	-	-
15. Mishra *et al*., 2014	-	1. Rapport building session 2. Group discussion 3. Group counseling	-	-	-
16. Levinson *et al*., 2015	1. Motivation interviewing	1. Smoking solution guides 2. Group sessions	1. Existing health system resource utilization	-	-
17. Bhagabaty *et al*., 2015	1. IEC materials 2. Home counseling	1. Medical social worker	-	-	-
18.Sarrafzadegan *et al*., 2009	-	1. Health professional	1. Mass media 2. Inter-sectoral cooperation and collaboration	1. Legislation and policy	-
19. Fornari *et al*., 2013	1. IEC material	1. Age appropriate classes	-	-	-
20.Austin and Claiborne, 2011	-	1.Workshop	-	-	Yes
21.Vojta *et al*., 2013	-	1. Lifestyle coaches 2. Education sessions	-	-	-
22. Katula *et al*., 2010, 2013	1. Individual meetings with a registered dietitian 2. Monthly newsletter	1. CHWs 2. Group education	-	-	-
23. Parikh *et al*., 2010	1. IEC materials	1. Workshop	-	-	yes
24. Colagiuri *et al*., 2010; Vita *et al*., 2016	1. Individual sessions 2. Telephone calls	1. Group sessions 2. Lifestyle officers 3. Primary care physician	-	-	-
25. Lu *et al*., 2015	1. IEC materials	1. Group education 2. Workshop	-	-	-
26. Zoellner *et al*., 2011	1. Pedometer diary self-monitoring	1. Walking groups 2. Education sessions	-	-	-
27.Thankappan *et al*., 2013	1. Booklets	1. Lay health volunteers 2. Anganwadi workers 3. Elected members	1. Video film	-	-
28. Land *et al*., 2014	1. Food switch	-	1. Community mobilization 2. Advertisement 3. Point of service	1. Public advocacy 2. Salt substitution	
29. Perry *et al*., 2015	-	1. Care group facilitators 2. Volunteers	-	-	
30. Tripathy *et al*., 2016	-	1. ASHA worker	-	-	
31. Yassin *et al*., 2013	-	1. Female health extension 2. Workers (HEWs)	-	1. Advocacy	
32. Eastmen *et al*., 2006	-	1.Interactive lecture	-	-	
33. Johnson *et al*., 2008	1. Individualized reports	-	-	-	
34. Woelk *et al*., 2016	-	1. Community leaders 2. Community peer group	1. Community days	-	
35. Morisky *et al*., 2004	-	1. Peer counselors	-	-	

CHW=Community health worker, HEWs=Health extension worker, ASHA=Accredited Social Health Activists, IEC=Information Education and Communication

Prevention study conducted on the high-risk male heterosexual population in the Philippines report a longitudinal crossover study design.[36] In this intervention study, peer counselors were selected from among the study population and were trained to educate fellow men. These trained peer counselors were expected to educate at least ten of their peers on STI/HIV/AIDS.

Discussion

This review exposes the paucity of community-based health intervention programs and research from the developing world. Nearly three-fourth (64%) of the studies reviewed were reported from developed countries. Owing to the increased burden of NCDs in the developed world since the 1960s, most of the integrated NCD prevention programs were reported from these countries.[1] A systematic review of obesity prevention programs in Europe showed fewer intervention programs were reported in the less affluent eastern and southern European countries.[49] The reason for fewer studies from the developing world may also be attributed to an overburdened and cash stripped public health systems in those countries. In many developing countries, communicable diseases are still a cause of worry.

Community-based programs reviewed in this paper described experimental and quasi-experimental study designs. The quasi-experimental designs include non-RCTs,[25,29,30,34,43,45,50] interventions without control[37,40,41,44,47,48] and longitudinal crossover design.[36] The quasi-experimental study design was used in half of the articles reviewed. Even though the randomized trial is the gold standard in the evaluation of community intervention trials, practical and ethical issues argue against it.[51] Random allocation often faces hurdles for implementation. Policy makers and administrators often demand to roll out of the intervention in a needy area. They may also advocate excluding "control areas" if the intervention is considered as useful and devoid of any ill effects.[52] In RCTs, subject recruitment may be difficult in the control group. These may be the reasons for the perceived preference observed in the review for quasi-experimental designs. A systematic review of CBPR showed few studies used RCT.[53]

About 81 of the reviewed articles reported interventions in specific groups such as ethnic, religious and linguistic minorities, women, smokers, prediabetic people, and high-risk individuals. A review of obesity prevention intervention found that half of the interventions were targeted at the general population.[49] The review by Gubbels *et al*.[49] was exclusively on obesity prevention but that condition is quite common among specific communities and the general population in developed countries. That may be the reason for reported targeting of the general population in half of the studies. In our study, we included articles detailing prevention strategies in different fields such as cancer, diabetes, hypertension, smoking, and cardiovascular disease. The prevalence of cardiovascular diseases, hypertension, diabetes, and other NCDs is higher among African Americans of the United States. This may be a reason for targeting specific population rather than the general population in the US-based NCD prevention studies.[54]

Community participatory models and behavioral modification theories of health promotion were used for program development in reviewed articles. Most of the studies describing the models and theories did not explain how they utilized these theories for developing the intervention. A systematic review of theory-based lifestyle intervention studies reports a similar observation that only a few articles explicitly mentioned the role of theory in all phases of the intervention program.[55] CBPR model was widely used in the reviewed articles. Participatory action research and social ecological models were identified as key to successful community-based physical activity intervention programs.[56] The co-learning process in community-based interventions result in the exchange of knowledge and skills and thus by empowers the participating communities.[13] CBPR will be an effective intervention research strategy if all the participants recognize the usefulness of such collaborations.[53]

Culture-sensitive interventions targeting religious and ethnic minorities were also reported.[17,19,21,22,24,26,27,33,34] This tailoring aims to address the culture divide existing between the urban-rural or ethnic, religious, and linguistic minorities. Culture-sensitive intervention approaches will help in program implementation and intervention penetration. Some other interventions were specifically focused on individuals at high risk of developing certain diseases like diabetes.[57,58] Culturally competent, CHW leads interventions to prevent chronic disease among culturally and linguistically diverse communities were found to be successful.[59] Intervention duration varies from 2 months to 6 years in our review. Community-based interventions are generally of greater durations. The North Karelia project was initially planned for 5 years only, but later, it was extended nationwide and concluded in 1997 only. The project still continues in North Karelia.[6] The community intervention projects commonly take 2–3 years for implementation and evaluation with some project extending to 5–7 years.[8]

Conclusion

Intervention programs that engage the population through multiple activities or activities that are spaced

over the entire duration of the program are more successful than the one based on a single activity. Person led interventions are also well accepted at the community level. Community-based health interventional studies are generally reported from the developed countries. These studies prefer quasi-experimental designs over RCTs due to practical, ethical, provider, and policy level reasons. Their intervention strategies are targeted at individuals, groups, communities, and policy levels. A single intervention program may target its intervention strategies at multiple levels. Group-level interventions were part of almost all intervention programs. Most of the interventions target a specific community rather than general populations. Interventions targeting specific groups such as linguistic, ethnic, or religious minorities or rural communities may adapt their interventions to suit the cultural and regional requirements of those communities. CBPR models are increasingly used in community interventions as these models ensure equal partnerships for all stakeholders at different levels of interventions. Care group approach and kin keeper's model were two intervention strategies which explored the women groups' potential for intervention delivery. One to one education, interactive group sessions, workshops, printed materials group counseling, and mass media were the frequently used intervention tools. CHWs, lay health workers, peer leaders, and clinic providers were used for intervention delivery. Interventions delivered in person had good acceptance but unviable in large community settings.

The paucity of articles from developing countries underscores the need for conducting similar studies in those countries to understand the practical difficulties in translating the knowledge gained through the experiences of developed countries in the field of community-based health interventions. We need to know how issues such as underdeveloped health-care system and insufficient health care spending for NCD prevention will affect the rolling out of large-scale community-based health intervention programs in the developing countries.

Acknowledgment

We would like to thank Dr. SankaraSarma P, Professor, Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Dr Jayakrishnan R, Associate Professor, Regional Cancer Centre, Trivandrum and Dr Jissa V T, scientist B, Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology for comments that greatly improved the manuscript.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Patient and Diagnostic Intervals in Oral Cancer: Protocol for a Sequential Explanatory Study

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ABSTRACT

Background: Oral cancer is an important public health problem in Southeast Asian countries. Generally, cases are reported in advanced stages, resulting in prolonged treatment, high financial burden, and poor prognosis. When diagnosed early, treatment is simple and inexpensive.

Materials and Methods: A sequential explanatory study design, cross-sectional survey followed by in-depth interviews, will be used to assess various factors contributing to the patient and diagnostic intervals in oral cancer. At the outset, Data collection tools will be developed and validated. The study protocol is designed as per the "Aarhus statement" for early diagnosis research. In-depth interviews with selected stakeholders and review of documents related to cancer control will constitute the explanatory component of the study design.

Discussion: Primary prevention helps in reducing cancer incidence whereas secondary prevention helps in reducing morbidity and mortality. Early diagnosis is a key secondary prevention strategy. Research on early diagnosis of cancer in general and oral cancer, in particular, is scarce. In this regard, a comprehensive and thorough evaluation of various factors facilitates or impede early oral cancer symptom presentation will help in designing policies and programs to promote early diagnosis of oral cancer.

Keywords: Early cancer diagnosis, Oral cancer, Patient interval, Diagnostic interval, Aarhus Statement

1. Background

Cancer incidence is increasing in the world with a staggering eighteen million new cancer cases in 2018. Nearly half of these cases were from Asia (Bray et al., 2018). Low middle-income countries account for 72% of worlds cancer deaths (Institute of Medicine, 2007). The cancer pattern also varies across different world regions. Breast cancer is the most common cancer in all six World Health Organization (WHO) regions. If we observe the cancer

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incidence among men, prostate cancer is the most common cancer in WHO regions of Europe, Africa, lung cancer in western pacific and east Mediterranean regions and lip, oral cavity cancers in South East Asia region (Bray et al., 2018). Oral cancer is the most common type of cancer among men in South Asian Countries like India, Srilanka, Pakistan, and Bangladesh and contributes nearly one-fourth of all new cases of cancer (Bray et al., 2018). Oral cancer is characterized by marked geographical variations in its incidence and prevalence rates (Warnakulasuriya, 2009). Oral cancer is the seventeenth most common cancer in the world with a share of 2.2% in total cancer incidence. India presents an entirely different scenario where oral cancer ranks second with a 10.4% share of total cancer incidence (Bray et al., 2018). WHO predicts a 66% increase in the incidence of oral cancer in India by the year 2040, which is higher than the similar estimate for Asia and the world (Ferlay J et al., 2018). The observed trends in incidence and mortality among men and women are closely correlated with the patterns and trends in tobacco and alcohol use (Sankaranarayanan, Ramadas, Amarasinghe, Subramanian, & Johnson, 2015). The five-year survival rate of early-stage cancer exceeds 80%, while that of patients with advanced stages falls below 20%. Globally, more than half of the oral cancer patients report in late stages (Sankaranarayanan et al., 2015; van der Waal, 2013; Warnakulasuriya, 2009). Oral cancer has a long preclinical phase that consists of well-documented precancerous lesions (Sankaranarayanan et al., 2015). Unlike other cancers, these lesions can be easily recognized (Farah et al., 2014). Early identification and proper management of these lesions will ward off mortality (Messadi, 2013). Health care providers including dentists can detect these precancerous and cancerous lesions through oral visual examination (Sankaranarayanan et al., 2015). Despite all these favorable circumstances for prevention, most of the time, the lesion is reported or diagnosed at an advanced stage (Güneri & Epstein, 2014). Primary prevention through control of risk factors and secondary prevention through early detection are the two strategies for oral cancer control (World Health Organization, 2017). Early detection has two components, namely, screening and early diagnosis. Screening refers to the identification of asymptomatic disease in an apparently healthy population. For a disease to be included in a screening program, it should pass through a detectable pre-clinical phase and early treatment should offer some advantage over late treatment (Isabel dos Santos Silva, 1999).

No national or international guidelines recommend population-based screening for oral cancer except for high-risk population (Brocklehurst et al., 2013; USPSTF, 2013). Early diagnosis is the recognition of symptomatic cancer in its early clinical phase (World Health Organization, 2007). The purpose here is to identify the disease at the earliest possible opportunity (World Health Organization, 2017). Early diagnosis integrated with approachable, affordable and efficacious treatment will lead to furtherance in both the stage of cancer at presentation and mortality from cancer (World Health Organization, 2017). Thus, delay in diagnosis is considered as an impediment for prognosis and survival. Pack and Gallo first introduced the concept of delay in 1938 and they defined it as an interval between the onset of symptoms and the first visit to a physician. The undue delay was arbitrarily defined as three months or more (Pack & Gallo, 1938). The first model to explain the delay in seeking cancer diagnosis was given by Andersen (Andersen, Cacioppo, & Roberts, 1995). The general model of patient delay proposed by Andersen comprised of a series of stages, each characterized by a distinct set of definitions and appraisal processes. The stages include Appraisal delay, Illness delay, Behavioral delay, Scheduling delay, and Treatment delay. Later, Olesen et al proposed a model with various milestones and time intervals to explain the processes leading to diagnosis and treatment of cancer (Olesen, Hansen, & Vedsted, 2009). They include Total delay, Patient delay, Doctor delay, System delay, Primary care delay, Secondary care delay, Diagnostic delay, and Treatment delay (Olesen et al., 2009). Walter et

al refined the Andersen model and proposed the Model pathways to treatment (Walter, Webster, Scott, & Emery, 2012). A recent document by the World Health Organization on early diagnosis of cancer recommends using the term "interval" instead of "delay" as the later amount to blame the patient and provider for the delay (World Health Organization, 2017). The document further refines the time points and intervals described in the above models. The intervals include patient interval, diagnostic interval, and treatment interval (World Health Organization, 2017). The patient interval is the period from the recognition of signs/symptoms suggestive of cancer to the day he/she meet a health care provider to discuss the same. The diagnostic interval is the period from the date of the first visit to a health care provider to discuss a symptom suggestive of cancer to the date of obtaining a definitive histopathological diagnosis (Walter et al., 2012; World Health Organization, 2017). Treatment interval is the duration from definitive diagnosis to initiation of cancer treatment (Walter et al., 2012; World Health Organization, 2017). Several factors including demographical, psychological, social, cultural, disease-related, and system-related factors affect the length of these intervals (Weller et al., 2012; World Health Organization, 2017).

A greater understanding of these intervals is essential for planning and implementing cancer control policies and programs (Coxon et al., 2018). Unfortunately, most of the studies carried out in the field of early diagnosis were marred by methodological incongruities, making it difficult for comparisons and interpretations (Andersen, Vedsted, Olesen, Bro, & Søndergaard, 2009; Weller et al., 2012). As a result of this, a consensus-working group comprising of experts in the field of early diagnosis research had gathered at Aarhus, Denmark in 2011 for evaluating existing research and to produce checklists and guidelines to guide early diagnosis researchers (Weller et al., 2012). The working group found that there is little consistency in the definitions and measurements of key time points and intervals. They also concluded that few studies have used a theoretical framework and there is no transparency in the use or development of study instruments (Weller et al., 2012). The recommendations put forward by the consensus-working group are known as “Aarhus Statement”. It provides recommendations for definitions and methodological approaches and a checklist for designing early diagnosis research studies (Weller et al., 2012). Studies published during the post-Aarhus statement period have also failed to follow Aarhus recommendations. Moreover, there are very few validated instruments to measure these intervals. The only validated tool (Neal et al., 2014) available for measuring the various intervals in the diagnostic journey of cancer did not have provision for measuring those time intervals in oral cancer patients. Knowing more about the magnitude of this late presentation as well as the contributing factors for longer intervals will help in managing this public health problem. The current literature on early diagnosis was largely from western countries. These literature focus much on cancers other than oral cavity cancers as the incidence of oral cancer is very low in those countries. There are very few studies exist in the literature on early diagnosis of oral cancer and within that, the contribution from South East Asia is meager. The scarcity of studies from India on early diagnosis of oral cancer necessitates designing a study for estimating various time intervals in the diagnostic journey of oral cancer and identifying various factors contributing to those intervals in line with the Aarhus statement.

The objectives of the current study are as follows:

1. Estimate the duration of patient interval in the diagnostic journey of oral cancer patients of a tertiary cancer center in northern Kerala.
2. Estimate the duration of diagnostic interval in the diagnostic journey of oral cancer patients of a tertiary cancer center in northern Kerala.

3. Study the various factors associated with the patient interval in the diagnostic journey of oral cancer patients of a tertiary cancer center in northern Kerala.
4. Mapping the structure and function of oral cancer control in the state.
5. To develop and validate instruments for capturing the duration of the patient interval, diagnostic interval and various factors contributing to the patient interval in the diagnostic journey of oral cancer.

2. Methods and Analysis

2.1 Study design

A sequential explanatory study design will be used for conducting this study. Sequential Explanatory Design is characterized by the collection and analysis of quantitative data followed by the collection and analysis of qualitative data. Priority is typically given to the quantitative data. The purpose of the sequential explanatory design is typically to use qualitative results to assist in explaining and interpreting the findings of a primarily quantitative study (Creswell, Plano Clark, Gutmann, & Hanson, 2003). This study has three phases.

Phase 1: Development and validation of tools for a cross-sectional survey
Tools will be developed and validated for conducting the cross-sectional survey. The outcome of phase 1 will be a newly developed and validated interview schedule for measuring patient and diagnostic interval and a questionnaire to identify the various factors related to the patient interval.

Steps for developing the tool:
1. Literature review: A literature review will be conducted to identify the various factors contributing to the patient interval. An inventory will be created from the previous questionnaires identified in the literature review.
2. Expert consultation: The inventory will be discussed with experts individually. The experts include Head and neck oncologists, Oral medicine specialists, ENT specialist, Epidemiologists, Psycho oncologists, Dentists, and General practitioners. These discussions will help in identifying factors unaddressed in other studies as well as factors relevant to our setting.
3. Content validity: Content validity will be objectively measured through a content validity index (CVI). CVI provides a quantitative measurement of content validity. The experts will be provided a copy of the tool individually and will be asked to rate each item based on relevance as relevant or irrelevant. The content validity index will be computed as the number of experts giving a rating of relevant divided by the total number of experts. The items having a CVI score of 0.80 or above only will be retained in the tool.
4. Back translation: Translation-back translation of the draft tool will be carried out to produce a conceptually equivalent version of the tool in the local language.
5. Face validity: The translated version of the questionnaire will be administered to 10 people as cognitive piloting. Cognitive piloting is a method for identifying problems with the question-wording. Besides the participants' overall assessment of the questionnaire, participants will be asked to review each question based on the following checklist:
a) The meaning, clarity, and purpose of the question
b) Difficulty in answering the question
c) Suggestions, if any, to improve the question

6. Reliability: The main outcome variables of the "patient interval" and "diagnostic interval" are time durations obtained from calendar dates. Reliability analysis will not be carried out as the instrument intends to collect only factual, objective information. The Protocol for calculating 'pseudo-exact' dates from estimated dates will be used for calculating the time intervals (Neal et al., 2014).

Phase 2: Hospital-based cross-sectional study

Hospital-based patient interview using the newly developed and validated instrument will constitute the second phase of the study. The patient interview will be done within 3 months from the date of patient registration at the institution to minimize recall bias. The expected outcome of phase 2 study includes the mean duration of the patient interval, mean duration of diagnostic interval and identifying various factors affecting patient interval.

Phase 3: In-Depth Interviews and Mapping the structure and function of oral cancer control

In-Depth Interviews: In-Depth Interviews with patients, health care providers, health care administrators, community leaders, etc. as per the findings of the cross-sectional survey conducted in phase 2 will constitute the explanatory part of this sequential explanatory study. Selection of participants, as well as the preparation of the interview guide, will depend on the outcome of the cross-sectional survey. In-Depth Interviews will help in explaining the findings of the hospital-based cross-sectional survey. The participants for the in-depth interview will be selected purposively. The expected outcome is interview guideline and findings from an in-depth interview.

Mapping the structure and function of oral cancer control: Mapping of the structure and function of the oral cancer control will be done by reviewing Govt documents, institutional documents, and other online resources. The expected outcome is to map existing public health facilities and their role for the prevention, early diagnosis, and treatment for oral cancer. It will also document the referral pattern and other government initiatives for the control of oral cancer.

2.2 Study setting

A tertiary cancer center in northern Kerala will be the study setting for the cross-sectional study. Data on the patient interval, diagnostic interval and factors contributing to these intervals will be collected in a direct patient interview using the newly developed and validated instrument. The principal investigator will inform each participant about the purpose of the research and will obtain signed informed consent from all participants. The participants will be interviewed in a room adjacent to the out-Patient Department or ward or any other place convenient to the patient ensuring privacy for the data collection. Time points like date of biopsy, date of biopsy report, patient registration number, and disease stage information will be collected from the patient case files. The secondary data to study the structure and function of oral cancer control in the state will be collected from published government reports and online government sources. The in-depth interview schedule will be prepared after evaluating the findings of the cross-sectional study. Participants, as determined after evaluating the outcome of phase 2, will be approached by the principal investigator for the interview. They will be interviewed at a place and time convenient to them.

2.3 Participants and sample size

The estimated sample size for the cross-sectional survey is 260. The sample size for the in-depth interview is 15 to 30 participants or until we reach saturation. The sample size was estimated by Epi info version 3.01. According to a study done in Uttar Pradesh, India (Akram, Siddiqui, & Karimi, 2014), the proportion of oral cancer patients with a patient interval of more than 3 months was 60%. Taking 60% as the anticipated prevalence of oral cancer patients with a patient interval of more than 3 months, with a 95% confidence interval between 54% and 66%, the sample size was estimated as 257 rounded off to 260. The latest published hospital-based cancer registry data (2015), from the institution where the study will be conducted, reports 450 new oral cancer patients for that year. Hence, we expect 260 new oral cancer patients within 7 months. All oral cancer patients reporting at the institution during the study period will be invited to participating in the study. All the invited patients consenting to participate in the study will be included in the study if they satisfy the inclusion criteria/exclusion criteria. The subjects for the in-depth interview will be selected purposively based on the findings of the cross-sectional survey conducted in phase 2. We plan to conduct 10 to 20 interviews or until we reach saturation. The inclusion-exclusion criteria for the study are as follows.

Inclusion criteria:

Newly registered Patients with the following malignant neoplasms will be included in the study. They are malignant neoplasm of lip (C00), base of tongue (C01), other and unspecified parts of tongue (C02), gum (C03), the floor of mouth (C04), palate (C05), other and unspecified parts of the mouth (C06).

Exclusion criteria:

- Those known to have, or had, other cancers; patients who were on routine surveillance for cancer and presence detected via that system.
- Those who are not consenting to participate.
- Oral cancer patients who are unable to participate due to health reasons or any other reasons.
- Oral cancer patients with recurrence.
- Patients who have completed treatment or partially treated for oral cancer from elsewhere.

2.4 Variables and data sources

The dependent variables for the study are the patient interval, diagnostic interval, and oral cancer stage at diagnosis. Time points used to calculate these intervals include ‘Date of the first symptom', ‘Date of the first presentation' and ‘Date of diagnosis'. Date of the first symptom is the date on which a patient identifies a bodily change or symptom in the oral cavity. Date of the first presentation is the date on which the patient consults a health care provider to discuss the bodily change or symptom in the oral cavity. Definitions of these time points are based on the ‘phases of clinical pathway' described by Olesen et al (Olesen et al., 2009). These time points are subject to recall bias. Thus, the timing of the patient interview is a determining factor in the accuracy of these measurements. Scheduling an interview date too close to the date of diagnosis may be insensitive and too long will lead to recall bias and participant attrition due to death and terminal illness. In this study, the patient interview will be done within 3 months from the date of diagnosis. Self-reported information on the date of first reporting will be crosschecked with prescription notes, if available. Date of diagnosis will be recorded based on the hierarchical rationale developed by the European Network of

Cancer Registries: Hierarchy for Defining the Date of Diagnosis. The independent variables identified through the preliminary literature review are as follows.

1. Socio-demographic factors:

Age (Allison, Franco, Black, & Feine, 1998; Gullatte, Hardin, Kinney, Powe, & Mooney, 2009; Hafström, Johansson, & Ahlberg, 2011; Jassem et al., 2014; Memon, Shaikh, Rizwan, & Sardar, 2013; Yu, Murugiah, Khan, & Mehmood, 2015).
Sex (Abu-Helalah, Alshraideh, Al-Hanaqtah, Da'na, & Mubaidin, 2016; Allison et al., 1998; Chandra, Mohan, Guleria, Singh, & Yadav, 2009; Gullatte et al., 2009; Hafström et al., 2011; Jassem et al., 2014; Memon et al., 2013; Stuver et al., 2011; Thakur, Humne, & Godale, 2015; Yu et al., 2015).
Marital status (Abu-Helalah et al., 2016; Hafström et al., 2011; Jassem et al., 2014; Memon et al., 2013; Stuver et al., 2011; Thakur et al., 2015; Yu et al., 2015).
Residential status (Chandra et al., 2009; Hafström et al., 2011; Jassem et al., 2014; Thakur et al., 2015).
Religion (Hafström et al., 2011).
Socioeconomic status (Jassem et al., 2014; Marlow, McGregor, Nazroo, & Wardle, 2014).
Knowledge of tobacco causes cancer (Marlow et al., 2014).
Education (Gullatte et al., 2009; Memon et al., 2013; Thakur et al., 2015).
Ethnicity (Jassem et al., 2014; Memon et al., 2013).
Migration status, distance from health facility and occupation (Hafström et al., 2011; Yu et al., 2015).

2. Health behavioral factors:

Cigarette smoking (Hafström et al., 2011; Memon et al., 2013; Thakur et al., 2015; Yu et al., 2015).
Alcohol use (Gullatte et al., 2009; Hafström et al., 2011; Memon et al., 2013; Thakur et al., 2015; Yu et al., 2015).
Betel quid use (Hafström et al., 2011).
Regular medical consultation (Marlow et al., 2014).
Regular dental consultation (Thakur et al., 2015).
Consulting for early detection (Marlow et al., 2014).

3. Psychosocial factors:

Attribution of the symptom as minor (Abu-Helalah et al., 2016).
Absence of fear (Abu-Helalah et al., 2016).
Use of alternate therapy (Abu-Helalah et al., 2016).
Negative thoughts on cancer (Marlow et al., 2014).
Perceptions of being under stress in the period before diagnosis (Jassem et al., 2014).
Severity of life events in the patient delay period (Memon et al., 2013).
Perceived ability to seek help for oral symptoms (Memon et al., 2013).

4. Disease factors:

Dental status (Stuver et al., 2011; Yu et al., 2015).
Tumor site (Hafström et al., 2011; Stuver et al., 2011).
Tumor size (Hafström et al., 2011; Stuver et al., 2011).
Comorbid conditions (Chandra et al., 2009).
TNM stage (Hafström et al., 2011).
Lymph node metastasis (Hafström et al., 2011).

Initial sign or symptom (Hafström et al., 2011; Jassem et al., 2014).
Medical history (Jassem et al., 2014).
Dental history (Jassem et al., 2014).
Experience of symptoms (Thakur et al., 2015).
Initial self-diagnosis (Thakur et al., 2015).

The list of independent variables will be finalized during instrument development. Data on the patient interval, diagnostic interval and factors contributing to these intervals will be collected in a direct patient interview using the newly developed and validated instruments. Neal et al guideline will be followed for calculating the pseudo exact date from the estimated date provided by the patient (Neal et al., 2014). Time points like date of biopsy, date of biopsy report, patient registration number, and disease stage information will be collected from the patient case files. The secondary data to study the structure and function of oral cancer control in the state will be collected from published government reports and online government sources. The in-depth interview schedule will be prepared after evaluating the findings of the cross-sectional study. Participants for the In-Depth Interview will be identified after evaluating the outcome of phase 2. They will be informed about the purpose of the study and the principal investigator will obtain the consent of those willing to take part. They will be interviewed at a place and time convenient to them.

2.5 Bias

As study requires recollection of past incidences, there is a possibility for recall bias. For reducing recall bias in this study, we will conduct the patient interview within 3 months from the date of diagnosis.

2.5 Limitations

The study participants will be selected from a single institution. This will have implications on the generalizability of results. However, the study setting is the only comprehensive cancer care center in the region and it provides subsidized treatment as per government norms. The early diagnosis research studies were conducted either in hospitals or from cancer registry data. The registry system in our place is in a developmental phase and they cover a less geographical area in comparison to the hospital's catchment area.

2.6 Plan for data analysis

Descriptive statistical methods will be used (frequencies, percentages, means, standard deviations depending on whether the variables are categorical or continuous). Binary logistic and multiple linear regression models will be constructed to identify significant predictors. Early (stage 1 and 2) vs. late (stage 3 and 4) stages of oral cancer will be further explored for differences in duration and factors related to the patient and diagnostic interval. Data will be analyzed to understand gender and class differentials. Thematic analysis will be used for qualitative data. Thematic analysis will be used for qualitative data. Cancer-related documents will be reviewed using a checklist.

2.7 Ethical consideration

The principal investigator (PI) has obtained approval from the Institutional Ethics Committee for conducting the study. The discomforts expected from the study are minimal. Participants have to spend 20-30 minutes for the data collection and they may have difficulty

in recollecting information related to their symptoms. Some of the cancer patients during the initial days of diagnosis may find it difficult to accept it. The study participants will be approached during the physician-waiting period, which is normally, extends to 30 min to 1hr. Thus, the patient will not have to spend extra time on the study. The instrument will have a checklist of all possible symptoms and a calendar that will help the patient to identify the past events. The timing of the data collection will be scheduled in such a way that it will not be too close to the date of diagnosis as the majority of the patients will find it difficult to accept the reality initially. The institution has a dedicated psycho-oncology department that provides psychological support to all newly diagnosed cancer patients. Data collection will be scheduled on a follow-up visit as convenient to them. No invasive procedures are involved in the study and therefore no adverse events are expected. PI will be responsible for safekeeping the data, privacy, and confidentiality of the subjects will be ensured at all levels. The PI before the data collection will obtain an informed signed consent from the participants, after briefing on the study objectives, purpose, benefit, risks and voluntariness to decide participation. The participant will be provided time (not less than 15 minutes) to read and understand the consent form. Ethical approval has been obtained from two Institutional ethics committees (1617/IRB-IEC/13/MCC/13-05-2019/5 and SCT/IEC/1388/JUNE-2019).

3. Discussion

The starting point of any discussion on the patient and the diagnostic interval is the quest for an acceptable duration. From the early study of Pack and Gallo (Pack & Gallo, 1938) to the present day studies (Abu-Helalah et al., 2016; Akram et al., 2014; Chandra et al., 2009; Ibrahim & Oludara, 2012; Mohd Mujar et al., 2017), three months is generally considered as an acceptable patient interval (Andersen et al., 2009; Thakur et al., 2015). Similarly, one month is considered an acceptable diagnostic interval (Abu-Helalah et al., 2016; Morelatto, Herrera, Fernández, Corball, & López de Blanc, 2007). There are other studies, which consider a shorter period for patient interval and a longer period for diagnostic interval as an acceptable period (Allison et al., 1998; Lim et al., 2014; Olesen et al., 2009). Multifarious study designs and summary measures were used for conducting the study and to report the findings in early diagnosis research. Although cross-sectional study design is the preferred one (Abu-Helalah et al., 2016; Bourdeanu et al., 2013; Garcia et al., 2012; Gullatte et al., 2009; Hafström et al., 2011; Ibrahim & Oludara, 2012; Jassem et al., 2014; Memon et al., 2013; Mohd Mujar et al., 2017; Yu et al., 2015), cohort (Stuver et al., 2011; Thakur et al., 2015) and qualitative designs (Marlow et al., 2014) were also used. Very few studies reported measures of dispersion to describe study findings. These observations confirm with expert review findings that lead to the preparation of Aarhus Statement (Andersen et al., 2009; Weller et al., 2012). An oral cancer-specific review of early diagnosis research also reported similar observations (Varela-Centelles et al., 2018). The mean patient interval duration reported from various countries (Kerdpon, Jantharapattana, & Sriplung, 2018) vary considerably necessitating the need for a region-specific estimate of these durations to assess the need and status of early cancer control initiatives.

Several factors influence the patient interval duration. Factors found to be significant in one study may appear as an insignificant one in another study. This poses the biggest challenge to the current research. Studies addressing factors related to this interval were generally focused on socio-demographic factors even though few have attempted to study the psychosocial, health behavioral and equity-related factors. Even though socio-demographic factors are the most frequently studied ones, it is too difficult to generalize the findings from these studies, as contradictory observations exist in the literature. Old age is a risk factor for

oral cancer (Ram et al., 2011) hence researchers also want to know its relationship with patient interval. Out of the eight studies evaluated its significance, only two (Akram et al., 2014; Panzarella et al., 2014) could demonstrate such a relationship. The majority found no such relations(Alahapperuma & Fernando, 2017; Guggenheimer, Verbin, Johnson, Horkowitz, & Myers, 1989; Kerdpon & Sriplung, 2001; Llewellyn, Johnson, & Warnakulasuriya, 2004; Onizawa et al., 2003; Scott, McGurk, & Grunfeld, 2008). Low socioeconomic status is an independent risk factor for developing oral cancer (Conway et al., 2008) and also for a prolonged patient interval (Akram et al., 2014). A study by Sandeep et al from India refutes the presence of such an influence on the patient interval (Sandeep et al., 2000).

Similarly, rural residence and levels of education were also examined in various studies but the current evidence is insufficient to make any inference. Studies from India, Srilanka, and Thailand (Alahapperuma & Fernando, 2017; Baishya et al., 2015; Kerdpon et al., 2018) found education as a significant factor in determining patient interval but those from USA, England, and Italy cannot establish such links (Guggenheimer et al., 1989; Panzarella et al., 2014; Scott et al., 2008). The stark reflection from this observation is the relevance of education in facilitating health care utilization in developing countries. Gender was also assessed for any possible association but none of the studies showed it as significant (Akram et al., 2014; Alahapperuma & Fernando, 2017; Baishya et al., 2015; Guggenheimer et al., 1989; Jovanovic, Kostense, Schulten, Snow, & van der Waal, 1992; Kerdpon & Sriplung, 2001; Llewellyn et al., 2004; Onizawa et al., 2003; Panzarella et al., 2014; Scott et al., 2008). A study based on the data from the Clinical Practice Research Datalink (CPRD) in the UK found gender delays diagnostic interval in some cancers including head and neck cancer (Din et al., 2015). Social support and social networks were minimally (Abu-Helalah et al., 2016; Brocklehurst et al., 2013; Gullatte et al., 2009; Morelatto et al., 2007) investigated in the reviewed studies. Marital status (Akram et al., 2014; Kerdpon & Sriplung, 2001; Panzarella et al., 2014; Scott et al., 2008), number of family members living in the same house (Onizawa et al., 2003), escorted by someone(Sandeep et al., 2000), disclosure to others (Akram et al., 2014) were the few variables that can be related to social support and network but none of them were associated with patient interval as per the study findings. Interestingly, a different study has found partner support and other support as significant factors for shortening patient interval in females (Pedersen, Olesen, Hansen, Zachariae, & Vedsted, 2011). The full spectrum of health behaviors was not investigated in any of these studies. Smoking, alcohol use, the regularity of visiting a dental or medical provider and use of domestic remedies were assessed but could not find any association (Hollows, McAndrew, & Perini, 2000; Onizawa et al., 2003; Panzarella et al., 2014; Sandeep et al., 2000). The lower amount of tobacco smoked is related to the increased patient interval (Llewellyn et al., 2004) as that might lead to underestimation of risk from smoking. Tumor factors, dental factors or comorbid conditions were also found to be insignificant (Jovanovic et al., 1992; Llewellyn et al., 2004; Sandeep et al., 2000). One study from Srilanka identified the impact of travel cost to a health facility as significant(Alahapperuma & Fernando, 2017).

Research in early oral cancer diagnosis done so far has failed to answer the few questions routinely revolve around patient interval duration. The socio-demographic, health-related, cognitive and psychological variables affecting the patient interval were either understudied or when evaluated, had given contradictory results. The methodologies or definitions used in these studies lacked uniformity and hence comparisons were not possible. In these circumstances, we have designed our study in conformity with the "Aarhus statement " which guides the early cancer diagnosis research (Weller et al., 2012) (Table 1). An exhaustive exploration of various factors affecting the reporting of cancer signs and symptoms to a

health care provider is necessary for developing policy measures to contain this public health challenge.

Table 1. Protocol consistency with 'The Aarhus checklist' for early cancer diagnosis research.

No	Item	Yes /No
Definitions Of Time Points And Intervals		
1	For studies requiring the measurement of an interval, are the beginning and endpoints of this interval clearly defined?	Yes. Time points used are the date of the first symptom, date of first presentation and date of diagnosis.
2	For all time points and intervals described, are there precise, transparent and repeatable definitions, and is the complexity of time points such as the date of first symptom and date of the first presentation addressed?	Yes
For studies that require an estimate of the date of the first symptom		
3	Do the researchers refer to a theoretical framework underpinning definition of this time point?	Yes. Phases of the clinical pathway by Olesen et al
4	Is there a discussion of the different biases influencing the measurement of this time point?	Yes
For studies that require measurement of a date of the first presentation to healthcare		
5	Do the researchers discuss the complexity of the date of the first presentation?	Yes
For studies that require measurement of date of referral		
6	Do the researchers discuss the nature of the referral and provide adequate detail – for example, whether it was for investigation or consultation by a colleague in secondary care?	NA
For studies that require measurement of the date of diagnosis		
7	Do the researchers use an existing hierarchical rationale for the date of diagnosis measurement?	Yes. European Network of Cancer Registries: Hierarchy for Defining the Date of Diagnosis
Measurement		
8	Is the healthcare context in which the study is based fully described?	Yes
9	Do the questions on time points and/or intervals clearly derive from stated definitions?	Questions will be developed as per stated definitions
10	Do researchers acknowledge the need for theoretical validation and refer to the theoretical framework(s) underpinning measurement and analysis of the time	Yes

	points?	
For studies using questionnaires and/or interviews with patients and/or health-care providers		
11	Has a validated instrument been used?	A new Instrument will be developed and validated for the study
12	Have the researchers included a copy of their instrument?	The developed instrument will be published in scientific journals
13	Is there some discussion of how reliability and validity (trustworthiness) has been established?	It is described in the steps for tool development
14	Do researchers acknowledge the need for theoretical validation and refer to the theoretical framework(s) underpinning measurement and analysis of the time points?	Yes
15	Is there discussion of the different biases influencing measurement of the time points, such as how and when the question is asked and who is being asked?	Yes
16	Is the timing of the interview about the date of diagnosis provided?	Yes
17	Is there any triangulation of self-reported data with other data sources such as case notes?	Yes
18	Is data analysis described in full including how and why data are categorized, how missing and incomplete data are managed, and how outliers at both ends of the spectrum are accounted for?	Not applicable as protocol paper
For studies using primary case-note audit and database analysis		
19	Case-note analysis: is there a clear and precise description of how case-note data were used to ascertain time points with an acknowledgment of limitations of such data?	Not applicable
20	For database analysis: is there a thorough description of the database chosen including sampling coverage and completeness of information?	Not applicable

Declarations

Funding Sources: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflict of interests: The authors declare that they have no conflict of interest.

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Publications

1. Phinse m Philip, Ipe Varghese, Jayarama, Extractions in orthodontics, Kerala Dental Journal,vol 3 2008.
2. Philip PM, Parambil NA, Bhaskarapillai B, Balasubramanian S. Evaluation of aspecially designed tobacco control program to reduce tobacco use among schoolchildren in Kerala. Asian Pac J Cancer Prev. 2013;14(6):3455-9. PubMed PMID:23886127
3. Philip PM, Nayak P, Philip S, Parambil NA, Duraisamy K, BalasubramanianS.Population-based cancer screening through community participation: Outcome of adistrict wide oral cancer screening program from rural Kannur, Kerala, India.South Asian J Cancer. 2018 Oct-Dec;7(4):244-248. doi: 10.4103/sajc.sajc_104_17.PubMed PMID: 30430093; PubMed Central PMCID: PMC6190395.
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5. Patient and Diagnostic Intervals in Oral Cancer Protocol for a Sequential Explanatory Study DOI:https://doi.org/10.7565/ssp.2019.2670
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7. Philip, P.M., Kannan, S., 2019. Patient and Diagnostic Intervals in Oral Cancer. Social Science Protocols 2, 1–17. https://doi.org/10.7565/ssp.2019.2670

Clinical and community activities

Joined Malabar cancer centre on 4th November 2010. Currently working as Lecturer in the community oncology department.

The main activities are conducting cancer and tobacco awareness program, early cancer detection programs and tobacco cessation treatment.

1. Awareness programs

a. Cancer awareness campaign**:** cancer awareness classes for general public and health
b. Tobacco awareness campaign at schools: anti-tobacco awareness classes using audio visual aids
c. Exhibitions and observation of cancer related health days:
d. Trainings and workshops: Training in tobacco control and cancer screening for health workers and volunteers.
e. Awareness generating public competitions:
f. Quarterly newsletter NETHI on tobacco awareness for school children.
g. Publication of IEC materials for awareness generation.
h. Short film for tobacco awareness "U- Turn"

2.Screening camps

a. Early oral cancer screening camps:
b. Survey based screening camps
c. Tribal community cancer programme
d. Risk group screening camps

3. Tobacco cessation clinic

Tobacco cessation treatment is provided to those addicted to all forms of tobacco use. People identified at the camps were directed to the department OPD. Tobacco cessation OPD functions on all Wednesdays

Internships, Workshops and Conferences

1. Internship in tobacco control strategies at centre for Oncological studies, Cancer Institute, ADYAR
2. Participated in a workshop on tobacco cessation strategies and setting up of tobacco cessation clinic organized by WHO and Govt of India at GKNM Hospital, Coimbatore.
3. Participated in the 15th world conference on tobacco or health (WCTOH) held at Singapore and presented a poster on study on tobacco use among school children in Kerala.
4. Participated and presented paper at Global cancer summit (2015). The title of the paper was" Effectiveness of population based screening in early detection of pre -cancerous and cancerous oral lesions in rural population in Kannur district, Kerala".
5. Participated in India's oral cancer conference (2015) organized by Indian academy of oral medicine and radiology (IAOMR) held at Melvaruvathoor, Chennai, India.
6. Participated and presented paper at the 61stannual national conference of Indian Public health association held at AIIMS, Jodhpur. **The paper got best paper award**. The title of the paper was "Community based cancer screening in rural Kerala: Results from the district level comprehensive cancer control program "ASWAS", 2011-2014."
7. Participated and presented paper at the 62nd annual national conference of Indian Public health association held at King George Medical University,Lukhnow. The title of the paper was" Effectiveness of clinic based tobacco cessation treatment in quitting tobacco habit: experiences from a tertiary cancer centre, northern Kerala, India."
8. Participated and presented paper at the 1st world NCD conference, 2017 held at PGIMER. The title of the paper was"community based oral cancer screening program conducted by a tertiary cancer centre in kerala –a two year audit"
9. Attended 64st annual national conference of Indian Public Health Association (IPHA) at AIIMS NEW DELHI from 29 February to 2nd March 2020 and presented a paper An exploratory study on the effectiveness of a structured health education program based on current curriculum in improving knowledge, attitude and practice about cancer among school children.
10. Attended ECHO India Immersion workshop held at New Delhi (14th - 15th January 2020)
11. Attended NATIONAL CANCER GRID- KERALA STATE CHAPTER-ANNUAL MEET held on 7/11/2012.
12. New project: AI-driven Large-Scale screening for Oral and Oropharyngeal cancer- Indo-Swedish Collaborative proposal by DBT - AI in Healthcare

IEC Clearance - Malabar Cancer Centre

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Dr. Phinse M Philip
Department of Community Oncology
Malabar Cancer Centre
Thalassery, Kerala

Sub: Approval for an Ethical clearance -Reg.

Dear Dr. Phinse

The Institutional Ethics Committee (IEC) of Malabar Cancer Centre (MCC), reviewed and discussed your application to conduct the research entitled "***A sequential explanatory study of patient and diagnostic intervals in the diagnostic journey of oral cancer patients at a tertiary care centre in northern Kerala"*** on 13th May 2019.

The following members of Ethics committee of MCC were present at the meeting held on 13-5-2019 at 2: 30 PM at Malabar Cancer Centre, Thalassery.

The members were Present:

1.	Dr. Babu Raveendran	:	Chairperson
2.	Dr. Balakrishnan Valliyot	:	Clinician
3.	Dr. Biju George	:	Clinician
4.	Dr. Sangeetha K Nayanar	:	Basic Medical Scientist
5.	Dr.Jeeja M C	:	Basic Medical Scientist
6.	Adv.Preethi	:	Member
7.	Mr. G. V. Rakesh	:	Lay person
8.	Adv.John Joseph	:	Legal expert
9.	Mrs. Chinnammu Sivadas	:	Social Scientist
10.	Dr. Satheesan B	:	Member Secretary

The lists of documents were reviewed:

a) Study Protocol
b) Patient Information Sheet and Informed Consent Form (in English and Malayalam version)
c) Principal Investigator's current CV
d) Investigator's Undertaking

The Ethics committee is **approved** the study proposal with its present form of protocol. The Ethics Committee suggested that the PI should inform the Ethics committee about the progression of the study, any changes in the protocol and patient information/informed consent form and also provide a final report of the study.

We confirm that none of your study members was present during decision making/voting procedure of this meeting.

Yours Sincerely.

Member Secretary

Member Secretary
Institutional Ethics Committee
Malabar Cancer Centre
Thalassery, Kerala-670 103

INSTITUTIONAL REVIEW BOARD
THALASSERY
KERALA-670 103
MALABAR CANCER CENTRE

IEC Approval of Study Proposal

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)
Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

Institutional Ethics Committee

(IEC Regn No. ECR/189/Inst/KL/2013/RR-16)

SCT/IEC/ 1388/JUNE-2019 05.07.2019

Dr. Phinse M Philip,
Part time PhD Scholar, AMCHSS
SCTIMST, Thiruvananthapuram

Dear Dr. Phinse M Philip,

The Institutional Ethics Committee reviewed your application to conduct the study entitled "A SEQUENTIAL EXPLANANTORY STUDY OF PATIENT AND DIAGNOSTIC INTERVALS IN THE DIAGNOSTIC JOURNEY OF ORAL CANCER PATIENTS AT A TERTIARY CARE CENTRE IN NORTHERN KERALA (IEC/1388)" on 5th July, 2019.

The following documents were reviewed:

Original submission

1. *Covering Letter addressed to the Member Secretary, IEC, SCTIMST dated 18.03.2019 with checklist*
2. *TAC Approval Letter* 3. *List of modifications in the application* 4. *IEC Application Form*
5. *Project Proposal* 6. *Forwarding letter from the HOD dated 18.03.2019* 7. *Proforma*
8. *CV of Principal Investigator and Co-Principal Investigator*

Revised submission

1. *Covering Letter addressed to the Member Secretary, IEC, SCTIMST dated 28.06.2019 with checklist*
2. *TAC Approval Letter* 3.*TAC Review comments* 4. *IEC Application Form* 5.*Project Proposal*
6. *Forwarding letter from PhD Guide dated 28.06.2019*
7. *Ethics Committee Approval Letter from Malabar Cancer Centre dated 27.05.2019*
8. *Participant Information Sheet and Consent Form for Cross sectional study and Participant Information Sheet and Consent Form for In Depth Interview in English and Malayalam*
9. *Copy of IEC Recommendation Letter dated 25.06.2019* 10. *CV of Principal Investigator and Co-Principal Investigator*

The IEC Review Criteria

The study fulfils the expedited criteria from ethics review criteria vide section 9.1 of the Standard Operating Procedures (April 2017) of the SCTIMST-IEC.

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

Mala Ramanathan
Member Secretary, IEC

IEC Approval of Data Collection Tool

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)
Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

Institutional Ethics Committee
(IEC Regn No. ECR/189/Inst/KL/2013/RR-16)

SCT/IEC/ 1388/OCTOBER-2019

06.12.2019

Dr. Phinse M Philip,
Part time PhD Scholar, AMCHSS
SCTIMST, Thiruvananthapuram

Dear Dr. Phinse M Philip,

The Institutional Ethics Committee reviewed your application to conduct the study entitled "A SEQUENTIAL EXPLANANTORY STUDY OF PATIENT AND DIAGNOSTIC INTERVALS IN THE DIAGNOSTIC JOURNEY OF ORAL CANCER PATIENTS AT A TERTIARY CARE CENTRE IN NORTHERN KERALA (IEC/1388)" on 6th December, 2019.

The following documents were reviewed:

Original submission

1. *Covering letter addressed to the Chairman, IEC, SCTIMST dated 11.10.2019*
2. *Data collection tool 1: Questionnaire on Factors Contributing to Patient Interval in Oral Cancer in English and Malayalam*
3. *Data collection tool 2: Interview Schedule on Patient and diagnostic interval duration – Oral Cancer Patient and diagnostic Interval Measure (OC-PDIM) in English and Malayalam*
4. *TAC Approval Letter dated 26.05.2019 and 16.10.2019* 5. *Forwarding Letter from the PhD Guide*
6. *TAC Review comments* 7. *Copy of IEC Approval Letter dated 05.07.2019* 8. *Project Proposal*

Revised submission

1. *Covering letter addressed to the Chairman, IEC, SCTIMST dated 29.11.2019*
2. *Copy of IEC Recommendation Letter dated 22.11.2019* 3. *Forwarding Letter from the PhD Guide*
4. *Copy of IEC Approval Letter dated 05.07.2019*
5. *Data collection tool 1: Questionnaire on Factors Contributing to Patient Interval in Oral Cancer in English and Malayalam*
6. *Data collection tool 2: Interview Schedule on Patient and diagnostic interval duration – Oral Cancer Patient and diagnostic Interval Measure (OC-PDIM) in English and Malayalam*

The IEC Review Criteria

The study fulfils the expedited criteria from ethics review criteria vide section 9.1 of the Standard Operating Procedures (April 2017) of the SCTIMST-IEC.

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

Mala Ramanathan
Member Secretary, IEC

IEC Approval of Checklist of Questions for In-depth Interview

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
THIRUVANANTHAPURAM—695 011, INDIA.
(An Institute of National Importance under Govt.of India)
Phone—(91)0471—2443152 Fax—(91)0471—2446433, 2550728, Grams—Chitramet
email : sct@sctimst.ac.in Web site—www.sctimst.ac.in

Institutional Ethics Committee

(IEC Regn No. ECR/189/Inst/KL/2013/RR-16)

SCT/IEC/ 1388/SEPTEMBER-2020 14.09.2020

Dr. Phinse M Philip
PhD Scholar, AMCHSS
SCTIMST, Thiruvananthapuram

Dear Dr. Phinse M Philip,

The Institutional Ethics Committee reviewed your application to conduct the study entitled "A SEQUENTIAL EXPLANATORY STUDY OF PATIENT AND DIAGNOSTIC INTERVALS IN THE DIAGNOSTIC JOURNEY OF ORAL CANCER PATIENTS AT A TERTIARY CARE CENTRE IN NORTHERN KERALA (IEC/1388)" on 14th September, 2020.

The following documents were reviewed:

Original submission

1. *Covering letter addressed to Chairman IEC, dated 16/07/2020*
2. *Checklist of questions for in-depth interviews for patients, health care providers, community leaders and health system administrators in English and Malayalam*
3. *TAC-Public Health approval for the tools* 4. *IEC approval dated 05/07/2019* 5. *Participant information sheet in English*
6. *Consent form in English* 7. *Participant information sheet in Malayalam* 8. *Consent form in Malayalam*

Revised submission

1. *Covering letter addressed to Chairperson, IEC, dated 11/09/2020*
2. *Copy of IEC Recommendation Letter dated 05.09.2020*
3. *Revised Checklist of questions for in-depth interviews for patients in English*
4. *Revised Checklist of questions for in-depth interviews for health care providers in English*
5. *Revised Checklist of questions for in-depth interviews for community leaders in English*
6. *Revised Checklist of questions for in-depth interviews for health system administrators in English*
7. *Revised Checklist of questions for in-depth interviews for patients in Malayalam*
8. *Revised Checklist of questions for in-depth interviews for community leaders in Malayalam*
9. *TAC-Public Health approval for the tools* 10. *Revised Participant information sheet in English*
11. *Revised Consent form in Malayalam* 12. *Revised Participant information sheet in Malayalam*
13. *Revised Consent form in English*

The IEC Review Criteria

The study fulfils the expedited criteria from ethics review criteria vide section 9.1 of the Standard Operating Procedures (April 2017) of the SCTIMST-IEC.

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

Mala Ramanathan
Member Secretary, IEC

Checklist of questions for in-depth interviews

A.1.1. Checklist for in-depth interviews among health care providers

1. How often you come across patients with oral cancer/oral pre-cancer in your routine practice.
2. Did you ever have any training related to oral cancer? Where did you learn about it?
3. Do you routinely conduct an oral cavity examination as part of a general examination? Do you screen patients for oral cancer?
4. Which all symptoms will raise the suspicion of oral cancer in a patient?
5. What is the referral pathway for oral cancer? How do you manage oral cancer cases?
6. How will you manage common oral premalignant lesions?
7. What are the challenges for implementing oral cancer screening in routine practice?

A.1.2. Checklist for in-depth interviews among health system administrators

1. What all initiatives/programs exist under the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) and National Oral Health Program for oral cancer prevention?
2. Is there any specific plan/policy for oral cancer control in the state?
3. Do we have a strategy for early diagnosis of oral cancer in the state?
4. What are the challenges for early oral cancer diagnosis?
5. Is there a referral pathway exist for oral cancer diagnosis and management?

A.1.3. Checklist for in-depth interviews among Community leaders

1. How common is cancer in your locality?
2. What all supports are provided to cancer patients by panchayath and NGOs
3. Do you have Facilities for cancer diagnosis and treatment in your area?
4. In your opinion, what all facilities/programs are needed in your area for cancer control?
5. Why do people fear cancer?
6. In your opinion, what are the causes of cancer/oral cancer?
7. Do you have any ideas about oral precancerous lesions?

Malayalam translation

1. നിങ്ങളുടെ പ്രദേശത്തു അർബുദരോഗത്തിന്റെ തോത് എങ്ങനെയാണ്?
2. അർബുദരോഗികൾക്ക്എന്തെല്ലാംതരത്തിലുള്ളപിന്തുണയാണ്പഞ്ചായത്തും മറ്റുസർക്കാർഇതരസംഘടനകളും നൽകുന്നത്?

3. നിങ്ങളുടെ പ്രദേശത്തു അർബുദരോഗനിർണയത്തിനും ചികിത്സയ്ക്കും വേണ്ട സൗകര്യങ്ങൾ ഉണ്ടോ?
4. നിങ്ങളുടെ അഭിപ്രായത്തിൽ അർബുദരോഗനിയന്ത്രണത്തിന് ഏതൊക്കെതരത്തിലുള്ള പദ്ധതികൾ/സംവിധാനങ്ങൾ നിങ്ങളുടെനാട്ടിൽ ഉണ്ടാവേണ്ടതുണ്ട്?
5. എന്തുകൊണ്ടാണ്ആളുകൾ അർബുദരോഗത്തെ ഭയപ്പെടുന്നത്?
6. നിങ്ങളുടെ അഭിപ്രായത്തിൽ അർബുദത്തിന്റെ /വായിലെ അർബുദത്തിന്റെ കാരണങ്ങൾ എന്തൊക്കെയാണ്?
7. വായിലെ അർബുദത്തിനു മുന്നോടിയായികാണപ്പെടുന്ന മാറ്റങ്ങളെക്കുറിച്ചു നിങ്ങൾക്കെന്തറിയാം?

A.1.4. Checklist for Patients

1. How did you respond to the abnormal changes in your oral cavity when you identified them for the first time?
2. According to you, what are the abnormal changes in the oral cavity that require the attention of a health care provider?
3. What was the response from your family /neighbors/ friends after knowing that you have cancer?
4. What was your experience of consulting with a health care provider for the abnormal change in your oral cavity?
5. What are the challenges that you encountered while seeking health care for the present problem in your oral cavity?
6. What went well for you while seeking health care for the present problem in your oral cavity?
7. Is there anything else that you would like to add?

Malayalam translation

1. നിങ്ങളുടെ വായിൽ അസ്വാഭാവികമായ മാറ്റങ്ങൾകണ്ടപ്പോൾ അതിനോട്നിങ്ങൾ ആദ്യം എങ്ങനെയാണ്പ്രതികരിച്ചത്?
2. നിങ്ങളുടെ അറിവിൽ വായിലെ ഏതുതരത്തിലുള്ള മാറ്റങ്ങളാണ് ഒരു ഡോക്ടറുടെ ശ്രദ്ധയിൽ കൊണ്ടുവരേണ്ടത്?
3. നിങ്ങൾക്ക്അർബുദമാണെന്ന വാർത്തയോട്നിങ്ങളുടെ വീട്ടുകാർ,അയൽക്കാർ,സുഹൃത്തുക്കൾ എങ്ങനെയാണ്പ്രതികരിച്ചത്?
4. നിങ്ങളുടെ വായിലെ അസ്വാഭാവികമായ മാറ്റങ്ങൾ കാണിക്കുന്നതിനായി നിങ്ങൾ ഒരു ഡോക്ടറിനെ സമീപിച്ചപ്പോഴുള്ള അനുഭവം എന്താണ്?
5. വൈദ്യസഹായം ലഭ്യമാക്കുന്നതിനായി എന്തെല്ലാം തടസ്സങ്ങൾ/വെല്ലുവിളികൾ നിങ്ങൾ നേരിട്ടു?
6. ഏതൊക്കെ കാര്യങ്ങൾ വൈദ്യസഹായം ലഭ്യമാക്കുന്നതിന്സഹായകരമായി?
7. നിങ്ങൾക്കൂട്ടെന്തെങ്കിലും കൂടുതലായി പറയാനുണ്ടോ?

Checklist for reviewing documents related to oral cancer control

1. Key institutions/organizations/departments involved in cancer control /oral cancer control
2. What are the functions/ responsibilities of different actors involved in the cancer control/oral cancer control
3. Existence of referral guidelines/diagnostic protocols
4. Discussion on Early diagnosis
5. Key persons/functionaries involved in the oral cancer control and their roles
6. Stated goals and objectives with regard to oral cancer control
7. Proposed measures /strategies for oral cancer control
8. Resources allocated –infrastructure and man power-for cancer control
9. Context of discussion on oral cancer
10. Administrative /technical content
11. Extent of participation

Participant Information Sheet in English (Cross-sectional Study)

Participant information sheet

(Cross sectional study)

A sequential explanatory study of patient and diagnostic intervals in the diagnostic journey of oral cancer patients at a tertiary care centre in northern Kerala

Study number: _____

You are being requested to participate in a research study conducted by Dr Phinse M Philip, a research scholar of Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for medical science and Technology, Trivandrum, India as part of his PhD dissertation. This study is planned to measure the period from detection or awareness of a bodily change to meeting a health care professional to discuss about the same. It also measures the period from meeting a health care provider to arriving at a definite diagnosis. Study investigates the various factors contributing to the length of these periods. Before agreeing to participate in this research study, it is important that you read the following explanation of the study that describes the purpose, benefits, risks, and rights as a study subject.

Title of the Study: A sequential explanatory study of patient and diagnostic intervals in the diagnostic journey of oral cancer patients at a tertiary care centre in northern Kerala

Principal investigator and affiliation: Dr Phinse M Philip, PhD Scholar, AMCHSS, SCTIMST and Lecturer, Malabar Cancer Centre, Thalassery

Background of this study: Oral cancer is the second most common cancer in India. The disease is generally diagnosed at advanced stages despite of favorable factors like easy access of the site for examination, known precancerous stages and risk factors. One of the reasons for late stage diagnosis is the increased time for reporting and diagnosing the disease. Estimating these periods and identifying the contributing factors will help in planning interventions to reduce these periods.

Details of enrolment: You are asked to participate in the study because you are a newly diagnosed oral cancer patient with no prior history of treatment for oral cancer. We are considering you as a person with no other physical or mental condition, which prevents your complete participation in the study. If you chose to participate in the study, the principal investigator will interview you. You will be asked about various time points in your oral cancer diagnostic journey. There will be questions on various factors affecting these intervals.The interview will take 20 -30 minutes. We are planning to include 225 people in the study.

Possible reasonably foreseeable risks or discomforts: No risks to you are expected due to participating in the study. The interview has no side effects. The only discomfort may be the uneasiness in reflecting the health behaviors, socio demographic factors and interpersonal factors.

Benefits of participating in the study: There are no direct benefits to the subject. The information provided by the patient will benefit the society as the results will guide policy makers in formulating policies to shorten these intervals.

Can you withdraw from this study after it starts?: Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way. The investigator may withdraw you from the study at any time, without your agreement.

Anonymity: The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, people associated with the study, without your additional permission, should you decide to participate in this study, may review your medical notes. No one outside the research team will have access to your data. The information collected from you will be stored with a code number instead of your name. Information collected by this interview will be detached from the consent forms.

Questions /parties to contact:

If you have any further questions, please ask Dr.Phinse M Philip, Principal Investigator, Ph:9496048817 , (email id is phinse1984@gmail.com), Dr.Mala Ramanathan, Member secretary, Institute Ethics Committee ,Ph.: 0471 2520256/257 (email id isiec.mem.sec@sctimst.ac.in) at any time. If you decide to take part in this research study, you must sign this form to show that you want to take part. You can keep a copy of the form for further reference.

Participant Information Sheet in Malayalam (Cross-sectional Study)

പഠനപങ്കാളികൾക്കുള്ള പഠന വിവര കുറിപ്പ്

(Cross sectional study)

ഉത്തര കേരളത്തിലെ ഒരു വിദഗ്ദ്ധ അർബുദ ചികിത്സാ കേന്ദ്രത്തിൽ ചികിത്സയ്ക്കായെത്തുന്ന വദനാർബുദ രോഗികളിൽ രോഗലക്ഷണങ്ങൾ തിരിച്ചറിഞ്ഞു വൈദ്യസഹായം തേടുന്നതിനും രോഗനിർണയം നടത്തുന്നതിനും എടുക്കുന്ന സമയദൈർഘ്യം മനസ്സിലാക്കുന്നതിനും സമയദൈർഘ്യത്തിലെ ഏറ്റക്കുറച്ചിലുകൾക്കു കാരണമാകുന്ന ഘടകങ്ങൾ തിരിച്ചറിയുന്നതിനുമായുള്ള പഠനം

പഠന നമ്പർ:_____

ശ്രീ ചിത്ര തിരുന്നാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആൻഡ് ടെക്നോളജിയിലെ അച്യുത മേനോൻ സെന്റർ ഫോർ ഹെൽത്ത് സയന്സസിലെ ഗവേഷകവിദ്യാർത്ഥിയാണ് ഞാൻ. ഗവേഷണ പഠനത്തിന്റെ ഭാഗമായി വദനാർബുദ രോഗികളിൽ ഒരു പഠനം നടത്തുകയാണ്.വദനാർബുദ രോഗികളിൽ രോഗലക്ഷണങ്ങൾ തിരിച്ചറിഞ്ഞു വൈദ്യസഹായം തേടുന്നതിനും രോഗനിർണയം നടത്തുന്നതിനും എടുക്കുന്ന സമയദൈർഘ്യം മനസ്സിലാക്കുന്നതിനും സമയദൈർഘ്യത്തിലെ ഏറ്റക്കുറച്ചിലുകൾക്കു കാരണമാകുന്ന ഘടകങ്ങൾ തിരിച്ചറിയുന്നതിനുമായുള്ള പഠനം ആണ് ഇത്. ഈ പഠനത്തിലേയ്ക്കു താങ്കളെ ക്ഷണിക്കുന്നു.പഠനത്തിൽ പങ്കെടുക്കുവാൻ സമ്മതം നൽകുന്നതിന് മുൻപ് താങ്കൾ പഠനലക്ഷ്യങ്ങളും ഉദ്ദേശങ്ങളും അറിഞ്ഞിരിക്കേണ്ടതാണ്.

ഗവേഷണവിഷയം:ഉത്തര കേരളത്തിലെ ഒരു ത്രിതീയ അർബുദ ചികിത്സാ കേന്ദ്രത്തിൽ ചികിത്സയ്ക്കായെത്തുന്ന വദനാർബുദ രോഗികളിൽ രോഗലക്ഷണങ്ങൾ തിരിച്ചറിഞ്ഞു വൈദ്യസഹായം തേടുന്നതിനും രോഗനിർണയം നടത്തുന്നതിനും എടുക്കുന്ന സമയദൈർഘ്യം മനസ്സിലാക്കുന്നതിനും സമയദൈർഘ്യത്തിലെ ഏറ്റക്കുറച്ചിലുകൾക്കു കാരണമാകുന്ന ഘടകങ്ങൾ തിരിച്ചറിയുന്നതിനുമായുള്ള പഠനം

ഗവേഷകൻ : ഡോ :ഫിൻസ് എം ഫിലിപ്പ്, ഗവേഷക വിദ്യാർത്ഥി, അച്യുതമേനോൻ സെന്റർ ഫോർ ഹെൽത്ത് സയൻസസ്, ശ്രീ ചിത്ര തിരുന്നാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ്, തിരുവനന്തപുരം, ലക്ചറർ,മലബാർ കാൻസർ സെന്റർ ,തലശ്ശേരി.

പഠനപശ്ചാത്തലം : ഇന്ത്യയിൽ ഏറ്റവും അധികം കണ്ടുവരുന്ന അർബുദങ്ങളിൽ രണ്ടാം സ്ഥാനമാണ് വദനാർബുദത്തിനുള്ളത്. രോഗം നേരത്തെ കണ്ടുപിടിക്കാനുള്ള നിരവധി അനുകൂല ഘടകങ്ങൾ ഉണ്ടെങ്കിലും ഭൂരിപക്ഷം രോഗികളും രോഗം മൂർച്ചിച്ച അവസ്ഥയിലാണ് ചികിത്സയ്ക്കായി എത്താറുള്ളത്. ഇതിനുള്ള ഒരു പ്രധാന കാരണം രോഗത്തിന്റെ പ്രാഥമിക ലക്ഷണങ്ങൾ തിരിച്ചറിയാൻ സാധിക്കാത്തതോ , സമയത്തു വൈദ്യസഹായം തേടാത്തതോ രോഗനിർണയത്തിനുള്ള കാലതാമസമോ ആണ്.

ഈ പഠനത്തിന്റെ ആവശ്യകത :വദനാർബുദ രോഗികളിൽ രോഗസൂചനയിൽ തുടങ്ങി രോഗനിർണയം വരെയുള്ള കാലയളവിനെ രേഖപ്പെടുത്തുന്നതും അതിന്റെ കാരണങ്ങൾ അന്വേഷിക്കുന്നതുമായ പഠനങ്ങൾ കുറവാണ്.രോഗലക്ഷണം തിരിച്ചറിഞ്ഞു വൈദ്യ സഹായം തേടാൻ എടുക്കുന്ന സമയം, വൈദ്യസഹായം തേടിയതിനു ശേഷം രോഗനിർണയത്തിനെടുക്കുന്ന സമയം എന്നിവമനസ്സിലാക്കുന്നതും അതിലേയ്ക്ക് നയിക്കുന്ന ഘടകങ്ങൾ തിരിച്ചറിയുന്നതും ഈ സമയദൈർഘ്യം കുറയ്ക്കുന്നതിനുള്ള ഇടപെടലുകൾ നടത്താൻ സഹായിക്കും.

പഠന പങ്കാളിത്തം : നിങ്ങൾ വദനാർബുദത്തിനു ചികിത്സ തേടുന്ന ഒരു വ്യക്തിയായതിനാൽ ഈ പഠനത്തിലേയ്ക്ക് ക്ഷണിക്കുന്നു. നിങ്ങൾക്ക് മുൻപ് ഈ രോഗം വരുകയോ ചികിത്സ തേടുകയോചെയ്തിട്ടുള്ളതല്ല എന്ന് മനസിലാക്കുന്നു. നിങ്ങൾ ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ സാധിക്കാത്ത മറ്റു ശാരീരിക ,മാനസിക പ്രശ്നങ്ങൾ ഉള്ള ഒരു വ്യക്തിയല്ല. നിങ്ങൾ ഈ പഠനത്തിൽ പങ്കെടുക്കുകയാണെങ്കിൽ മുഖ്യ ഗവേഷകൻ നിങ്ങളോടു വദനാർബുദ നിർണയം വരെയുള്ള കാലഘട്ടവുമായി ബന്ധപ്പെട്ട ചില ചോദ്യങ്ങൾചോദിക്കുന്നതാണ്.ഏകദേശം ഇരുപതു മുതൽ മുപ്പതു മിനിറ്റ് വരെ സമയം ഇതിനായി ചിലവഴിക്കേണ്ടിവരും. ഈ പഠനത്തിൽ 300 ആളുകൾപങ്കെടുക്കുന്നതാണ്.

മുൻകൂട്ടി കണ്ടുപിടിക്കാൻ സാധ്യമായ അപകടങ്ങളും ബുദ്ധിമുട്ടുകളും: യാതൊരുവിധ അപകടങ്ങളും ഈ പഠനത്തിന്റെ ഭാഗമായി സംഭവിക്കുന്നതല്ല. ആരോഗ്യ ,സാമൂഹിക,സാമ്പത്തിക,വൈകാരിക ഘടകങ്ങളെക്കുറിച്ചുള്ള ചോദ്യങ്ങൾ ചോദിക്കുമ്പോൾ അല്പം അസ്വസ്ഥത അനുഭവപ്പെട്ടേക്കാം.

പഠനത്തിൽ പങ്കെടുക്കുന്നത് കൊണ്ടുള്ള പ്രയോജനങ്ങൾ :ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നത് കൊണ്ട് യാതൊരുവിധ സാമ്പത്തിക ആനുകൂല്യങ്ങളും ലഭിക്കുന്നതല്ല. താങ്കൾ തരുന്ന വിവരങ്ങൾ ഭാവിയിൽ വദനാർബുദ നിയന്ത്രണ പ്രവർത്തനങ്ങൾ രൂപം കൊടുക്കുന്നതിനു സഹായിക്കും

സ്വമേധയാ ഉള്ള പങ്കാളിത്തം:ഈ പഠനത്തിലുള്ള താങ്കളുടെപങ്കാളിത്തം തീർച്ചയായും സ്വന്തം ഇഷ്ടപ്രകാരമാണ് .ഇതിൽ പങ്കെടുക്കാനും പങ്കെടുക്കാതിരിക്കാനുമുള്ള സ്വാതന്ത്ര്യം താങ്കൾക്കുണ്ട്. മുൻകൂട്ടി കാരണങ്ങൾ ബോധിപ്പിക്കാതെ തന്നെ താങ്കൾക്ക് ഏതു നിമിഷവുംഈ പഠനത്തിൽ നിന്ന് പിൻമാറാവുന്നതാണ്. താങ്കൾ പഠനത്തിൽ പങ്കെടുക്കാതിരിക്കുന്നതോ പിന്മാറുന്നതോ താങ്കളുടെ ചികിത്സയെയാതൊരു കാരണവശാലും ബാധിക്കുന്നതല്ല.

പഠനവിവരങ്ങളുടെ രഹസ്യ സ്വഭാവം :പഠനഫലം ആരോഗ്യശാസ്ത്ര പ്രസിദ്ധീകരണങ്ങളിൽ പ്രസിദ്ധീകരിക്കുന്നതാണ്. നിങ്ങളെതിരിച്ചറിയുന്ന യാതൊരു സൂചനകളും ഇത്തരംപ്രസിദ്ധീകരണങ്ങളിലൂടെയോ മറ്റു രീതികളിലൂടെയോ പുറത്തുവിടുന്നതല്ല. ഗവേഷകസംഘത്തിനല്ലാതെ മറ്റാർക്കും ഈ വിവരങ്ങൾ അറിയാൻ സാധിക്കില്ല. താങ്കളിൽ നിന്ന് ശേഖരിക്കുന്ന വിവരങ്ങൾ പേരില്ലാതെ സൂക്ഷിക്കുന്നതാണ്. ഒരു കോഡ് നമ്പറിന്റെസഹായത്തോടെ മാത്രമേ ഈ വിവരങ്ങൾ തിരിച്ചറിയാൻസാധിക്കുക.

കൂടുതൽ വിവരങ്ങൾക്ക്

ഈ പഠനവുമായി ബന്ധപ്പെട്ട കൂടുതൽ വിവരങ്ങൾക്ക് നിങ്ങൾക്ക് ഡോ :ഫിൻസ് എം ഫിലിപ്പ്നെയോ (Ph:9496048817, email id is phinse1984@gmail.com) എത്തിക്സ് കമ്മിറ്റി സെക്രട്ടറി ഡോ :മാല രാമനാഥനെയോ (Ph.: 0471 2520256/257 ,email id is iec.mem.sec@sctimst.ac.in) ബന്ധപ്പെടാവുന്നതാണ്. നിങ്ങൾ ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ ആഗ്രഹിക്കുകയാണെങ്കിൽ ഇതിൽ നിങ്ങളുടെ ഒപ്പ് ഇടേണ്ടതാണ്. ഈ രേഖയുടെ ഒരു കോപ്പി നിങ്ങളുടെ അറിവിലേക്കായി നൽകുന്നതാണ്

Consent Form in English (Cross-sectional Study)

Consent form

(Cross sectional study)

I have been given a chance to read and understand the consent form thoroughly. I understand that I can contact Dr Phinse M Philip at any point of time to ask questions regarding my participation in this research study and that I will be answered to my satisfaction.

I understand that my participation in this study is voluntary and I can quit at any time without any problem. I also understand that the investigator can decide at any point that I should no longer participate in the study.

If I have any questions about my rights as a subject in the study, I may contact Dr Phinse M Philip, PhD Scholar, AMCHSS, SCTIMST, Trivandrum, Ph.: 9496048817.

I have read and understood the above information. I agree to participate in this study. I understand that I will be given a copy of this signed and dated form for my own records. I have initialed the boxes below to indicate my consent to complete the questionnaire.

Are you willing to participate? Yes ☐ No ☐

Study Participant (Signature)_____Date_____

Name _____

Signature of Person obtaining consent: _____

Name: _____Date:_____

Consent Form in Malayalam (Cross-sectional Study)

സമ്മതപത്രം

(Cross sectional study)

ഈ ഗവേഷണ പഠനത്തെക്കുറിച്ചു എനിക്ക് ചോദ്യങ്ങൾ ചോദിക്കാൻ അവസരം ലഭിച്ചിട്ടുണ്ട്.എന്റെ ചോദ്യങ്ങൾക്കു തൃപ്തികരമായ മറുപടി ലഭിച്ചിട്ടുണ്ട്. ഇതിൽ പങ്കെടുക്കുന്നതിനെക്കുറിച്ചു കൂടുതൽ അറിയാൻ ഡോ :ഫിൻസ് എം ഫിലിപ്പ് നെ സമീപിക്കാവുന്നതാണ്.

ഈ ഗവേഷണ പഠനത്തിലെ പങ്കാളിത്തം സ്വന്തം ഇഷ്ടപ്രകാരമാണെന്നു എനിക്ക് മനസ്സിലായി.എപ്പോൾ വേണമെങ്കിലും ഈ പഠനത്തിൽ നിന്ന് എനിക്ക് പിന്മാറാവുന്നതാണ് എന്നും എന്നെ ഈ പഠനത്തിൽ നിന്നും ഗവേഷകന് എപ്പോൾ വേണമെങ്കിലും ഒഴിവാക്കാവുന്നതാണെന്നും എനിക്ക് മനസ്സിലായി.

ഈ പഠനത്തിൽ പങ്കെടുക്കുന്ന ആളെന്നനിലയിൽ എന്റെ അവകാശങ്ങളെക്കുറിച്ചു എന്തെങ്കിലും സംശയങ്ങളുണ്ടെങ്കിൽ എനിക്ക് ഡോ :ഫിൻസ് എം ഫിലിപ്പ് നെ ബന്ധപ്പെടാവുന്നതാണ്.

ഈ സമ്മതപത്രം ഒപ്പു വയ്ക്കുന്നതിലൂടെ എന്റെ നിയമപരമായ അവകാശങ്ങൾ ഒന്നും തന്നെ ഞാൻ വേണ്ടെന്നു വെയ്ക്കുന്നില്ല.

ഞാൻ മുകളിൽ പറഞ്ഞ വിവരങ്ങൾ വായിക്കുകയും മനസ്സിലാക്കുകയും ചെയ്തു. ഈ പഠനത്തിൽ പങ്കെടുക്കുവാൻ എനിക്കു സമ്മതമാണ്. ഈ സമ്മത പത്രത്തിന്റെ ഒരു പകർപ്പ് എന്റെ ആവശ്യത്തിനായി തരുമെന്നും എനിക്ക് മനസ്സിലായി. എന്റെ സമ്മതം വ്യക്തമാക്കാനായി അടയാളപ്പെടുത്തിയ ഭാഗത്തു എന്റെ ഒപ്പ് ഇട്ടു നൽകുന്നു.

ഈ പഠനത്തിൽ പങ്കെടുക്കുവാൻ എനിക്കു സമ്മതമാണ്.

പങ്കെടുക്കുന്ന വ്യക്തിയുടെഒപ്പ്_____തിയതി_____

പങ്കെടുക്കുന്ന വ്യക്തിയുടെ പേര്_____

സമ്മതപത്രം ഒപ്പിട്ടു വാങ്ങിയ വ്യക്തിയുടെ ഒപ്പ്_____

തിയതി_____സമ്മതപത്രം ഒപ്പിട്ടു വാങ്ങിയ വ്യക്തിയുടെ പേര്_____

Participant Information Sheet in English (In-depth Interview)

Participant information sheet

(In Depth Interview)

A sequential explanatory study of patient and diagnostic intervals in the diagnostic journey of oral cancer patients at a tertiary care centre in northern Kerala

Study number: _____

You are being requested to participate in a research study conducted by Dr Phinse M Philip, a research scholar of Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for medical science and Technology, Trivandrum, India as part of his PhD dissertation. This study is planned to measure the period from detection or awareness of a bodily change to meeting a health care professional to discuss about the same. It also measures the period from meeting a health care provider to arriving at a definite diagnosis. Study investigates the various factors contributing to the length of these periods. The study also explores the structure and functions of oral cancer control in the state. Before agreeing to participate in this research study, it is important that you read the following explanation of the study that describes the purpose, benefits, risks, and rights as a study subject.

Title of the Study: A sequential explanatory study of patient and diagnostic intervals in the diagnostic journey of oral cancer patients at a tertiary care centre in northern Kerala

Principal investigator and affiliation: Dr Phinse M Philip, PhD Scholar, AMCHSS, SCTIMST and Lecturer, Malabar Cancer Centre, Thalassery

Background of this study: Oral cancer is the second most common cancer in India. The disease is generally diagnosed at advanced stages despite of favorable factors like easy access of the site for examination, known precancerous stages and risk factors. One of the reasons for late stage diagnosis is the increased time for reporting and diagnosing the disease. Estimating these periods and identifying the contributing factors will help in planning interventions to reduce these periods.

Details of enrolment: You are asked to participate in the study because you are a person capable of providing relevant information regarding various factors affecting patient delay. We are considering you as a person with no other physical or mental condition, which prevents your complete participation in the study. If you chose to participate in the study, the principal investigator will interview you. You will be asked about various functions of oral cancer control activities in the state. The interview will take 20 -30 minutes. We are planning to include 30 people in the study.

Possible reasonably foreseeable risks or discomforts: No risks to you are expected due to participating in the study. The interview has no side effects. The only discomfort may be spending your valuable time for the interview.

Benefits of participating in the study: There are no direct benefits to the subject. The information provided by the patient will benefit the society as the results will guide policy makers in formulating policies to shorten these intervals.

Can you withdraw from this study after it starts?: Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way. The investigator may withdraw you from the study at any time, without your agreement.

Anonymity: The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, people associated with the study, without your additional permission, should you decide to participate in this study, may review your medical notes. No one outside the research team will have access to your data. The information collected from you will be stored with a code number instead of your name. Information collected by this interview will be detached from the consent forms.

Questions /parties to contact:

If you have any further questions, please ask Dr.Phinse M Philip, Principal Investigator, Ph:9496048817 , (email id is phinse1984@gmail.com), Dr.MalaRamanathan, Member secretary, Institute Ethics Committee ,Ph.: 0471 2520256/257 (email id is iec.mem.sec@sctimst.ac.in) at any time. If you decide to take part in this research study, you must sign this form to show that you want to take part. You can keep a copy of the form for further reference.

Participant Information Sheet in Malayalam (In-depth Interview)

പഠനപങ്കാളികൾക്കുള്ള പഠനവിവരകുറിപ്പ്

(In Depth Interview)

ഉത്തര കേരളത്തിലെ ഒരു വിദഗ്ദ്ധ അർബുദ ചികിത്സാ കേന്ദ്രത്തിൽ ചികിത്സയ്ക്കായെത്തുന്ന വദനാർബുദ രോഗികളിൽ രോഗലക്ഷണങ്ങൾ തിരിച്ചറിഞ്ഞു വൈദ്യസഹായം തേടുന്നതിനും രോഗനിർണയം നടത്തുന്നതിനും എടുക്കുന്ന സമയദൈർഘ്യം മനസ്സിലാക്കുന്നതിനും സമയദൈർഘ്യത്തിലെ ഏറ്റക്കുറച്ചിലുകൾക്കു കാരണമാകുന്ന ഘടകങ്ങൾ തിരിച്ചറിയുന്നതിനുമായുള്ള പഠനം

പഠന നമ്പർ:_____

ശ്രീ ചിത്ര തിരുന്നാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആൻഡ് ടെക്നോളജിയിലെ അച്യുത മേനോൻ സെന്റർ ഫോർ ഹെൽത്ത് സയന്സസിലെ ഗവേഷകവിദ്യാർത്ഥിയാണ് ഞാൻ. ഗവേഷണ പഠനത്തിന്റെ ഭാഗമായി വദനാർബുദ രോഗികളിൽ ഒരു പഠനം നടത്തുകയാണ്.വദനാർബുദ രോഗികളിൽ രോഗലക്ഷണങ്ങൾ തിരിച്ചറിഞ്ഞു വൈദ്യസഹായം തേടുന്നതിനും രോഗനിർണയം നടത്തുന്നതിനും എടുക്കുന്ന സമയദൈർഘ്യം മനസ്സിലാക്കുന്നതിനും സമയദൈർഘ്യത്തിലെ ഏറ്റക്കുറച്ചിലുകൾക്കു കാരണമാകുന്ന ഘടകങ്ങൾ തിരിച്ചറിയുന്നതിനുമായുള്ള പഠനം ആണ് ഇത്. ഈ പഠനത്തിലേയ്ക്കു താങ്കളെ ക്ഷണിക്കുന്നു.പഠനത്തിൽ പങ്കെടുക്കുവാൻ സമ്മതം നൽകുന്നതിന് മുൻപ് താങ്കൾ പഠനലക്ഷ്യങ്ങളും ഉദ്ദേശങ്ങളും അറിഞ്ഞിരിക്കേണ്ടതാണ്.

ഗവേഷണവിഷയം:ഉത്തര കേരളത്തിലെ ഒരു ത്രിതീയ അർബുദ ചികിത്സാ കേന്ദ്രത്തിൽ ചികിത്സയ്ക്കായെത്തുന്ന വദനാർബുദ രോഗികളിൽ രോഗലക്ഷണങ്ങൾ തിരിച്ചറിഞ്ഞു വൈദ്യസഹായം തേടുന്നതിനും രോഗനിർണയം നടത്തുന്നതിനും എടുക്കുന്ന സമയദൈർഘ്യം മനസ്സിലാക്കുന്നതിനും സമയദൈർഘ്യത്തിലെ ഏറ്റക്കുറച്ചിലുകൾക്കു കാരണമാകുന്ന ഘടകങ്ങൾ തിരിച്ചറിയുന്നതിനുമായുള്ള പഠനം

ഗവേഷകൻ : ഡോ :ഫിൻസ് എം ഫിലിപ്പ്, ഗവേഷക വിദ്യാർത്ഥി, അച്യുതമേനോൻ സെന്റർ ഫോർ ഹെൽത്ത് സയൻസസ്, ശ്രീ ചിത്ര തിരുന്നാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ്, തിരുവനന്തപുരം, ലക്ചറർ,മലബാർ കാൻസർ സെന്റർ ,തലശ്ശേരി.

പഠനപശ്ചാത്തലം : ഇന്ത്യയിൽ ഏറ്റവും അധികം കണ്ടുവരുന്ന അർബുദങ്ങളിൽ രണ്ടാം സ്ഥാനമാണ് വദനാർബുദത്തിനുള്ളത്. രോഗം നേരത്തെ കണ്ടുപിടിക്കാനുള്ള നിരവധി അനുകൂല ഘടകങ്ങൾ ഉണ്ടെങ്കിലും ഭൂരിപക്ഷം രോഗികളും രോഗം മൂർച്ഛിച്ച അവസ്ഥയിലാണ് ചികിത്സയ്ക്കായി എത്താറുള്ളത്. ഇതിനുള്ള ഒരു പ്രധാന കാരണം രോഗത്തിന്റെ പ്രാഥമിക ലക്ഷണങ്ങൾ തിരിച്ചറിയാൻ സാധിക്കാത്തതോ , സമയത്തു വൈദ്യസഹായം തേടാത്തതോ രോഗനിർണയത്തിനുള്ള കാലതാമസമോ ആണ്.

ഈ പഠനത്തിന്റെ ആവശ്യകത :വദനാർബുദ രോഗികളിൽ രോഗസൂചനയിൽ തുടങ്ങി രോഗനിർണയം വരെയുള്ള കാലയളവിനെ രേഖപ്പെടുത്തുന്നതും അതിന്റെ കാരണങ്ങൾ അന്വേഷിക്കുന്നതുമായ പഠനങ്ങൾ കുറവാണ്.രോഗലക്ഷണം തിരിച്ചറിഞ്ഞു വൈദ്യ സഹായം തേടാൻ എടുക്കുന്ന സമയം, വൈദ്യസഹായം തേടിയതിനു ശേഷം രോഗനിർണയത്തിനെടുക്കുന്ന സമയം എന്നിവമനസ്സിലാക്കുന്നതും അതിലേയ്ക്ക് നയിക്കുന്ന ഘടകങ്ങൾ തിരിച്ചറിയുന്നതും ഈ സമയദൈർഘ്യം കുറയ്ക്കുന്നതിനുള്ള ഇടപെടലുകൾ നടത്താൻ സഹായിക്കും.

പഠന പങ്കാളിത്തം :. നിങ്ങൾ വദനാർബുദ നിർണയത്തിലെ കാലതാമസത്തിനു കാരണമായ ഘടകങ്ങൾ സംബന്ധിച്ചു പ്രസക്തമായ വിവരങ്ങൾ പങ്കുവെയ്ക്കാൻ സാധിക്കുന്ന വ്യക്തിയാണെന്നു മനസിലാക്കുന്നു. നിങ്ങൾ ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ സാധിക്കാത്ത മറ്റു ശാരീരിക ,മാനസിക പ്രശ്നങ്ങൾ ഉള്ള ഒരു വ്യക്തിയല്ല. നിങ്ങൾ ഈ പഠനത്തിൽ പങ്കെടുക്കുകയാണെങ്കിൽ മുഖ്യ ഗവേഷകൻ നിങ്ങളോടു വദനാർബുദ നിയന്ത്രണ പ്രവർത്തനങ്ങളുമായി ബന്ധപ്പെട്ട ചില ചോദ്യങ്ങൾ ചോദിക്കുന്നതാണ്.ഏകദേശം ഇരുപതു മുതൽ മുപ്പതു മിനിറ്റ് വരെ സമയം ഇതിനായി ചിലവഴിക്കേണ്ടിവരും. ഈ പഠനത്തിൽ 30 ആളുകൾ പങ്കെടുക്കുന്നതാണ്.

മുൻകൂട്ടി കണ്ടുപിടിക്കാൻ സാധ്യമായ അപകടങ്ങളും ബുദ്ധിമുട്ടുകളും: യാതൊരുവിധ അപകടങ്ങളും ഈ പഠനത്തിന്റെ ഭാഗമായി സംഭവിക്കുന്നതല്ല.

പഠനത്തിൽ പങ്കെടുക്കുന്നത് കൊണ്ടുള്ള പ്രയോജനങ്ങൾ :ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നത് കൊണ്ട് യാതൊരുവിധ സാമ്പത്തിക ആനുകൂല്യങ്ങളും ലഭിക്കുന്നതല്ല. താങ്കൾ തരുന്ന വിവരങ്ങൾ ഭാവിയിൽ വദനാർബുദ നിയന്ത്രണ പ്രവർത്തനങ്ങൾ രൂപം കൊടുക്കുന്നതിനു സഹായിക്കും

സ്വമേധയാ ഉള്ള പങ്കാളിത്തം:ഈ പഠനത്തിലുള്ള താങ്കളുടെപങ്കാളിത്തം തീർച്ചയായും സ്വന്തം ഇഷ്ടപ്രകാരമാണ് .ഇതിൽ പങ്കെടുക്കാനും പങ്കെടുക്കാതിരിക്കാനുമുള്ള സ്വാതന്ത്ര്യം താങ്കൾക്കുണ്ട്. മുൻകൂട്ടി കാരണങ്ങൾ ബോധിപ്പിക്കാതെ തന്നെ താങ്കൾക്ക് ഏതു നിമിഷവുംഈ പഠനത്തിൽ നിന്ന് പിൻമാറാവുന്നതാണ്. താങ്കൾ പഠനത്തിൽ പങ്കെടുക്കാതിരിക്കുന്നതോ പിന്മാറുന്നതോ താങ്കളുടെ ചികിത്സയെയാതൊരു കാരണവശാലും ബാധിക്കുന്നതല്ല.

പഠനവിവരങ്ങളുടെ രഹസ്യ സ്വഭാവം :പഠനഫലം ആരോഗ്യശാസ്ത്ര പ്രസിദ്ധീകരണങ്ങളിൽ പ്രസിദ്ധീകരിക്കുന്നതാണ്. നിങ്ങളെതിരിച്ചറിയുന്ന യാതൊരു സൂചനകളും ഇത്തരംപ്രസിദ്ധീകരണങ്ങളിലൂടെയോ മറ്റു രീതികളിലൂടെയോ പുറത്തുവിടുന്നതല്ല. ഗവേഷകസംഘത്തിനല്ലാതെ മറ്റാർക്കും ഈ വിവരങ്ങൾ അറിയാൻ സാധിക്കില്ല. താങ്കളിൽ നിന്ന് ശേഖരിക്കുന്ന വിവരങ്ങൾ പേരില്ലാതെ സൂക്ഷിക്കുന്നതാണ്. ഒരു കോഡ് നമ്പറിന്റെസഹായത്തോടെ മാത്രമേ ഈ വിവരങ്ങൾ തിരിച്ചറിയാൻസാധിക്കുക.

കൂടുതൽ വിവരങ്ങൾക്ക്

ഈ പഠനവുമായി ബന്ധപ്പെട്ട കൂടുതൽ വിവരങ്ങൾക്ക് നിങ്ങൾക്ക് ഡോ :ഫിൻസ് എം ഫിലിപ്പ്നെയോ (Ph:9496048817, email id is phinse1984@gmail.com) എത്തിക്സ് കമ്മിറ്റി സെക്രട്ടറി ഡോ :മാല രാമനാഥനെയോ (Ph.: 0471 2520256/257 ,email id is iec.mem.sec@sctimst.ac.in) ബന്ധപ്പെടാവുന്നതാണ്. നിങ്ങൾ ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ ആഗ്രഹിക്കുകയാണെങ്കിൽ ഇതിൽ നിങ്ങളുടെ ഒപ്പ് ഇടേണ്ടതാണ്. ഈ രേഖയുടെ ഒരു കോപ്പി നിങ്ങളുടെ അറിവിലേക്കായി നൽകുന്നതാണ്

Consent Form in English (In-depth Interview)

Consent form

(In Depth Interview)

I have been given a chance to read and understand the consent form thoroughly. I understand that I can contact Dr Phinse M Philip at any point of time to ask questions regarding my participation in this research study and that I will be answered to my satisfaction.

I understand that my participation in this study is voluntary and I can quit at any time without any problem. I also understand that the investigator can decide at any point that I should no longer participate in the study.

If I have any questions about my rights as a subject in the study, I may contact Dr Phinse M Philip, PhD Scholar, AMCHSS, SCTIMST, Trivandrum, Ph.: 9496048817.

I have read and understood the above information. I agree to participate in this study. I understand that I will be given a copy of this signed and dated form for my own records. I have initialed the boxes below to indicate my consent to complete the questionnaire.

Are you willing to participate? Yes ☐ No ☐

Study Participant (Signature)_____Date_____

Name _____

Signature of Person obtaining consent: _____

Name: _____Date:_____

Consent Form in Malayalam (In-depth Interview)

സമ്മതപത്രം

(In Depth Interview)

ഈ ഗവേഷണ പഠനത്തെക്കുറിച്ചു എനിക്ക് ചോദ്യങ്ങൾ ചോദിക്കാൻ അവസരം ലഭിച്ചിട്ടുണ്ട്.എന്റെ ചോദ്യങ്ങൾക്കു തൃപ്തികരമായ മറുപടി ലഭിച്ചിട്ടുണ്ട്. ഇതിൽ പങ്കെടുക്കുന്നതിനെക്കുറിച്ചു കൂടുതൽ അറിയാൻ ഡോ :ഫിൻസ് എം ഫിലിപ്പ് നെ സമീപിക്കാവുന്നതാണ്.

ഈ ഗവേഷണ പഠനത്തിലെ പങ്കാളിത്തം സ്വന്തം ഇഷ്ടപ്രകാരമാണെന്നു എനിക്ക് മനസ്സിലായി.എപ്പോൾ വേണമെങ്കിലും ഈ പഠനത്തിൽ നിന്ന് എനിക്ക് പിന്മാറാവുന്നതാണ് എന്നും എന്നെ ഈ പഠനത്തിൽ നിന്നും ഗവേഷകന് എപ്പോൾ വേണമെങ്കിലും ഒഴിവാക്കാവുന്നതാണെന്നും എനിക്ക് മനസ്സിലായി.

ഈ പഠനത്തിൽ പങ്കെടുക്കുന്ന ആളെന്നനിലയിൽ എന്റെ അവകാശങ്ങളെക്കുറിച്ചു എന്തെങ്കിലും സംശയങ്ങളുണ്ടെങ്കിൽ എനിക്ക് ഡോ :ഫിൻസ് എം ഫിലിപ്പ് നെ ബന്ധപ്പെടാവുന്നതാണ്.

ഈ സമ്മതപത്രം ഒപ്പു വയ്ക്കുന്നതിലൂടെ എന്റെ നിയമപരമായ അവകാശങ്ങൾ ഒന്നും തന്നെ ഞാൻ വേണ്ടെന്നു വെയ്ക്കുന്നില്ല.

ഞാൻ മുകളിൽ പറഞ്ഞ വിവരങ്ങൾ വായിക്കുകയും മനസ്സിലാക്കുകയും ചെയ്തു. ഈ പഠനത്തിൽ പങ്കെടുക്കുവാൻ എനിക്കു സമ്മതമാണ്. ഈ സമ്മത പത്രത്തിന്റെ ഒരു പകർപ്പ് എന്റെ ആവശ്യത്തിനായി തരുമെന്നും എനിക്ക് മനസ്സിലായി. എന്റെ സമ്മതം വ്യക്തമാക്കാനായി അടയാളപ്പെടുത്തിയ ഭാഗത്തു എന്റെ ഒപ്പ് ഇട്ടു നൽകുന്നു.

ഈ പഠനത്തിൽ പങ്കെടുക്കുവാൻ എനിക്കു സമ്മതമാണ്.

പങ്കെടുക്കുന്ന വ്യക്തിയുടെ ഒപ്പ്_____

തിയതി_____

പങ്കെടുക്കുന്ന വ്യക്തിയുടെ പേര്_____

സമ്മതപത്രം ഒപ്പിട്ടു വാങ്ങിയ വ്യക്തിയുടെ ഒപ്പ്_____

തിയതി_____

സമ്മതപത്രം ഒപ്പിട്ടു വാങ്ങിയ വ്യക്തിയുടെ പേര്_____

Interview Schedule in English

Interview Schedule on Patient and diagnostic interval duration

Oral Cancer Patient and diagnostic Interval Measure (OC-PDIM) Tool

Study number: **Registration number:** **Date:**

……

Site of lesion in the oral cavity (From Patient case file):…….

……..

Directions for question A (Number 1 to 17)

1: Ask only those questions which are relevant for the above recorded site of lesion in the oral cavity

2. Ask for an exact date (or a date closer to) of recognizing the following CHANGES or DIFFICULTIES in their oral cavity

……

A. Have you noticed the following signs/symptoms in your oral cavity and if "yes" when did you first notice them? (Questions 1 to 17)

s/n	Sign /Symptom/Change in oral cavity	Yes /No	If yes, please give an exact date /closer date of symptom recognition	What did you think that the condition was?
1	A non-scrapable white patch or plaque			
2	A non-scrapable red patch or plaque			
3	A non-healing oral ulcer with pain			
4	A non-healing oral ulcer without pain			
5	Burning sensation			
6	Dryness			
7	Inability to take hot or spicy food			
8	Restricted mouth opening			

9	**Difficulty for tongue movements**			
10	**An abnormal growth in the oral cavity without pain**			
11	**An abnormal growth in the oral cavity with pain**			
12	**Difficulty in swallowing**			
13	**Un explained tooth mobility**			
14	**Un explained bleeding from oral cavity**			
15	**Un explained change of sensation in oral cavity**			
16	**Mucosal erosions in oral cavity**			
17	**Any other change you observed in the oral cavity/head and neck region**			

B. If your answer to the questions from 1 to 17 is "No", how did you come to know about the problems in your oral cavity?

C. What was your first response, if you had recognized any of the change/difficulty mentioned in question 1 to 17 in your oral cavity?

1. Attributed symptoms as minor
2. Waited to see whether it will be resolved spontaneously
3. Tried some home remedy
4. I prayed to the god
5. Consulted a doctor
6. Tried herbal medicine
7. Others……..

D. Did you mention or discuss the problems in your mouth with anyone else before meeting a Health Care Provider for the first time for discussing the same?

1. Yes
2. No

E. If yes, how much time you took to discuss the same with that person?

F. If yes, what did the person you talked to suggest?

G. What is this person's relationship to you?

1.Spouse 2. Son 3. Daughter 4. Father 5.Mother 6.Brother
7. Sister 8. Relative 9. Personal friend 10. Colleague
11. Others……

H. When did you meet a health care provider for the above-mentioned symptom (Response to question 1 to 17)? (Please give an exact date /closer date)

I. Which type of Health Care Provider did you meet first?

Provider type

1. General practitioner
2. Dental surgeon
3. ENT surgeon
4. General surgeon
5. Other medical specialists
6. Cancer specialist
7. Ayurveda practitioner
8. Homeopathy practitioner
9. Other AYUSH Practitioner
10. Traditional healers
11. Other ……..

J. What was the first advice you received from that health care provider?

1. Ignored the symptom as minor
2. Asked for review
3. Advised biopsy
4. Referred to higher centre
5. Others ……

K. What prompted you to see the above Health Care Provider?

1. Pain
2. Discomfort
3. Increase in size
4. Insistence by family
5. Insistence by friends
6. Affected normal routine
7. Other ……

L. Please describe the important incidents/events/occasions that happened in your life in the period after you recognize the above-mentioned problem in your oral cavity?

M. So far, how many Health Care Providers were consulted for the above-mentioned problem in your oral cavity? (Please provide the exact date/closer date of consultation, specialty and their advice in the chronological order)

s/n	Date	Specialty	Advice

N. Stage of disease at the time of diagnosis (from patient case file)

……

O. Date of diagnosis (from patient case file)

……

Interview Schedule in Malayalam

വായിലെ അർബുദലക്ഷണങ്ങൾക്ക് വൈദ്യസഹായം തേടാനും രോഗനിർണയം നടത്താനും വേണ്ടി വരുന്ന സമയദൈർഘ്യം മനസ്സിലാക്കാനുള്ള ചോദ്യങ്ങൾ

പഠന നമ്പർ: **രെജിസ്ട്രേഷൻ നമ്പർ:**

തിയതി::

വായിൽ അർബുദം ബാധിച്ച ഭാഗം(ആശുപത്രി രേഖകളിൽ നിന്ന്) :

നിർദേശം 1 :ചോദ്യം A (ഒന്ന് മുതൽ 17വരെയുള്ള ഉപചോദ്യങ്ങളിൽ മുകളിൽ രേഖപ്പെടുത്തിയ വായിൽ അർബുദം ബാധിച്ച ഭാഗവുമായി ബന്ധമുള്ള ചോദ്യങ്ങളാണ് ഓരോ പഠന പങ്കാളിയോടും ചോദിക്കേണ്ടത്)

നിർദേശം 2 (ഉപചോദ്യം 1 മുതൽ 17വരെ): നിങ്ങൾക്ക് ഇപ്പോൾവായിൽ അനുഭവപ്പെടുന്ന പ്രശ്നങ്ങൾക്കുനോടിയായി താഴെപറയുന്ന ഏതെങ്കിലും മാറ്റങ്ങൾ കാണപ്പെടുകയോ ബുദ്ധിമുട്ടുകൾ അനുഭവപ്പെടുകയോ ചെയ്തിട്ടുണ്ട് എങ്കിൽ അത്തിരിച്ചറിഞ്ഞ ദിവസമോ അതിനോട് ഏറ്റവും അടുത്ത്നിൽക്കുന്ന മറ്റു സമയസൂചനകളോ നൽകുക

.....

A. താഴെ പറയുന്ന ലക്ഷണങ്ങൾ /സൂചനകൾ / മാറ്റങ്ങൾ നിങ്ങളുടെ വായിൽ നിങ്ങൾ എപ്പോഴെങ്കിലും ശ്രദ്ധിച്ചിരുന്നുവോ?(ഉപചോദ്യം 1 മുതൽ 17വരെ)

ക്രമ നമ്പർ	താഴെ പറയുന്ന ലക്ഷണങ്ങൾ /സൂചനകൾ / മാറ്റങ്ങൾവായിൽ എപ്പോഴെങ്കിലും ശ്രദ്ധിച്ചിരുന്നുവോ?	1.ഉണ്ട് 2.ഇല്ല	നിങ്ങളുടെ ഉത്തരം "ഉണ്ട്" എന്നാണെങ്കിൽ അത് തിരിച്ചറിഞ്ഞ ദിവസമോ അതിനോട് ഏറ്റവും അടുത്ത് നിൽക്കുന്ന മറ്റു സമയ സൂചനകളോ നൽകുക	അത് എന്തായിരുന്നു എന്നാണ് നിങ്ങൾ കരുതിയത് ?
1	വായിൽ കാണപ്പെട്ട തുടച്ചു മാറ്റാൻ പറ്റാത്ത വെള്ള പാട്/തടിപ്പ്			
2.	വായിൽ കാണപ്പെട്ട തുടച്ചു മാറ്റാൻ പറ്റാത്ത ചുവന്ന പാട് / തടിപ്പ്			
3	വായിൽ ഭേദമാവാത്ത, വേദനയോടു കൂടിയ ഒരു വ്രണം/മുറിവ്			
4	വായിൽ ഭേദമാവാത്ത, വേദന ഇല്ലാത്ത ഒരു വ്രണം/മുറിവ്			
5.	വായിൽ പുകച്ചിൽ അനുഭവപ്പെടുക			

6.	വായ ഉണങ്ങിപ്പോയത് പോലെ അനുഭവപ്പെടുക			
7.	ചൂട് ഉള്ളതോ എരിവുള്ളതോ ആയ ആഹാരപദാർത്ഥങ്ങൾ കഴിക്കാൻ ബുദ്ധിമുട്ട് അനുഭവപ്പെടുക			
8	വായ തുറക്കാൻ ബുദ്ധിമുട്ട് അനുഭവപ്പെടുക			
9	നാക്ക് ചലിപ്പിക്കാൻ ബുദ്ധിമുട്ട് അനുഭവപ്പെടുക			
10	വായിൽ അസ്വാഭാവികമായ വേദനയോടു കൂടിയ തടിപ്പ് അനുഭവപ്പെടുക			
11	വായിൽ അസ്വാഭാവികമായ വേദന ഇല്ലാത്ത തടിപ്പ് അനുഭവപ്പെടുക			
12	വായിൽ പല്ലുകൾക്ക് അകാരണമായ ഇളക്കം അനുഭവപ്പെടുക			
13	വായിൽ നിന്ന് അകാരണമായി രക്തം വരിക			
14	വായിൽ സംവേദനവുമായി ബന്ധപ്പെട്ട് അസ്വാഭാവികത (തരിപ്പ് ,മരവിപ്പ് തുടങ്ങിയവ) അനുഭവപ്പെടുക			
15	വെള്ളമോ ,ഭക്ഷണമോ ഇറക്കാൻ ബുദ്ധിമുട്ട് അനുഭവപ്പെടുക			
16	വായിലെ തൊലി നഷ്ടപ്പെട്ടു പോകുക			
17	നിങ്ങൾക്ക് വായിൽ മറ്റ് എന്തെങ്കിലും മാറ്റങ്ങൾ / ബുദ്ധിമുട്ടുകൾ അനുഭവപ്പെട്ടിരുന്നോ?			

B. ഒന്ന് മുതൽ പതിനേഴ് വരെയുള്ള ചോദ്യങ്ങൾക്ക് നിങ്ങൾ "ഉണ്ടായിരുന്നില്ല" എന്നാണ് ഉത്തരം നൽകിയത്എങ്കിൽ നിങ്ങൾ വായിലെ ഈ ബുദ്ധിമുട്ടു എങ്ങനെയാണ് തിരിച്ചറിഞ്ഞത് എന്ന് വ്യക്തമാക്കുക

C. മുകളിൽ സൂചിപ്പിച്ച മാറ്റം /ബുദ്ധിമുട്ടിനോട് നിങ്ങൾ എങ്ങനെയാണ് ആദ്യം പ്രതികരിച്ചത്?

1. **സാരമുള്ള മാറ്റങ്ങൾ അല്ല എന്ന് നിരീക്ഷിച്ചു**
2. **തനിയെ മാറുമോ എന്ന് നോക്കാൻ കാത്തിരുന്നു**
3. **വീട്ടിലുള്ള ചില പൊടിക്കൈകൾ പ്രയോഗിച്ചു**
4. **ദൈവത്തോടു പ്രാർത്ഥിച്ചു**
5. **ഒരു ഡോക്ടറിനെ കണ്ടു**
6. **നാട്ടു ചികിത്സ ചെയ്തു**

7. മറ്റുള്ളവ
(വിശദമാക്കുക).....

D. നിങ്ങൾ (1 മുതൽ 17 വരെയുള്ള ചോദ്യങ്ങൾക്കുള്ള ഉത്തരമായി) സൂചിപ്പിച്ച നിങ്ങളുടെ വായിലെ പ്രശ്നങ്ങൾ ഒരു ചികിത്സകനെ കാണിക്കുന്നതിന് മുൻപ് മറ്റാരോടെങ്കിലും പങ്കുവെച്ചിരുന്നോ ?

1. ഉണ്ട് 2.ഇല്ല

E.നിങ്ങളുടെ ഉത്തരം "ഉണ്ട്" എന്ന് ആണെങ്കിൽ വായിലെ മാറ്റം തിരിച്ചറിഞ്ഞു കഴിഞ്ഞു എത്ര സമയത്തിനു ശേഷമാണ് നിങ്ങൾ ആ വ്യക്തിയോട് ഈ വിവരം പങ്കുവെച്ചത് ?

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F.നിങ്ങളുടെ ഉത്തരം "ഉണ്ട്"എന്ന് ആണെങ്കിൽ ആ വ്യക്തി എന്ത് നിർദ്ദേശമാണ് നിങ്ങൾക്ക് നൽകിയത്?

G. ഈ വ്യക്തി നിങ്ങളുടെ ആരാണ് ?

1. ജീവിത പങ്കാളി
2. മകൻ
3. മകൾ
4. അച്ഛൻ
5. 'അമ്മ
6. സഹോദരൻ
7. സഹോദരി
8. ബന്ധു
9. കൂട്ടുകാരൻ
10. സഹപ്രവർത്തകൻ
11. മറ്റുള്ളവ (വ്യക്തമാക്കുക).....

H.എന്നാണ് നിങ്ങൾ നിങ്ങളുടെ വായിലെ പ്രശ്നങ്ങൾ (1 മുതൽ 17 വരെയുള്ള ചോദ്യങ്ങൾക്കുള്ള ഉത്തരമായി സൂചിപ്പിച്ച) ഒരു ചികിത്സകനെകാണിച്ചത്?(കൃത്യമായ തിയതിയോ അതിനോടടുത്തു നിൽക്കുന്ന സമയ സൂചനയോ നൽകുക)

I.ഏതു വിഭാഗത്തിൽ പെട്ട ചികിത്സകനെയാണ് നിങ്ങൾ ആദ്യം കണ്ടത്?

1. മെഡിക്കൽ ഡോക്ടർ
2. ഡെന്റൽ സർജൻ
3. ഇ എൻ ടി സർജൻ
4. ജനറൽ സർജൻ
5. മറ്റു വിദഗ്ദ്ധ മെഡിക്കൽ ഡോക്ടർമാർ
6. അർബുദ രോഗ വിദഗ്ദ്ധൻ
7. ആയുർവേദ ഡോക്ടർ
8. ഹോമിയോ ഡോക്ടർ
9. മറ്റ് ആയുഷ് ഡോക്ടർമാർ
10. നാട്ടു വൈദ്യന്മാർ
11. മറ്റുള്ളവർ (വിശദമാക്കുക).....

J. നിങ്ങൾക്ക് അവരിൽ നിന്ന് എന്ത് ഉപദേശമാണ് ലഭിച്ചത്?

1. സാരമായ വിഷയമല്ല എന്ന ഉപദേശം
2. വീണ്ടും കാണുവാനുള്ള നിർദേശം

3. ബൈയോപ്സി പരിശോധന നടത്താനുള്ള നിർദേശം
4. വിദഗ്ദ്ധ കേന്ദ്രങ്ങളിലേക്ക് പോകുവാനുള്ള നിർദേശം
5. മറ്റുള്ളവ(വിശദമാക്കുക).....

K. മുകളിൽ സൂചിപ്പിച്ച ചികിത്സകനെകാണുവാൻ നിങ്ങളെ പ്രേരിപ്പിച്ച കാരണമെന്താണ്?

1. വർദ്ധിച്ചു വരുന്ന വേദന
2. വർദ്ധിച്ചു വരുന്ന ബുദ്ധിമുട്ട്
3. വലിപ്പം കൂടിവരുക
4. ദൈനംദിന പ്രവർത്തങ്ങളിൽ തടസ്സം
5. കുടുംബാംഗങ്ങളുടെനിർബന്ധം
6. സുഹൃത്തുക്കളുടെനിർബന്ധം
7. മറ്റുള്ളവ(വിശദമാക്കുക).....

L.വായിൽ ഇപ്പോഴുള്ള ബുദ്ധിമുട്ട് തിരിച്ചറിഞ്ഞതിനു ശേഷമുള്ള കാലയളവിൽ നിങ്ങളുടെ ജീവിതത്തിൽ ഉണ്ടായ പ്രധാനപ്പെട്ട കാര്യങ്ങൾ,സംഭവങ്ങൾ,വിശേഷങ്ങൾ എന്നിവയെ പറ്റി വിവരിക്കുക ?

.....

M. നിങ്ങളുടെ വായിലെ പ്രശ്നങ്ങളുമായി ബന്ധപ്പെട്ടു നിങ്ങൾ ഇതുവരെ ഏതൊക്കെ ചികിത്സകരെ കാണുകയുണ്ടായി? (ചികിത്സകരെ നിങ്ങൾ കണ്ട സമയം, അവർ ചികിൽസിക്കുന്ന വിഭാഗം,അവരിൽ നിന്ന് ലഭിച്ച നിർദേശം എന്ന ക്രമത്തിൽ രേഖപ്പെടുത്തുക)

ക്രമ നമ്പർ	ചികിത്സവിഭാഗം	സമയം	ലഭിച്ച നിർദ്ദേശം

N. രോഗനിർണയസമയത്തെ കാൻസർ സ്റ്റേജ്: (ഹോസ്പിറ്റൽ രേഖകളിൽ നിന്നും)

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O. രോഗനിർണയ തിയതി :(ഹോസ്പിറ്റൽ രേഖകളിൽ നിന്നും)

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Questionnaire in English

Questionnaire on Factors Contributing To Patient Interval in Oral Cancer

Study number: **Registration number:** **date:**

Section 1: Socio demographic factors

General instructions:

1. For questions having multiple choices, please put a tick (✔) mark to the most appropriate answer.

2. For open-ended questions, please write your answers

Directions for questions 1 to 5: Please provide the following basic information about you

1. Age (At the time of diagnosis)

……

2. Sex:

1. Male
2. Female
3. Transgender

3. Religion:

1. Hindu
2. Muslim
3. Christian
4. Others ……..

4. Caste:

1. General
2. Other backward class
3. Scheduled caste
4. Scheduled tribe
5. Others ……..

5. Place of residence: …….

1. Panchayath

2. Municipality
3. Corporation

6. Highest educational qualification:

1. Cannot read and write
2. Can read
3. Can read and write
4. Primary
5. Upper primary
6. High school
7. Higher secondary
8. Diploma
9. Graduation
10. Post-graduation
11. Professional degree
12. Others
13. Not applicable

7. Years of schooling :……..

8. What is/was your occupation?

……

9. Which type of ration card you have?

1. APL
2. BPL
3. AAY(Antyodaya)

10. What is your household monthly income?

---

1. No income
2. Below 1000
3. 1001to 3000
4. 3001 to 5000
5. 5001 to 10000
6. 10001to 15000
7. 15001 to 20000
8. 20001to 30000
9. 30001 and above

11. What type of house you have?

1. Pucca house
2. Semi pucca house
3. Kachha house

12. What is your present marital status?

1. Married
2. Unmarried
3. Widow/widower
4. Separated
5. Divorced

13. How many people live in your house?

……

14. Type of family

1. Nuclear family
2. Joint family

15. Which of the following members live in your house?

1. Spouse
2. Son
3. Daughter
4. Mother
5. Father
6. Brother
7. Sister
8. Other relatives
9. Other non-relatives
10. Others…….

…….

Section 2: Habit related factors

……

1. **Habit related questions**

s/n	Habit	Which of the following best describes your habit status?	If your answer is option "1"or "2", please provide the duration of your	If your answer is option "2", please provide the duration of abstinence from

			habit	habit
	Smoking	**1.Current user 2.Ex user 3.Never used**		
	Betel quid	**1.Current user 2.Ex user 3.Never used**		
	Hans /pan parag	**1.Current user 2.Ex user 3.Never used**		
	Alcohol	**1.Current user 2.Ex user 3.Never used**		

2.How did the problems in your mouth change your habit?

s/n	Habit	Increased	Decreased	Stopped	No change	1. Not applicable
1	Smoking					
2	Betel quid					
3	Hans /Pan parag					
4	Alcohol					

……

Section 3: General health seeking behavior

……

1. Do you have any other diseases /disabilities?

1. Yes
2. No

2. If yes, please specify

……
……

3. How often you meet a medical practitioner

1. Every 6 month for routine checkup
2. Yearly for routine checkup

3. During Free Medical camps
4. In case of any illness
5. In case of emergency
6. Others ……

4. How often you meet a dental surgeon

1. Every 6 month for routine checkup
2. Yearly for routine checkup
3. During Free Dental camps
4. In case of any illness
5. In case of emergency
6. Others ……

5. What will be your first response in case of any health problem?

1. I will try home remedies
2. I will Get medicines from medical store
3. I will consult Primary health centre doctor
4. I will consult private allopathic practitioner
5. I will consult my Family doctor
6. I will consult Traditional healers
7. I will consult a Ayurveda practitioner
8. I will consult a Homeopathy practitioner
9. I will consult a Unani practitioner
10. I will consult a Nurse
11. I will discuss with a friend working in health sector
12. Others ……..

……

Section 4: Barriers to health seeking

……

A. Did any of the following ever put you off from going to the doctor?

(Directions: You have five choices to mark your response to the following statements. Choices include strongly agree, Agree, Neither agree or disagree, Disagree and strongly disagree.)

1. I found it embarrassing talking to the doctor about my symptoms

1. Strongly agree
2. Agree
3. Neither agree or disagree
4. Disagree
5. Strongly disagree

2. I found it difficult to get an appointment with a particular doctor

1. Strongly agree
2. Agree
3. Neither agree or disagree
4. Disagree
5. Strongly disagree
1.

3. I was too busy to make time to go to the doctor.

1. Strongly agree
2. Agree
3. Neither agree or disagree
4. Disagree
5. Strongly disagree

4. I had too many other things to worry about.

1. Strongly agree
2. Agree
3. Neither agree or disagree
4. Disagree
5. Strongly disagree

5. I was worried about what tests they might want to do.

1. Strongly agree
2. Agree
3. Neither agree or disagree
4. Disagree
5. Strongly disagree

6. I did not have a person to accompany me during hospital visits/consultations.

1. Strongly agree
2. Agree
3. Neither agree or disagree
4. Disagree
5. Strongly disagree

7. I have had a bad experience with hospital/treatment in the past.

1. Strongly agree
2. Agree
3. Neither agree or disagree
4. Disagree
5. Strongly disagree

8. Generally, I do not get any diseases. Mild symptoms, if any, would get resolved by themselves

1. Strongly agree
2. Agree
3. Neither agree or disagree
4. Disagree
5. Strongly disagree

9. I did not want to be seen as somebody who makes a fuss

1. Strongly agree
2. Agree
3. Neither agree or disagree
4. Disagree
5. Strongly disagree

10. I did not have money to consult a doctor/visit a hospital

1. Strongly agree
2. Agree
3. Neither agree or disagree
4. Disagree
5. Strongly disagree

11. I was worried about what the doctor might find out

1. Strongly agree
2. Agree
3. Neither agree or disagree
4. Disagree
5. Strongly disagree

12. I was worried about what others might think

1. Strongly agree
2. Agree
3. Neither agree or disagree
4. Disagree
5. Strongly disagree

13. I may be comfortable discussing my symptoms with a nurse than a doctor

1. Strongly agree
2. Agree
3. Neither agree or disagree

14. I did not believe in Allopathic medicines and treatment; I prefer alternative medicines

1. Strongly agree
2. Agree
3. Neither agree or disagree
4. Disagree
5. Strongly disagree

15. Is there anything else that would put you off going to the doctor?

……
……

B. Do you have any previous experiences with cancer?

1. Yes
2. No

B.1. If your answer is: yes", Please describe your experiences?

……

Section 5: Other factors

……

1. How far is the nearest health facility?

……

2. How long does it usually take you to reach the nearest health facility?

……

3. What was the common transportation option to reach the nearest health facility?

1. Travel by foot
2. Bus
3. jeep
4. Auto rickshaw
5. Bus+ Travel by foot
6. Bus +Auto rickshaw /jeep
7. Bus +Auto rickshaw /jeep+ travel by foot
8. Travel by foot+ Auto rickshaw /jeep

9. Two wheeler
10. Car
11. Others …….. ……

4. Do you have subscribed to any government health insurance scheme?

1. Yes
2. No

5. Do you have subscribed to any private health insurance scheme?

1. Yes
2. No

6. In general, who takes care of your financial needs? (You can choose more than one answer)

1. Self
2. Spouse
3. Son
4. Son in law
5. Daughter
6. Daughter in law
7. Father
8. Mother
9. Brother
10. Sister
11. Relative
12. Personal friend
13. Others……..…….

7. Are you the only earning member of your family?

1. Yes
2. No

8. If "No" who are the other earning members in your family?

……

9. Do you have any other financial liability, which is not related to the current treatment?

1. Yes
2. No

10. If "yes", please specify

…….....

Questionnaire in Malayalam

വായിലെ അർബുദ സൂചനകൾ തിരിച്ചറിയാനും വൈദ്യസഹായം തേടാനും വേണ്ടിവരുന്ന സമയദൈർഘ്യത്തെ നിർണയിക്കുന്ന വിവിധ ഘടകങ്ങൾ മനസ്സിലാക്കാനുള്ള ചോദ്യാവലി

പഠന നമ്പർ: **രജിസ്ട്രേഷൻ നമ്പർ:** **തിയതി:**

.....

വിഭാഗം 1 : സാമൂഹിക പശ്ചാത്തലം സംബന്ധമായ ചോദ്യങ്ങൾ

.....

പൊതുവായ നിർദ്ദേശങ്ങൾ

1. ഉത്തരങ്ങൾ തിരഞ്ഞെടുക്കേണ്ട ചോദ്യങ്ങൾക്ക്: ഉചിതമായ ഉത്തരത്തിനു നേരെ ശരി (✔)ചിഹ്നം രേഖപ്പെടുത്തുക)
2. മറ്റു ചോദ്യങ്ങൾക്ക്: നിങ്ങളുടെ ഉത്തരങ്ങൾ എഴുതുക

(ഒന്ന് മുതൽ അഞ്ചു വരെയുള്ള ചോദ്യങ്ങൾക്കുള്ള നിർദേശങ്ങൾ: ദയവായി താങ്കളുമായി ബന്ധപ്പെട്ട ചുവടെ പറയുന്ന അടിസ്ഥാന വിവരങ്ങൾ പങ്കുവയ്ക്കുക)

1.പ്രായം:(രോഗനിർണയ സമയത്തുള്ളത്)

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2. ലിംഗഭേദം:

1. സ്ത്രീ
2. പുരുഷൻ
3. ഭിന്നലിംഗം

3.മതം:

1. ഹിന്ദു
2. മുസ്ലിം
3.
4. ക്രിസ്ത്യൻ
5. മറ്റുള്ളവർ (വ്യക്തമാക്കുക).....

4.ജാതി:

1. പൊതുവിഭാഗം
2. മറ്റു പിന്നോക്ക വിഭാഗം
3. പട്ടിക ജാതി
4. പട്ടിക വർഗം
5. മറ്റുള്ളവർ (വ്യക്തമാക്കുക).....

5.താമസസ്ഥലം:.....

1. പഞ്ചായത്ത്
2. മുൻസിപ്പാലിറ്റി
3. കോർപറേഷൻ

6.നിങ്ങളുടെ ഏറ്റവും ഉയർന്ന വിദ്യാഭ്യാസ നില:

1. എഴുത്തും വായനയും അറിയില്ല

2. വായിക്കാൻ അറിയാം
3. എഴുത്തും വായനയും അറിയാം
4. ഒന്ന് മുതൽ നാല് ക്ലാസുകൾ
5. അഞ്ചു മുതൽ ഏഴു ക്ലാസുകൾ
6. എട്ടു മുതൽ പത്ത് ക്ലാസ് വരെ
7. പ്ലസ് ടു /പ്രീ ഡിഗ്രി
8. ഡിപ്ലോമ
9. ബിരുദം
10. ബിരുദാനന്തര ബിരുദം
11. പ്രൊഫഷണൽ ബിരുദം
12. മറ്റുള്ളവ (വ്യക്തമാക്കുക).....

7. ആകെ വിദ്യാഭ്യാസ കാലയളവ്:.....

8.നിങ്ങളുടെ തൊഴിൽ

.....

9.നിങ്ങളുടെ റേഷൻ കാർഡ് ഏതു വിഭാഗത്തിൽ പെടുന്നു?

1. ദാരിദ്ര്യ രേഖയ്ക്ക് മുകളിൽ (APL)
2. ദാരിദ്ര്യ രേഖയ്ക്ക് ഉള്ളിൽ (BPL)
3. ദാരിദ്ര്യ രേഖയ്ക്ക് ഉള്ളിൽ അന്ത്യോദയ (BPL-AAY)

10.നിങ്ങളുടെ കുടുംബമാസ വരുമാനം എത്രയാണ്?

.....

1. വരുമാനമില്ല
2. 1000വരെ
3. 1001 മുതൽ 3000വരെ
4. 3001മുതൽ 5000വരെ
5. 5001 മുതൽ 10000വരെ
6. 10001 മുതൽ 15000വരെ
7. 15001 മുതൽ20000വരെ
8. 20001 മുതൽ30000വരെ
9. 30001-ഉം അധികവും

11.നിങ്ങളുടെ വീട് ഏത് തരത്തിൽ പെട്ടതാണ് ?

1. കോൺക്രീറ്റ് വീട്
2. ഓടിട്ട വീട്
3. ഓല/പുല്ല് മേഞ്ഞ വീട്

12.നിങ്ങളുടെ നിലവിലെ വിവാഹാവസ്ഥ എന്താണ്

1. വിവാഹിതൻ
2. അവിവാഹിതൻ
3. പങ്കാളി മരണപ്പെട്ടു
4. വിവാഹമോചനം നേടി
5. പങ്കാളിയുമായി അകന്നു കഴിയുന്നു

13.നിങ്ങളുടെ വീട്ടിൽ എത്ര ആളുകൾ താമസിക്കുന്നുണ്ട്?

.....

14.നിങ്ങളുടെ കുടുംബം ഏതു വിഭാഗത്തിൽ പെടുന്നു ?

1. അണുകുടുംബം
2. കൂട്ട് കുടുംബം

15.ചുവടെ പറയുന്നവരിൽ ആരൊക്കെ ഇപ്പോൾ നിങ്ങളുടെ വീട്ടിൽ താമസിക്കുന്നുണ്ട്?

1. ജീവിത പങ്കാളി
2. മകൻ
3. മകൾ
4. അച്ഛൻ

5. അമ്മ
6. സഹോദരൻ
7. സഹോദരി
8. മറ്റ് ബന്ധുക്കൾ
9. ബന്ധുക്കൾ അല്ലാത്ത മറ്റ് വ്യക്തികൾ
10. മറ്റുള്ളവർ (വ്യക്തമാക്കുക).....

.....

വിഭാഗം 2:ശീലങ്ങളുമായി ബന്ധപ്പെട്ട ചോദ്യങ്ങൾ

.....

1.ശീലങ്ങളുമായി ബന്ധപ്പെട്ട ചോദ്യങ്ങൾ

	ശീലങ്ങൾ	നിങ്ങളുടെ ശീലത്തെ ചുവടെ കൊടുത്ത ഉത്തരങ്ങളിൽ ഏതാണ് ഏറ്റവും കൃത്യമായി വിവരിക്കുന്നത്?	നിങ്ങൾ ഒന്നാമത്തെയോ രണ്ടാമത്തെയോ ഉത്തരമാണ് തിരഞ്ഞെടുത്തതെങ്കിൽ ഉപയോഗ കാലയളവ് രേഖപ്പെടുത്തുക	നിങ്ങൾ രണ്ടാമത്തെ ഉത്തരമാണ് തിരഞ്ഞെടുത്തതെങ്കിൽ ഉപയോഗം നിർത്തിയിട്ട് എത്ര കാലമായെന്ന് രേഖപ്പെടുത്തുക
1	പുകവലി	1.നിലവിൽ ഉപയോഗിക്കുന്നു 2.മുൻപ് ഉപയോഗിച്ചിരുന്നു 3.ഇതുവരെ ഉപയോഗിച്ചിട്ടില്ല		
2	വെറ്റിലമുറുക്ക്	1.നിലവിൽ ഉപയോഗിക്കുന്നു 2.മുൻപ് ഉപയോഗിച്ചിരുന്നു 3.ഇതുവരെ ഉപയോഗിച്ചിട്ടില്ല		
3	(ഹാൻസ് , പാൻപരാഗ് മുതലായവ)	1.നിലവിൽ ഉപയോഗിക്കുന്നു 2.മുൻപ് ഉപയോഗിച്ചിരുന്നു 3.ഇതുവരെ ഉപയോഗിച്ചിട്ടില്ല		
4	മദ്യപാനം	1.നിലവിൽ ഉപയോഗിക്കുന്നു 2.മുൻപ് ഉപയോഗിച്ചിരുന്നു 3.ഇതുവരെ ഉപയോഗിച്ചിട്ടില്ല		

2.നിങ്ങളുടെ വായിൽ ഇപ്പോൾ ഉള്ള പ്രശ്നങ്ങൾ നിങ്ങളുടെ ശീലത്തിൽ എന്ത് മാറ്റമാണ് വരുത്തിയത്?

	ശീലങ്ങൾ	ഉപയോഗം കൂടി	ഉപയോഗം കുറഞ്ഞു	ഉപയോഗം നിർത്തി	മാറ്റമില്ല	ബാധകമല്ല
1	പുകവലി					
2	വെറ്റിലമുറുക്ക്					
3	(ഹാൻസ് പാൻപരാഗ് മുതലായവ)					
4	മദ്യപാനം					

വിഭാഗം 3 : പൊതുവായ ആരോഗ്യരീതികൾ സംബന്ധിച്ച ചോദ്യങ്ങൾ

.....

1.നിങ്ങൾക്ക് മറ്റെന്തെങ്കിലും രോഗങ്ങളോ പരിമിതികളോ ഉണ്ടോ?

1. ഉണ്ട്
2. ഇല്ല

2."ഉണ്ട്" എങ്കിൽ അവ വ്യക്തമാക്കുക

.....

3.നിങ്ങൾ പൊതുവിൽ ഒരു മെഡിക്കൽ ഡോക്ടർ -നെ കാണുന്നത് സംബന്ധിച്ച് ചുവടെ ചേർത്തിട്ടുള്ള ഉത്തരങ്ങളിൽ ഏറ്റവും ഉചിതമായത് തിരഞ്ഞെടുക്കുക

1. ആറുമാസം കൂടുമ്പോൾ ഒരു ആരോഗ്യപരിശോധന നടത്താറുണ്ട്
2. വർഷത്തിൽ ഒരു ആരോഗ്യപരിശോധന നടത്താറുണ്ട്
3. സൗജന്യ മെഡിക്കൽ ക്യാമ്പുകളിൽ വെച്ച്
4. എന്തെങ്കിലും രോഗം വരുമ്പോൾ മാത്രം
5. വളരെ അത്യാവശ്യം വരുമ്പോൾ മാത്രം
6. മറ്റുള്ളവ.....

4.നിങ്ങൾ പൊതുവിൽ ഒരു ദന്ത ഡോക്ടർ -നെ കാണുന്നത് സംബന്ധിച്ച് ചുവടെ ചേർത്തിട്ടുള്ള ഉത്തരങ്ങളിൽ ഏറ്റവും ഉചിതമായത് തിരഞ്ഞെടുക്കുക

1. ആറുമാസം കൂടുമ്പോൾ ഒരു ദന്ത ആരോഗ്യ പരിശോധന നടത്താറുണ്ട്
2. വർഷത്തിൽ ഒരു ദന്ത ആരോഗ്യ പരിശോധന നടത്താറുണ്ട്
3. സൗജന്യ ദന്ത ആരോഗ്യ പരിശോധന ക്യാമ്പുകളിൽ വെച്ച്
4. എന്തെങ്കിലും ദന്തരോഗം വരുമ്പോൾ മാത്രം
5. വളരെ അത്യാവശ്യം വരുമ്പോൾ മാത്രം
6. മറ്റുള്ളവ.....

5.പൊതുവെ എന്തെങ്കിലും ആരോഗ്യ പ്രശ്നങ്ങൾ വരുമ്പോൾ നിങ്ങൾ അതിനോട് ആദ്യംഎങ്ങനെയാണ് പ്രതികരിക്കുക

1. വീട്ടിലെ ചില പൊടിക്കൈകൾ പ്രയോഗിക്കും
2. മെഡിക്കൽ ഷോപ്പിൽ നിന്ന് മരുന്ന് വാങ്ങി കഴിക്കും
3. കുടുംബ ഡോക്ടറിനെ കാണും
4. പ്രാഥമിക ആരോഗ്യകേന്ദ്രത്തിലെ അലോപ്പതി ഡോക്ടറിനെ കാണും
5. സ്വകാര്യ ആശുപത്രിയിലെ അലോപ്പതി ഡോക്ടറിനെ കാണും
6. നാട്ടു വൈദ്യന്മാരെ കാണും
7. ആയുർവേദ ഡോക്ടറിനെ കാണും
8. ഹോമിയോ ഡോക്ടറിനെ കാണും
9. യൂനാനി ഡോക്ടറിനെ കാണും
10. ഒരു നേഴ്സ്-നെ കാണും
11. ആരോഗ്യമേഖലയിൽ പ്രവർത്തിക്കുന്ന സുഹൃത്തിനെയോ ബന്ധുവിനെയോ കാണും
12. മറ്റുള്ളവ

.....

വിഭാഗം 4:പൊതുവായിവൈദ്യ സഹായം തേടുന്നതിൽ നിന്നും പിന്തിരിപ്പിക്കുന്ന ഘടകങ്ങൾ

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A. ചുവടെ സൂചിപ്പിക്കുന്ന ഏതെങ്കിലും ഘടകങ്ങൾ നിങ്ങളെ ഒരു ചികിത്സകനെ കാണുന്നതിൽ നിന്നും പിന്തിരിപ്പിച്ചിട്ടുണ്ടോ ?

(ഈ ചോദ്യങ്ങൾക്കുള്ള നിങ്ങളുടെ മറുപടി അഞ്ചു തരത്തിൽ പ്രകടിപ്പിക്കാവുന്നതാണ്: ശക്തമായി യോജിക്കുന്നു , യോജിക്കുന്നു, യോജിക്കുകയോ വിയോജിക്കുകയോ ചെയ്യുന്നില്ല , വിയോജിക്കുന്നു , ശക്തമായിവിയോജിക്കുന്നു,)

1.ഡോക്ടറോട് എന്റെ ബുദ്ധിമുട്ടുകളെ പറ്റി പറയാൻ എനിക്ക് ചമ്മലാണ്

1. ശക്തമായി യോജിക്കുന്നു
2. യോജിക്കുന്നു

3. യോജിക്കുകയോ വിയോജിക്കുകയോ ചെയ്യുന്നില്ല
4. വിയോജിക്കുന്നു
5. ശക്തമായിവിയോജിക്കുന്നു

2.ഞാൻ കാണിക്കാൻ ഉദ്ദേശിക്കുന്ന ഡോക്ടറുടെ ടോക്കൺ (കാണാനുള്ള സമയം) കിട്ടാനുള്ള ബുദ്ധിമുട്ട്

1. ശക്തമായി യോജിക്കുന്നു
2. യോജിക്കുന്നു
3. യോജിക്കുകയോ വിയോജിക്കുകയോ ചെയ്യുന്നില്ല
4. വിയോജിക്കുന്നു
5. ശക്തമായി വിയോജിക്കുന്നു

3.ഡോക്ടറെ കാണാൻ പോകാൻ എനിക്ക് പൊതുവെ സമയം കിട്ടാറില്ല

1. ശക്തമായി യോജിക്കുന്നു
2. യോജിക്കുന്നു
3. യോജിക്കുകയോ വിയോജിക്കുകയോ ചെയ്യുന്നില്ല
4. വിയോജിക്കുന്നു
5. ശക്തമായി വിയോജിക്കുന്നു

4.എന്നെ ആകുലപ്പെടുത്തുന്ന വേറെ ഒരുപാട് കാര്യങ്ങളുണ്ട്

1. ശക്തമായി യോജിക്കുന്നു
2. യോജിക്കുന്നു
3. യോജിക്കുകയോ വിയോജിക്കുകയോ ചെയ്യുന്നില്ല
4. വിയോജിക്കുന്നു
5. ശക്തമായി വിയോജിക്കുന്നു

5.ഡോക്ടറിനെ കാണുമ്പോൾ ഏതൊക്കെ പരിശോധനകൾക്കാണ് നിർദേശിക്കുക എന്നത് എന്നെ ആശങ്കപ്പെടുത്തുന്നു

1. ശക്തമായി യോജിക്കുന്നു
2. യോജിക്കുന്നു
3. യോജിക്കുകയോ വിയോജിക്കുകയോ ചെയ്യുന്നില്ല
4. വിയോജിക്കുന്നു
5. ശക്തമായി വിയോജിക്കുന്നു

6.ഡോക്ടറെ കാണാൻ /ആശുപത്രിയിൽ പോകാൻ കൂടെ വരാൻ ആരുമില്ല

1. ശക്തമായി യോജിക്കുന്നു
2. യോജിക്കുന്നു
3. യോജിക്കുകയോ വിയോജിക്കുകയോ ചെയ്യുന്നില്ല
4. വിയോജിക്കുന്നു
5. ശക്തമായി വിയോജിക്കുന്നു

7.ആശുപത്രിയുമായി/ചികിത്സയുമായി ബന്ധപ്പെട്ട് മുൻപ് എനിക്ക് ഒരു മോശം അനുഭവം ഉണ്ടായി

1. ശക്തമായി യോജിക്കുന്നു
2. യോജിക്കുന്നു
3. യോജിക്കുകയോ വിയോജിക്കുകയോ ചെയ്യുന്നില്ല
4. വിയോജിക്കുന്നു
5. ശക്തമായി വിയോജിക്കുന്നു

8.എനിക്ക് പൊതുവെ രോഗങ്ങൾ ഒന്നും വരാറില്ല. ചെറിയ മാറ്റങ്ങളൊക്കെ തനിയെ മാറാറാണ് പതിവ്

1. ശക്തമായി യോജിക്കുന്നു
2. യോജിക്കുന്നു
3. യോജിക്കുകയോ വിയോജിക്കുകയോ ചെയ്യുന്നില്ല
4. വിയോജിക്കുന്നു
5. ശക്തമായി വിയോജിക്കുന്നു

9.ഞാൻ ഒരു അനാവശ്യ ഉൽകണ്ഠ പ്രകടിപ്പിക്കുന്ന വ്യക്തിയായി തോന്നുമോ എന്ന ചിന്ത

1. ശക്തമായി യോജിക്കുന്നു
2. യോജിക്കുന്നു
3. യോജിക്കുകയോ വിയോജിക്കുകയോ ചെയ്യുന്നില്ല
4. വിയോജിക്കുന്നു
5. ശക്തമായി വിയോജിക്കുന്നു

10.ഒരു ഡോക്ടറിനെ കാണാനോ ആശുപത്രിയിൽ പോകാനോ ഉള്ള പണം ഇല്ല

1. ശക്തമായി യോജിക്കുന്നു
2. യോജിക്കുന്നു
3. യോജിക്കുകയോ വിയോജിക്കുകയോ ചെയ്യുന്നില്ല
4. വിയോജിക്കുന്നു
5. ശക്തമായി വിയോജിക്കുന്നു

11.ഡോക്ടർ എന്തു കണ്ടുപിടിക്കും എന്ന ഭയം

1. ശക്തമായി യോജിക്കുന്നു
2. യോജിക്കുന്നു
3. യോജിക്കുകയോ വിയോജിക്കുകയോ ചെയ്യുന്നില്ല
4. വിയോജിക്കുന്നു
5. ശക്തമായി വിയോജിക്കുന്നു

12.മറ്റുള്ളവർ എന്ത് കരുതുമെന്ന ആശങ്ക

1. ശക്തമായി യോജിക്കുന്നു
2. യോജിക്കുന്നു
3. യോജിക്കുകയോ വിയോജിക്കുകയോ ചെയ്യുന്നില്ല
4. വിയോജിക്കുന്നു
5. ശക്തമായി വിയോജിക്കുന്നു

13.എനിക്ക് എന്റെ പ്രശ്നങ്ങൾ ഒരു ഡോക്ടറിനോട് സംസാരിക്കുന്നതിനേക്കാൾ ആശ്വാസകരം ഒരു നഴ്സിനോട് സംസാരിക്കുന്നതാണ്

1. ശക്തമായി യോജിക്കുന്നു
2. യോജിക്കുന്നു
3. യോജിക്കുകയോ വിയോജിക്കുകയോ ചെയ്യുന്നില്ല
4. വിയോജിക്കുന്നു
5. ശക്തമായി വിയോജിക്കുന്നു

14. "എനിക്ക് ഇംഗ്ലീഷ് മരുന്നിലും ചികിത്സയിലും വിശ്വാസമില്ല. നാടൻ ചികിത്സകളാണ് താൽപര്യം"

1. ശക്തമായി യോജിക്കുന്നു
2. യോജിക്കുന്നു
3. യോജിക്കുകയോ വിയോജിക്കുകയോ ചെയ്യുന്നില്ല
4. വിയോജിക്കുന്നു
5. ശക്തമായി വിയോജിക്കുന്നു

15.ഇതല്ലാതെ മറ്റെന്തെങ്കിലും കാരണങ്ങൾ നിങ്ങളെ ഒരു ഡോക്ടറിനെ കാണുന്നതിൽ നിന്നും പിന്തിരിപ്പിക്കുന്നുണ്ടെങ്കിൽ അവ വ്യക്തമാക്കുക

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B.അർബുദരോഗവുമായി ബന്ധപ്പെട്ട് നിങ്ങൾക്ക് എന്തെങ്കിലും മുൻകാല അനുഭവങ്ങൾ ഉണ്ടോ?

1. ഉണ്ട്
2. ഇല്ല

B.1: നിങ്ങളുടെ ഉത്തരം ഉണ്ട് എന്നാണെങ്കിൽ അത് വിവരിക്കുക

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വിഭാഗം 5: മറ്റു ഘടകങ്ങൾ

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1.നിങ്ങളുടെ വീട്ടിൽ നിന്നും എത്ര ദൂരെയാണ് ഏറ്റവും അടുത്തുള്ള ആരോഗ്യകേന്ദ്രം?

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2.നിങ്ങളുടെ വീട്ടിൽ നിന്നും എത്ര സമയമെടുക്കും ഏറ്റവും അടുത്തുള്ള ആരോഗ്യകേന്ദ്രത്തിലേയ്ക്ക്?

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3.നിങ്ങളുടെ വീട്ടിൽ നിന്നും ആരോഗ്യകേന്ദ്രത്തിലേക്കുള്ള പ്രധാന യാത്രാ മാർഗ്ഗങ്ങൾ എന്തൊക്കെയാണ്?

1. കാൽനട
2. ബസ്
3. ഓട്ടോറിക്ഷ
4. ജീപ്പ്
5. ബസ്+ ഓട്ടോറിക്ഷ/ ജീപ്പ്
6. കാൽനട + ബസ്
7. ബസ്+ ഓട്ടോറിക്ഷ/ ജീപ്പ്+കാൽനട
8. ഓട്ടോറിക്ഷ/ ജീപ്പ്+കാൽനട
9. ഇരുചക്രവാഹനം
10. കാർ
11. മറ്റുള്ളവ.....00000

4.നിങ്ങൾ ഏതെങ്കിലും സർക്കാർ ആരോഗ്യ ഇൻഷുറൻസ് പദ്ധതിയിൽ അംഗമാണോ?

1. അതെ
2. അല്ല

5.നിങ്ങൾ ഏതെങ്കിലും സ്വകാര്യ ആരോഗ്യ ഇൻഷുറൻസ് പദ്ധതിയിൽ അംഗമാണോ?

1. അതെ
2. അല്ല

6.നിങ്ങളുടെ പൊതുവെയുള്ള സാമ്പത്തിക ആവശ്യങ്ങൾ ആരാണ് നിറവേറ്റുന്നത്?

1. സ്വന്തം കണ്ടെത്തും
2. ജീവിത പങ്കാളി
3. മകൻ
4. മകൾ
5. മരുമകൻ
6. മരുമകൾ
7. അച്ഛൻ
8. 'അമ്മ
9. സഹോദരൻ
10. സഹോദരി
11. ബന്ധു
12. കൂട്ടുകാരൻ
13. മറ്റുള്ളവ(വ്യക്തമാക്കുക).....

7.നിങ്ങളുടെ കുടുംബത്തിലെ വരുമാനമുള്ള ഏക വ്യക്തി നിങ്ങളാണോ?

1. അതെ
2. അല്ല

8.അല്ല എങ്കിൽ നിങ്ങളുടെ കുടുംബത്തിൽ സ്വന്തമായി വരുമാനമുള്ള എത്ര ആളുകൾ ഉണ്ട് ?

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9.നിങ്ങൾക്ക് എന്തെങ്കിലും സാമ്പത്തിക ബാധ്യതകൾ (നിലവിലെ ചികിത്സയുമായി ബന്ധമില്ലാത്ത കടങ്ങൾ) ഉണ്ടോ?

1. ഉണ്ട്
2. ഇല്ല

10.ഉണ്ട് എങ്കിൽ അത് വ്യക്തമാക്കുക

……