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DRAFT

NATIONAL ACADEMY OF MEDICAL SCIENCES (INDIA)

DIRECTORATE GENERAL OF HEALTH SERVICES

MINISTRY OF HEALTH & FAMILY WELFARE GOVERNMENT OF INDIA

REPORT OF TASK FORCE $O\mathcal{N}$ ORAL CANCER



NATIONAL ACADEMY OF MEDICAL SCIENCES (INDIA)

REPORT OF TASK FORCE ONORAL CANCER



PREFACE

Oral Cancer is now widely recognized as an important public health issue. Oral Cancer, one of the most debilitating, devastating and disfiguring of all cancers, poses significant morbidity and mortality across the world. With widespread use of tobacco, its chief causative factor, the trend of oral cancer is expected to rise in coming years. Due to its increasing healthcare burden, the oral cancer prevention, screening and management becomes an important aspect needing initiatives on part of the healthcare professionals and policy makers. It is now acknowledged that more concerted efforts are required to address the burden of this problem. The report of the Task Force on Oral Cancer of the National Academy of Medical Sciences, India provides an insight into Oral Cancer as a public health problem along with strategies to diagnose, treat and prevent while providing recommendations to improve upon the availability and delivery of treatment for oral cancer in India.

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LIST OF ABBREVIATIONS

AJCC - American Joint Committee on Cancer

ANM - Auxillary Nurse Midwife

BQ - Betel Quid

CHO - Community Health Officers

CI - Confidence Interval

CRT - Chemotherapy and Radiation Therapy

CT - Computed Tomography
 FNA - Fine Needle Aspiration
 FRLU - First Referral Level Units

JAS - Jan Aarogya Samiti MAS - Mahila Aarogya Samiti

MESUs - Mobile Education-cum-Screening Units
MoHFW - Ministry of Health and Family Welfare

MPWs - Multipurpose Workers

MRI - Magnetic Resonance Imaging

NCCN - National Comprehensive Cancer Network

NCG - National Cancer Grid

NP-NCD - National Program for Non-communicable Diseases

OC - Oral Cancer

OPMDs - Oral Pre-malignant Diseases
OPML - Oral Pre-malignant Lesions

OR - Odds Ratio

OVI - Oral Visual Inspection

PBS - Population-Based Screening
PET-CT - Positron Emission Tomography

PHC - Primary Health Care
PHW - Primary Health Workers

RR - Relative Risk

RT - Radiation Therapy
SHG - Self Help Groups
SLT - Smokeless Tobacco

TNM - Tumor Node and Metastasis

UICC - International Union Against Cancer

VHSNC - Village Health Sanitation and Nutrition Committee

OPERATIONAL DEFINITIONS

- a. **Oral Cancer:** Oral cancer is defined as the cancer of the lip, mouth, and tongue, to include the anatomic description of the oral cavity. This case definition is adopted, and conforms to the definitions of oral cavity cancer by the International Classification of Diseases (ICD) Coding scheme, WHO case definitions and IARC.
- b. **Oral Potentially Malignant Disorder:** Any oral mucosal abnormality that is associated with a statistically increased risk of developing oral cancer (The WHO Collaborating Centre for Oral Cancer Workshop, 2020).
- c. **Screening:** The identification of unrecognized disease by the application of a test to people who are asymptomatic, in order to identify those who probably have the disease and to distinguish them from those who probably do not (UK National Screening Committee, 2003).
- d. **Cancer Screening:** Checking for cancer (or for abnormal cells that may become cancer) in people who have no symptoms is called screening (NIH, National Cancer Institute, USA).
- e. **Substance use disorder:** Involves patterns of symptoms caused by using a substance (such as tobacco, alcohol, etc) that an individual continues taking despite its negative effects.
- f. **Leukoplakia:** A predominantly white plaque of questionable risk having excluded (other) known diseases or disorders that carry no increased risk of cancer (The WHO Collaborating Centre for Oral Cancer Workshop, 2007).
- g. **Erythroplakia:** A predominantly fiery red patch that cannot be characterized clinically or pathologically as any other definable disease (The WHO Collaborating Centre for Oral Cancer Workshop, 2007).
- h. **Oral Lichen Planus:** An autoimmune chronic inflammatory disease of unknown etiology, characterized by the presence of white reticular lesions and/or erosive and/or atrophic lesions (The WHO Collaborating Centre for Oral Cancer Workshop, 2007).
- i. **Oral Submucous Fibrosis:** A chronic, insidious disease that affects the oral mucosa resulting in loss of fibro-elasticity of the lamina propria and ultimately, fibrosis of the lamina propria and the submucosa with epithelial atrophy (The WHO Collaborating Centre for Oral Cancer Workshop, 2007).



EXECUTIVE SUMMARY

Oral cancer is the term described as cancers occurring in the mouthparts that include lips, cheeks, sinuses, tongue, hard and soft palate or the base of the mouth extending up to the oropharynx. Globally, oral cancer ranks seventeenth among all types of cancer in terms of both incidence and mortality. India has the largest number of oral cancer cases in the world and this constitutes more than one-third of the total global burden.

In India, oral cancer ranks as the second most common cancer, and is the number one cancer among males. In India, around 1.3 lakh new cases and >75,000 deaths were reported only in the year 2020, with an expected doubling of incidence by 2040. This burden of oral cancer is further complicated by the late stage diagnosis and low survival rates. In India, majority of oral cancer cases are reported in the advanced stages and hence the chances of cure are very low.

This report provides an insight into oral cancer as a public health problem in India along with etiology, strategies to diagnose, treat and prevent it while providing recommendations to improve upon the availability and delivery of treatment for oral cancer.

The predominant risk factor for developing oral cancer is tobacco consumption. The continual use of tobacco in both smoking and smokeless forms is a major contributor to tumor development in the oral cavity. Other risk factors such as alcohol, diet and nutrition, oral thrush, dental problems, chronic irritation from sharp teeth or ill-fitting dentures, and HPV infection also contribute to the burden. Further, social, cultural, and psychological factors too play an important role in developing oral cancer.

Oral potentially malignant disorders (OPMDs) are a diverse group of conditions which are the precursors of oral cancer. It is important to recognize that a patient diagnosed with an OPMD have an increased risk of developing oral cancer compared to a person with a healthy mucosa. Lesions such as Erythroplakia, Erythroleukoplakia, Leukoplakia, Proliferative verrucous leukoplakia, Submucous fibrosis, Palatal lesions associated with reverse smoking, Oral lichenoid lesions, Oral lichen planus, Smokeless tobacco keratosis, etc are the common OPMDs seen in the country. Oral cancer screenings, which are conducted to identify any clinical premalignant phase (accessible to visual inspection) are usually done on a mass-scale, and shows a decreased burden of advanced oral cancer incident cases and deaths as compared to no-screening. Among the screening strategies, it is suggested that high-risk screening is cost-effective compared to the mass-screening at periodic intervals. Oral cancer screening methods vary across healthcare settings, each with its advantages and limitations. While visual inspection remains a fundamental tool, adjunctive technologies are sometimes used in dental clinics; community outreach programs and telemedicine extends accessibility to screening.

The Ministry of Health and Family Welfare, Govt of India has prepared a universal and objective Operational Framework for Cancer Screening and Management that aims to promote, coordinate, and conduct research to better understand, detect, diagnose, and treat cancer. The framework makes it mandatory to perform screening of oral, cervix and breast cancer for males and females above the age of 30.

Concerning oral cancer treatment, several modalities are available, however, cure depends on the cancer stage when diagnosed and delay in starting treatment. Primary surgery is the preferred modality of treatment for vast majority of operable oral cancers. Radiotherapy is an alternate for early stage oral cancers with comparable control rates to surgery.

Typically, the primary treatment for oral cancer is surgery. The primary goal of surgical resection is to ensure complete removal of the tumor tissue. However, the potential negative impacts on appearance and functionality due to the extent of the disease and the necessary surgical removal stress the importance of using less invasive surgical methods. The National Cancer Grid Management Guidelines for early stage cancer recommends surgical local excision with a minimum of 1 cm gross margin, accompanied by appropriate Neck Dissection and suitable reconstruction. For advanced stages, surgery is preferred along with adjuvant radiotherapy or chemotherapy.

Oral cancer, in its entirety, imposes a significant fiscal burden on a national, institutional, family and individual level. Funding of cancer care in India is a complex mixture of state and government accountabilities, with the government shouldering most of the responsibility. Oral cancer as such has not been given a separate budget in India. But it has been covered under various facilities of the Government, schemes and programs for Cancer.

This report entails the Task Force Committee recommendation for Screening, Diagnosis, Prevention and Management of Oral Cancer along with research, policy, advocacy recommendations to address this immense public health problem in the country.

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INTRODUCTION

"The human spirit is stronger than anything that can happen to it" – Jack Thorne

Cancer, once a poorly understood illness, has emerged as the target of vigorous scientific enquiry and medical advancements. Any uncontrolled growth of cells that invade and cause the adjacent tissue impairment is known as cancer. Oral cancer is the term described as cancers occurring in the mouthparts that include lips, cheeks, sinuses, tongue, hard and soft palate or the base of the mouth extending up to the oropharynx¹. Oral Cancer is regarded as one of the most debilitating, devastating and disfiguring of all cancers. It presents the whole healthcare team with important obligations, challenges and a real opportunity to save life. Oral cancer often begins as a small, unfamiliar, unexplained growth or sore within the oral cavity.

Globally, oral cancer ranks seventeenth among all types of cancer in terms of both incidence and mortality. India has the largest number of oral cancer cases and more than one-third of the total global burden. In India, oral cancer ranks as the second most common cancer, and is the number one cancer among males². Oral cancer care, therefore, poses a serious health challenge to such developing nations undergoing rapid economic transition. In India, around 1.3 lakh new cases and >75,000 deaths were reported only in the year 2020, with an expected doubling of incidence by 2040 based on accounting of demographic changes. The increasing cases of oral cancer become an important public health concern.

This burden of oral cancer is further complicated by the late stage diagnosis and low survival rates. In India, about 70% of oral cancer cases are reported in the advanced stages. Because of detection in the late phase, the chances of cure are very low, leaving five-year survival rates at around 50 percent. Oral cancer incidence from 1990 to 2005 reveals the benefit of public health interventions such as screening demonstrating potential significant reductions in oral cancer incidence. Oral cancer incidence in India has shown a downward trend. However, the reduction is much more dramatic, where there is a much higher prevalence of oral cancer. Early detection and treatment therefore, becomes the key to lower mortality rates and better survival rates for oral cancer patients in the country³.

Oral squamous cell carcinoma (OSCC) dominates among all oral cancer cases, which usually originates in the oral cavity with some discernible oral potentially malignant disorders (OPMDs). Tobacco consumption (both smoking and smokeless forms), chewing areca nut products with or without tobacco, excessive alcohol consumption, unhygienic oral condition, and sustained viral infections including the human papillomavirus (HPV) are some of the chief risk factors for the incidence of oral cancer⁴. Lack of knowledge, variations in exposure, and behavioral risk factors are responsible for a wide variation in its incidence and outcomes⁵.

Back in the 1960s, the oral cancer management guidelines focused primarily on surgical approaches and the treatment of advanced cases. However, a new direction was taken in the perspective of oral cancer in the next few decades which started with the growing recognition of the role of human papillomavirus (HPV) in oropharyngeal cancers. Along with this, the global fleet of health professionals managing the oral cancers turned towards more conservative treatment options for certain cases, such as organ-sparing surgeries and radiation therapy.

Guidelines began to address the importance of multidisciplinary care involving surgeons, oncologists, radiologists, and other specialists. Increased focus on targeted therapies and immunotherapies in advanced cases. However, the real breakthrough happened a decade later when early detection and prevention through routine screenings, especially in high-risk populations became the clarion call of the torch-bearing health professionals of oral cancer. Till today with each new document being published by each health organization is an addition to the herculean task of reducing the mortality and morbidity caused by the oral premalignant lesions and oral cancers.

Over time, there were numerous lateral integrations in varied ways which made battle against oral cancer a multidisciplinary healthcare approach. From primordial to primary to tertiary prevention, each step became a complex continuum of care and a crosslinked framework. Amongst which the most important was the Alma Ata Declaration approach to place people's health in people's hands. Many international organizations initiated awareness campaigns to educate the public about the risk factors, signs, and symptoms of oral cancer. The policy became stronger and advocacy became more challenging. Then came the phoenix Framework Convention on Tobacco Control (FCTC), the international treaty developed by the World Health Organization (WHO) to address the global health epidemic caused by tobacco consumption and exposure to tobacco smoke. The FCTC is considered one of the most significant international public health treaties and provides a comprehensive framework for tobacco control measures adopted by the World Health Assembly in 2003 and entered into force in 2005. The treaty provides a roadmap for countries to implement evidence-based strategies to combat the tobacco epidemic and harm reduction for population health.

With advent of COVID-19 the digital technology has evolved in leaps and bounds in all healthcare sectors including oral cancers. There have been number of innovative ideas for reducing oral cancer burden ranging from mobile applications to artificial intelligence and now quantum computing.

The National Academy of Medical Sciences, India understands the mammoth prevalence of oral cancer in the country and this side of the world and plays a crucial role in various aspects of prevention, awareness, research, treatment, and support. The key roles taken up are advocacy and public awareness, education and outreach, support for patients and caregivers, research and innovation, collaboration and partnerships, surveillance, guidelines and standards. With this policy document we intend to hammer an effective and efficient nail in the coffin of tobacco burden, morbidity and mortality of oral cancer. We thus aim to provide each citizen of India with an affordable and accessible, preventive and health promotive care with regard to oral cancer and achieve the highest possible quality of life.

This high burden of oral cancer cases, increased mortality, lack of awareness, and a higher out- of-pocket expenditure in its care calls for a multipronged and multifaceted action. Apart from strengthening therapeutic efforts, increasing preventive efforts in an aggressive manner through research in various diagnostic adjuncts^{6,7} and screening programs is also essential for reducing the magnitude of the problem. Despite preventive approaches and availability of services, oral cancer burden remains a serious problem at the community level in India. Thus, the present white paper, under the auspices of the National Academy of Medical Sciences discusses the manner in which oral cancer and tobacco use can be tackled better.

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METHODOLOGY

The report of the task force on oral cancer provides an insight into oral cancer as a public health problem along with etiology, strategies to diagnose, treat and prevent it while providing recommendations to improve upon the availability and delivery of treatment for oral cancer in India.

As the experts in the taskforce were from across the country, a virtual mode of conducting the proceedings were agreed upon on mutually agreed upon dates. The task force during the initial meetings developed a consensus on the key themes and sub-themes with a focus on Indian context. Once the themes were identified based on consensus, they were divided which were allocated to technical experts. They reviewed the recent evidence along with current reports and data pertaining to various aspects of oral cancer in India on different databases like Pubmed, Scopus, LILACS, Cochrane using different MeSH terms and synonyms for Oral cancer. Following this the sections were revised and compiled through an iterative process of feedback and discussions while generating consensus of individual panel member opinions on critical issues.

The initial working draft was circulated among the task force expert members, and comments were sought. The working draft was modified based on the suggestions. Subsequently, multiple online meetings were held in which the experts deliberated on the various aspects of the document. Further modifications were made to the document based on the final observations and recommendations received from the experts and finally, the draft was finalized.

SITUATION OF ORAL CANCER IN INDIA

Oral cancer is of significant public health concern in India as it is one of the most common types of cancer affecting a large population. The predominant risk factor for developing oral cancer is tobacco consumption. The continual use of tobacco in both smoking and smokeless forms is a major contributor to tumor development in the oral cavity in both young as well as the adult Indian population thereby affecting all age groups¹.

A gender-based distinction has been for oral cancer cases, where males show a high incidence of tobacco-related cancer².

In India, epidemiologically, Kerala has the lowest incidence of oral cancer while West Bengal reports the highest. In the western regions of the country like in Maharashtra, the highest occurrence of oral malignancy is reported in the age group of ≥ 60 years. Another study from Chennai reported that oral cancer is most prevalent at the base of the tongue which further enhances chances of metastasis³. Other locations reported are buccal mucosa, alveolus, and the base of the mouth for the occurrence of oral cancer⁴. It is also reported that the nutritional diet is important for oral cancer patients to maintain the oral health-related quality of life.

India is now the world capital for oral cancer cases as it shares one-third of the global burden. Southern parts of India present the highest incidence rate of oral cancer. Risk factors such as tobacco, alcohol, diet and nutrition, oral thrush, dental problems, chronic irritation from sharp teeth or ill-fitting dentures etc. play an important role in developing cancer, with poor oral health and HPV infection as the two emerging causes.

The financial burden towards the patient is very high during the treatment of oral cancer and most of the patients leave the treatment midway, which further adds to the mortality rate. The treatment of oral malignancy primarily depends on the location and size of the tumor, and the feasibility of organ preservation in patients. Screening, Early diagnosis, and timely treatment are critical aspects to tackle oral cancer-related burden in India².

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SOCIO-CULTURAL AND ECONOMIC ATTRIBUTES OF ORAL CANCER

"Sociocultural factors refer to a wide array of societal and cultural influences that impact thoughts, feelings, behaviors, and ultimately health outcomes. There are several dimensions encompassed by the term which can include race, ethnicity, ethnic identity, sex, language, beliefs, value systems, attitudes, and religion". There are other factors included under this domain such as socioeconomic status, age, level of acculturation, occupational issues, family structure and intergenerational issues, religious beliefs, and spirituality. The majority of the studies have reported predominantly on behavioral factors and few of the social factors.

Hence a thorough literature review was conducted to explore the reported sociocultural factors in the context of the Indian population. The search yielded 26 articles and 12 other articles were obtained through manual search referring to the bibliography of other articles conducted in the Indian population and reported elsewhere which were both analytical and cross-sectional studies.

The literature review revealed limited recognition of the association between social, cultural, and psychological factors and oral cancer despite an abundance of literature on these factors being responsible for inequalities in health. The search also revealed limited descriptive and analytical studies related to oral cancer and associated factors, but the emphasis was more on behavioral factors with tobacco consumption as the primary factor. Since cross-sectional studies do not give the true picture of association, we have emphasized predominantly the results from analytical studies.

Socioeconomic status: The published work on the relationship between socioeconomic status (SES) and oral cancer has mainly been in the form of cross-sectional studies. From such studies, increased risk of oral cancer appears to be associated with lower socioeconomic status as compared to higher class and an inverse association between education level and oral cancer¹. Similar results have been reported with an OR of 6.5 in South India and an OR of 3.4 in North India². Very few studies have reported on the totality of the SES scale, rather individual measures were reported³. However, studies from Bhopal⁴ and Jharkhand⁵ have reported no association between education and oral cancer with an OR of 1.0 at 95% CI.

Income has also been reported to be associated, with lower income and higher chances of oral cancer (OR 2.41) lower occupational class (OR 1.84), and lower education (OR 1.85)³. The socioeconomic perspective has been shown to be a potential major risk factor in the etiology of oral cancer, by being recognized as the cause of the cause'. Low education comes with a lack of awareness, which is confirmed as a risk factor for oral cancer⁶.

Age: Oral cancer has traditionally been considered as a disease mainly affecting the older age group with a substantial portion of people of older ages, and a proportion of cases arising between 30 and 40 years. The age-standardized incidence and mortality rates for lip and oral cavity cancer were 9.8 and 5.4 respectively per 100,000 population in the world scenario, whereas it was 10.3% of new cases in India⁷. The age groups of 41 to 50 years had the OR 1.63 and 51 to 60 years had the OR of 1.798. The age of initiating the habit of tobacco consumption is before the age of twenty9 with the lowest being reported as 15 years¹⁰.

Gender: Oral cancer has been reported to be the most common cancer among males in the Indian subcontinent¹⁰. The incidence of lip and oral cancer among males is 16.2 and for

females is 4.6 per 100,000 population⁷. The pooled data from the registries reports on new cases amongst males to be 679421 and females is 712,758.¹¹ The age-standardized incidence and mortality rates are 14.8 for males and 4.6 for females per 100,000. The odds of developing oral cancer among men was 2.49,⁸ whereas when it comes to tobacco consumption in all forms, women were in higher percentage (90%) as compared to men (59%) and OR of 42.4 and 5.1 respectively,⁹ though women were reported to start consuming tobacco at an early age than men.¹²

Geographical location: The central region of India was found to have the highest incidence of oral cancer,¹⁰ which includes four states (Rajasthan, Uttar Pradesh, Madhya Pradesh, Chhattisgarh). The largest difference was observed in central India with OR 5.0 (3.6-7.0) and south India OR 3.8 (2.9-5.1).² Oral cancer incidence increases with age with typical pattern of cancer of associated sites of oral cavity seen in the northeast region (Cachar district, Kamrup urban, Manipur, Mizoram, Nagaland, Meghalaya, Sikkim and Tripura). Oral cancer was maximum in the central region among males (64.8%) in the 70 to 75 year age group followed by AAR in northeast and west regions of India (58.4%) in 60 to 69 year age group.¹⁰ The total tobacco consumption in rural areas of country is 38.4% compared to urban areas with smoking prevalence of 25.3%.¹³

<u>Cultural Factors</u>: Since time immemorial, tobacco and areca nut consumption has been indigenous and socially and culturally acceptable in India. Betel quid chewing has cultural and traditional significance among the Indian population. It is consumed during religious meetings, events, celebrations, and festivals Irrespective of age group, gender, and SES. Betel quid is a mixture of areca nut and slaked lime wrapped within betel leaf to which tobacco, spices, and sugar are added and is optional. Areca nut and tobacco consumption have been recognized as a known risk factor for oral leukoplakia, oral sub-mucous fibrosis, and oral squamous cell carcinoma. Migration studies have reported on 2 times and 5 times risk for oral cancer mortality for men and women respectively than the native English and Welsh. 15

<u>Tobacco consumption</u>: Tobacco consumption in all forms has been identified as a key risk factor. Various risk factors discovered in various Indian studies include smokeless tobacco, Gutka, Khaini, Zarda, Bidi, Betel quid, Mishri, Paan, Supari, with a hierarchy of risk with gutkha (OR = 12.8), chewing tobacco (OR = 8.3), supari (OR = 6.6), bidi (OR = 4.1), and mishri (OR = 3.3). When compared to control groups, a relatively high percentage of cases (42.9%) had the practice of retaining quid in mouth, and this finding was determined to be highly statistically significant (Odds Ratio = 18 (CI 5.88 OR 61.65). One of the key predictors of incidence is the average duration between tobacco and tobacco produc t consumption. Multiple epidemiological studies showed that the incidence of oral cancer varies considerably between different parts of the world with the highest levels in the Indian subcontinent.

<u>Alcohol consumption</u>: Alcohol consumption is a known risk factor for oral cancer contributing to 75% of oral cancer in Western countries both individually and when consumed with tobacco.¹⁹ Such figures are not available for Indian population but alcohol as a risk factor has been reported. At the same time, the possibility of alcohol consumption with Oral Submucous Fibrosis with OR 2.1 (95% CI, 1.0-4.4) was reported.²⁰ The habit of drinking and consuming tobacco simultaneously increased with age predominantly among 30 to 69 years of age group.²¹

Alcohol consumption appears to be linked to tobacco use as well, as drinking increases the odds of smoking and chewing tobacco by two times. According to studies, smoking is a gateway to drinking alcohol, and those who smoke have a much higher risk of doing so than those who don't. Studies have shown that consumption of both tobacco and alcohol is more addictive and increases the risk of developing oral cancer as compared with tobacco use alone.²²

Smoked tobacco: Bidis and cigarettes are the two popular forms of smoked tobacco, of which Bidis are smoked majorly by the poor with cost being less than 5th of the cost of cigarettes. The age adjusted relative risk for bidi smokers was 1.64 (95% CI 1.47 to 1.81) and increased risk from 1.42 (95% CI 1.20 to 1.68) to 1,78 (95% CI 1.57 to 2.02) with increasing number of bidis per day.²³

Areca nut: Areca nut has recently been identified as a risk factor for oral cancer though its beneficial use has been reported in food, medicine and socio-cultural customs.²⁴ Despite limited documentation on its benefits, the principal alkaloid, arecoline, triggers stimulation within the nervous system, providing subjective enhancements like heightened well-being and alertness.²⁵ The meta-relative risk (RR) generated from 13 studies from India, summarized a relative risk estimate of 2.41 (95% CI, 1.82-3.19) with a moderate level of heterogeneity (I2=65%). When restricted to studies that adjusted for tobacco smoking, the RR for BQ was 2.94 in the Indian subcontinent. Restricting the analysis to nonsmokers, the RR for BQ was 20.21 2.20 in the Indian subcontinent. The RR was much higher in women (RR = 14.5, 95% CI, 7.63 - 27.76) than men in India for the consumption of betel quid.¹⁴ The carcinogenicity of betel quid is well established^{26,27} with risk in betel quid chewers without tobacco 6.6 (3.0 to 14.8).¹⁶

The risk of developing OPMD among betel quid chewers was; leukoplakia 4 (2.7 to 6.1), Oral Submucous Fibrosis 47.2 (20.2 to 110.4), Erythroplakia 12.5 (1.6 to 19.2)26 and OPMD as a whole was 5.5 (1.6 to 19.2).²⁸

<u>Dietary factors</u>: Fresh fruits and vegetables consumption was more in controls compared to cases.¹ The OR for betel quid containing raw tobacco and areca-nut was 35.25 with OR of 0.22 for vegetarian diet.

Sociopolitical Factors: There are around 200 million users in India representing about two-thirds of global SLT users with more than 350000 people dyeing due to SLT related diseases. Alarming is the fact that we are the largest producers of tobacco both in crops and in the form of products.²⁹ The predominant reason being the availability of SLT products in informal markets (homemade, unregulated, untaxed products) markets and the brand stretching and brand sharing strategy of SLT industry.³⁰ Since manufacturing bidi is a small-scale cottage industry and home-based activity, close to 10 million people are employed from the vulnerable and underprivileged groups, which has the risk of exposing the employees to tobacco during the manufacturing process. Most of the SLT products are made for single use thus making them inexpensive and challenging for tax administration.^{23,31,32}

<u>Other Factors</u>: The role of peer influence, role models, family history of tobacco, valuing tobacco as medicine, traditionally acceptance has other sociocultural factors³³ and residence, marital status, caste, religion, material deprivations have been reported as major social determinants of tobacco use.³⁴ There are several studies which shows the influence of

sedentary life style, family history of cancer on delayed seeking consultation. Fear of treatment, lack of access to quality healthcare, and time constraints were other major factors reported.³² These factors have been established through cross-sectional studies, hence scope for further analytical studies is needed to support this literature.

In conclusion, our present report offers an overview on the risk factors and oral cancer among Indian population with tobacco consumption emerging as a major risk factor and each of the gender being at risk either for initiating the habit early or for manifestation. Aggressive programs aimed at all age groups, genders and socioeconomic class for prevention of tobacco use and geographic location specific policy initiative owing to differing use of tobacco products may be the need of the hour.

A table depicting studies confirming the association of tobacco types and alcohol with oral cancer as per the literature reported from Indian studies is mentioned in Annexure 1.

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ORAL POTENTIALLY MALIGNANT DISORDERS AND ORAL CANCER

Oral potentially malignant disorders (OPMDs) consist of a diverse group of conditions with an increased risk of malignancy. The term OPMD was introduced in 2007 following a collaborative meeting led by the WHO Collaborating Centre for Oral Cancer. Recognizing that late-stage oral cancer is linked with poorer prognosis compared to cases detected in their early stages, considerable emphasis is placed on identifying oral cancer at a nascent stage—ideally prior to invasion—when the abnormality is still an OPMD.

It is important to recognize that a patient diagnosed with any of these OPMDs have an increased risk of developing oral cancer compared to a person with a healthy mucosa. The risk of malignancy in a patient with an OPMD can fluctuate based on multiple factors, and it has been approximated to be between 5 to 100 times higher than the risk in the general population.

Major risk factors for prevalent OPMDs are comprehensively delineated in the literature. These encompass the use of tobacco in both smoked and smokeless forms, excessive alcohol consumption, and the practice of chewing betel quid containing area nut. While the potential involvement of human papillomavirus has been deliberated, its role needs to be further explored. The following entities are included in the 2022 WHO classification of OPMD:

- 1. Erythroplakia
- 2. Erythroleukoplakia
- 3. Leukoplakia
- 4. Proliferative verrucous leukoplakia
- 5. Submucous fibrosis
- 6. Palatal lesions associated with reverse smoking
- 7. Oral lichenoid lesions
- 8. Oral lichen planus
- 9. Smokeless tobacco keratosis
- 10. Oral graft versus host disease
- 11. Lupus erythematosus
- 12. Familial cancer syndromes including Fanconi anemia, dyskeratosis congenita, xeroderma pigmentosum, Li Fraumeni syndrome, Blooms syndrome, ataxia telangiectasia and Cowden's syndrome.¹

Oral Leukoplakia: Leukoplakia is defined as "White plaques of questionable risk having excluded (other) known diseases or disorders that carry no increased risk for cancer" - WHO Collaborating Centre (2007). Oral leukoplakia is recognized as the most prevalent OPMD. The average worldwide occurrence of leukoplakia spans from 1% to 4%; however, notably higher rates are documented in South-Eastern Asia. While leukoplakia is more frequently observed in males, women face an elevated risk of malignant transformation.

In terms of their clinical presentation, leukoplakias are categorized as either homogeneous or non-homogeneous. Homogeneous leukoplakia manifests as a primarily white lesion that is uniformly flat and possesses consistent texture. The majority of leukoplakias (90%) exhibit homogeneity. In contrast to non-homogeneous leukoplakias, these homogeneous forms have a lower likelihood of undergoing malignant transformation. Non-homogeneous leukoplakia, on the other hand, can display a combination of white and red speckled surface (Figure 5.1).

This type of leukoplakia might have an irregularly flat, nodular, verrucous, or ulcerated appearance.

Erythroplakia: Erythroplakia is uncommon, with a prevalence of less than 0.1% with higher malignant transformation rate than leukoplakia. Erythroplakia is a thin, or slightly depressed, red patch of the oral mucosa and is less common than leukoplakia. Erythroplakia is much more likely to be associated with high-grade dysplasia or carcinoma (>90%) in comparison to leukoplakia (Figure 5.2).

Proliferative verrucous leukoplakia: Hansen et al defined PVL as Leukoplakias that tend to spread and become multifocal. PVL occurs predominantly in elderly women with a mean age of 66.8 years. Gingiva and alveolar ridge are the most frequently involved sites followed by the buccal mucosa, tongue. PVL is slow growing, persistent, and irreversible, and in time areas become exophytic and wart like. Initial lesions in PVL patients are often indistinguishable from oral lichen planus and homogeneous oral leukoplakias, forming smooth to fissured/ verruciform or verrucous white or mixed white and red patches usually without ulceration. Multiple non-contiguous lesions or single lesion >40 mm involving one site; or single lesion >30 mm involving contiguous sites are characteristic. Thick, verrucoid marginal gingival leukoplakias that encircle the tooth especially when multifocal are characteristic of PVL.

Histology (Leukoplakia, Erythroplakia, Proliferative Verrucous Leukoplakia): The histo-pathological evaluation of Oral Epithelial Dysplasia (OED) vary between OPMDs and is considered to be one of the most critical factors in risk assignment and determination of prognosis. OED is a spectrum of architectural and cytological epithelial changes resulting from accumulation of genetic alterations. OED can be diagnosed on the basis of architectural or cytological features alone.

Traditionally OED is divided into three grades of severity and judging the number of thirds affected is one factor in assigning grades. Architectural and cytological atypia usually increases in higher grade lesions, with mild dysplasia characterized by cytological atypia limited to the basal third, moderate dysplasia by extension to the middle third, and severe dysplasia by extending to the upper third. However, defining dysplasia grade only in this manner oversimplifies the complexity of grading. Cytological atypia confined to the basal third may be sufficient for a diagnosis of severe dysplasia depending on individual features present, particularly bulbous rete processes, budding and disorganization of basal cells, and marked cytological atypia. Similarly, a lesion with a verrucous or papillary surface with only mild atypia may be considered to be a high-risk lesion. Histological features of PVL reflect the clinical appearance as early lesions show keratosis, often without dysplasia. Lichenoid/interface mucositis features may be present in early PVL cases. These gradually develop the typical verrucous morphology. Further progression to corrugated hyperkeratotic to proliferative stage and ultimately to malignancy can be seen.

Corrugated hyperkeratotic lesions exhibit verruco-papillary or disproportionate flat hyper ortho-/parakeratosis with minimal or no dysplasia. Skip areas of normal to abnormal to normal is a common finding. A sharp abrupt transition from adjacent unaffected normal epithelium is usually seen (Figure 5.3). Proliferative bulky epithelial lesions demonstrate atypical, hyperkeratotic epithelial architecture with/without dysplasia. Both an exophytic and endophytic growth pattern can be present and the epithelium shows bulbous rete pegs that sometimes coalesce. Histopathology alone is not able to provide a risk assessment of the

disease. Recent applications of more sensitive risk assessments include assessment of the DNA ploidy status - aneploid lesions indicate a higher risk.

<u>Oral Submucous Fibrosis</u>: "Oral submucous fibrosis (OSF) is a chronic, insidious disease characterized by progressive fibrosis of submucosal tissues of the oral cavity and the oropharynx with a risk of transformation to SCC". It is common in South Asian countries where the betel quid habit is prevalent. Malignant transformation rate has been found to be 7.6%. Clinical features include burning mouth, depapillation of the tongue, blanching, and leathery mucosa. Later stages shows development of fibrous bands.

Early stages showed hyperplastic epithelium to atrophy with loss of rete ridges in later stages. Epithelial dysplasia can be noticed with the progression of the disease. Budding Changes in the submucosa at early stage are minimal with slightly increased vascularity, inflammatory infiltrate, and increased fibrillar collagen and collagen fiber bundles with interspersed fibroblasts. Later the collagen becomes homogeneous, starting superficially with juxtaepithelial hyalinization. Advanced cases show loss of vascularity, hyalinization of collagen, dense fibrosis extending to underlying tissues with muscle degeneration and complete replacement of loose connective tissue (areolar and reticular tissue) by fibrous tissue (Figure 5.4).

Oral Lichen Planus (OLP) and Oral Lichenoid Lesion (OLL:) The lack of clarity with the definitions of OLP and OLL has caused much of the controversy. Oral Lichen planus is defined as "A chronic inflammatory disease associated with cell-mediated immunological dysfunction." Oral lichenoid lesion is defined as "oral lesions resembling lichen planus but lacking typical clinical or histopathological appearances." The histological distinction between some cases of OLP and OED with interface mucositis can be difficult. OLL includes atypical OLP, e.g., unilateral lesions, lesions in close proximity to a dental restoration, lichenoid drug reaction, oral lesions developing after the intake of specific substances and the oral lesions of graft vs. host disease. Until recently, most studies assessing malignant transformation in OLP and OLL included cases with dysplasia, which is likely to have led to an overestimate of their malignant potential. Currently, most pathologists agree that if a biopsy shows clear evidence of OED, OLP is excluded.^{2,3}

<u>Oral Squamous cell carcinoma:</u> Oral cavity cancer is the sixth most prevalent cancer worldwide, with squamous cell carcinoma accounting for 90% of cases. Despite advances in treatment, oral squamous cell carcinoma is associated with high morbidity, tumor recurrence, and a low-rate survival rate. OSCC can arise from any oral mucosal site In South-Central Asia, OSCC most commonly affects the buccal mucosa because of the prevalence of areca nut/betel quid habit.

Patients with OSCCs may be completely asymptomatic, particularly at early stage, whereas advanced tumors are associated with pain, alteration in sensation, restriction of tongue movement or swallowing. OSCCs may appear as white, red, or mixed, flat/nodular/mass lesions of varying size. When present, advanced ulcers often have a raised and rolled margin, however early OSCC can manifest as deceptively innocent appearing lesions. Other clinical findings may include tissue fixation and induration, mobility of teeth, trismus, bone destruction and pathological fracture, dependent on the localization of the neoplasm.

OSCC is associated with tobacco smoke, alcohol consumption, and human papillomavirus infection. Poor general oral health and diets lacking in fruits and vegetables may act as contributory factors to oral SCC incidence and poor clinical outcomes.

OSCC may be preceded by oral potentially malignant disorders such as leukoplakia, erythroplakia, and oral submucous fibrosis (OSMF). Majority of OSCC are genetically unstable and exhibit significant chromosomal alterations and high somatic mutation burden. Chromosomal losses at 3p, 8p, 9p, and 17p with gains at 3q, 5p, 8q and 11q are reproducibly observed. Several large scale sequencing studies have defined the mutational landscape for OSCC with somatic mutations being observed in a number of genes including TP53, CDKN2A, FAT1, NOTCH1, KMT2D, CASP8, AJUBA, NSD1, HLA-A, TGFBR2, USP9X, MLL4, HRAS, UNC13C, ARID2 and TRPM3.

The majority of oral cavity and mobile tongue cancers take the form of conventional keratinizing squamous cell carcinoma (SCC). Nevertheless, there are other infrequent subtypes that can arise, including Acantholytic SCC, Adenosquamous carcinoma, Basaloid SCC, Carcinoma Cuniculatum, Lymphoepithelial carcinoma, Papillary SCC, Spindle cell SCC, and Verrucous SCC (Figure 5.5). Well-differentiated SCC contain large nests, cords and islands of cells with pink cytoplasm, prominent intercellular bridging, with round, often hyperchromatic, nuclei. Squamous pearls and dyskeratotic cells are also prominent.

Higher grade neoplasms may demonstrate marked nuclear and cellular pleomorphism, nuclear hyperchromasia, mitotic figures (including atypical forms), and small islands or individual cells can be observed at the invasive front. Desmoplastic stroma with various degrees of inflammation can be found around invading tumor cell nests and islands. Perineural and lymphovascular invasion may occur, generally in poorly differentiated high-grade tumors. Adjacent mucosal epithelium may show various grades of dysplasia. Grading alone does not correlate well with prognosis. However, a number of specific features may have important biological relevance.^{3,4,5}

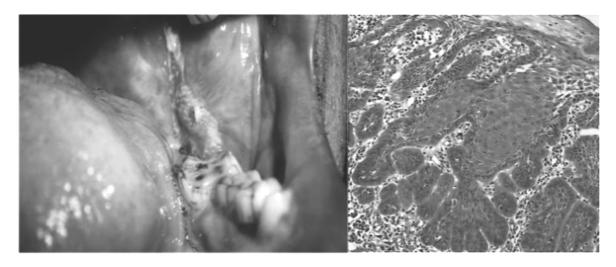


Figure 5.1: Speckled leukoplakia with histology of high risk dysplasia.

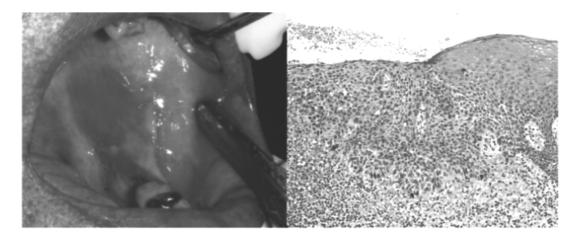


Figure 5.2: Erythroplakia with histopathological features of abrupt transition from normal epithelium to severely dysplastic epithelium.

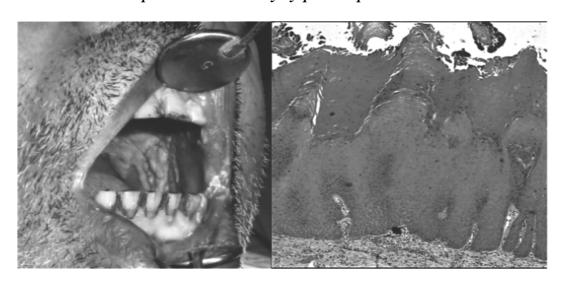


Figure 5.3: Proliferative verrucous leukoplakia with histopathological features of corrugated ortho(para)hyperkeratotic lesion, not reactive.

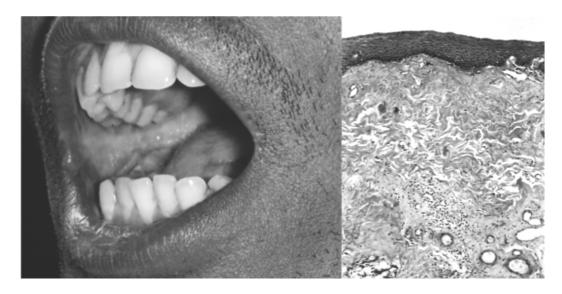


Figure 5.4: Oral Submucous Fibosis with histological features of dense collagen ber bundles and epithelial atrophy.

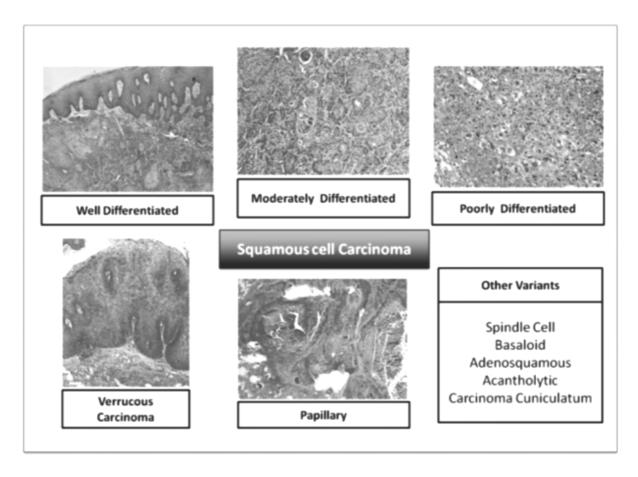


Figure 5.5: Histopathological subtypes of oral squamous cell carcinoma.

(*Picture Credits: Prof Vinay K Hazarey and Dr Deepika Mishra*)

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ORAL CANCER SCREENING IN DIFFERENT SETTINGS

Oral cavity cancer is often preceded by a clinical premalignant phase accessible to visual inspection. Thus, there are opportunities for early detection to reduce morbidity and mortality due to oral cavity cancers. The only Randomized Controlled Trial (RCT) on oral cavity screening is from Trivandrum, India. This trial demonstrated efficacy of Oral Visual Inspection (OVI) conducted by trained health workers in reducing mortality due to oral cavity cancers among high risk population i.e. those using tobacco and/ or alcohol.¹ Thus OVI i.e. systemic oral visual inspection under a bright light source and palpation and evaluation of the neck for any enlarged lymph nodes is the screening tool used in most programs and studies to detect abnormal oral findings - oral cavity cancer or Oral Pre-malignant Diseases (OPMDs).²

Different Settings and Health Care Personnel for Oral Cavity Screening: Oral cavity screening can easily be conducted in various settings such as primary care, dental clinics, and community outreach programs in urban, rural, tribal communities, workplaces and also among special population groups.

1. <u>Primary Care Settings</u>: Primary care Physicians play a crucial role in detecting OPMDs and oral cavity cancers during routine check-ups. OVI remains the most common screening method. Research by Speight and Khawaja (2019) highlights the importance of training primary care providers in recognizing early signs of oral cancer, leading to improved detection rates and patient outcomes. However, limitations include the relatively low sensitivity and specificity of visual inspection alone.³

Under the National Program for Prevention and Control of Non-communicable Diseases (NP-NCD, 2023) population-based screening of persons aged 30 years and above for oral cavity cancer by Community health officers (CHO) and associated team (ANM/MPWs) at the Subcentre/ Sub-health centre-Health and wellness centre (SHC-HWC) has been incorporated in the operational guidelines.⁴

- **2.** <u>Dental Clinics</u>: Dental professionals are well-positioned to identify oral cavity lesions and contribute to early cancer detection. A systematic review by Patton et al. (2018) on adjunctive techniques for oral cancer examination and diagnosis concludes that there is lack of evidence to either endorse or disprove the use of adjuncts based on visual examinations. Thus, Clinicians should depend on a comprehensive examination of the oral mucosa, accompanied by specialized consultation and/or conducting a tissue biopsy when diagnosing OPML.⁵ Regular dental visits further facilitate the monitoring of suspicious lesions over time.
- **3.** <u>Community-based Outreach Programs:</u> In underserved communities, community outreach programs provide a platform for raising awareness and conducting screening. Study by Sankaranarayanan et al. (2019) emphasizes the effectiveness of utilizing trained community health workers for oral cancer screening in resource-limited settings. Community health workers use simple visual inspection techniques and refer screen positive cases for further evaluation. This approach ensures greater reach and early detection in populations with limited access to healthcare facilities. Feasibility of implementing screening in communities has been demonstrated in both urban and rural settings. However, linkages to referral, diagnostic and treatment facilities need to be ensured.

Tata Memorial Centre under their Rural Outreach Program (TMC-ROP 2003-2012), carried out systematic cancer awareness and screening activities in rural districts of Maharashtra's Konkan area through mobile education-cum-screening units (MESUs). Preliminary examinations were conducted at the village level by trained health workers and screen positive cases received confirmation of the diagnosis at their village through mobile first referral level units (FRLUs). The diagnosed cases received treatment at the designated Nodal hospital within the selected districts.^{6,7}

A community-based program for awareness and screening of oral cavity cancers was conducted among women residing in low socioeconomic areas of Mumbai. Screening was conducted by oral visual inspection by trained primary health workers (PHWs). This study helped in identification of factors that influence adherence to oral cavity screening. Additionally, it highlights the effectiveness of various strategies in achieving high compliance rates, including conducting multiple home visits, extending personal invitations during health camps, implementing structured Health Education Programs, and utilizing a cost-effective visual inspection test administered by trained Public Health Workers (PHWs).8

Another community-based cancer awareness and screening program was conducted among urban women in Mumbai, India. Twelve slum clusters comprising of 138,383 population and 13,492 tobacco-using women were covered, and many oral precancers and cancers were detected and treated.9

4. Workplace based Programs: Occupational health programs have incorporated awareness, risk factor assessment, tobacco cessation and targeted oral cancer screening to detect early pre-cancers and cancers at workplaces. In study conducted among the 400 cab drivers in Mumbai, 255 (63.8%) were tobacco users and majority consumed smokeless forms. All the cab drivers examined by OVI. This led to detection of 112 oral precancerous lesions and one cab driver with invasive oral carcinoma.¹⁰

A community-based oral cancer screening program conducted in municipal corporation wards of Mumbai city suggests the need of oral cancer screening along with tobacco cessation and control programs in manual laborers, as the prevalence of tobacco use is high among this group. In this program 256 participants were screened for oral cavity cancers and 23 oral pre-cancers were diagnosed.¹¹

With the smoke free public places legislation that was implemented during 2nd October 2008, smoking has been prohibited on public transport bus premises in India. A Mumbai based study conducted on 4000 public transport bus drivers, conductors and other staff showed that the prevalence of tobacco uses and oral pre-cancers was high among the public transport bus employees in Mumbai. Hence, it was recommended that awareness, oral cavity screening and tobacco cessation counseling needed to be incorporated within annual health check-up of public transport bus employees.

Workplace environments offer the potential to create opportunities and facilitate access to tobacco prevention initiatives. A single group study conducted at workplace to evaluate tobacco use prevention and cessation through a structured three stage intervention program for tobacco users comprising education on harmful effects of tobacco, oral cancer screening and behavior therapy for tobacco cessation at the worksite for confectionary factory employees located in Mumbai, India demonstrated good acceptance and participation by

workers and the initiative was welcomed by employers for overall health benefits. It also set a momentum for an effective tobacco free policy for the company.¹⁴

Following a one-year workplace tobacco cessation intervention, there was an observed regression of oral precancers in 80% of cases. This demonstrates the effectiveness of combining oral cavity screening with tobacco cessation efforts in a workplace setting.¹⁵

- **5.** Rural and Remote Communitie:s Community-based oral cancer screening programs addresses disparities like lack of access to comprehensive healthcare services. Oral cancer screening is feasible and implementable. Oral cancer screening study conducted by Shankarnarayan et al. in Kerala, demonstrated positive predictive value of one percent and the program sensitivity for detection of oral cancers of 76.6% with specificity of 76.2%. ¹⁶
- **6.** <u>Tribal and Indigenous Populations</u>: Tribal and indigenous communities may have distinct cultural and linguistic barriers that impact healthcare utilization. Collaborative initiatives such as engaging community leaders and incorporating culturally sensitive education materials have shown benefits.

Healthcare providers' perspectives at the primary healthcare (PHC) level regarding the practicality of introducing a cost-efficient cancer screening initiative, with a specific focus on underserved rural and tribal regions lacking adequate access to cancer services, was assessed in the study done in tribal block of Maharashtra. The study recommended the need of continuous support of primary care providers during the actual implementation of the program along with training and the establishment of feedback mechanism from tertiary care to enhance the engagement of the providers in patient management.¹⁷

7. **Special Populations:**

- a. Oral Cancer Screening among School Children: A tobacco cancer awareness program conducted among school children in rural areas of Ratnagiri district of Maharashtra State in India demonstrates the effectiveness of increased awareness about the adverse consequences of tobacco use and cancer among school children. Subsequent research is required to assess whether educating school children influences the broader community's comprehension of this disease.¹⁸
- b. *Oral Cancer Screening in Street Populations:* Street populations, including the homeless and those with unstable housing, face unique challenges that hinder access to healthcare services, including oral cancer screening. Innovative outreach initiatives have been developed to address these barriers.
- c. *Correctional Facilities*: Oral health services in correctional facilities are often limited. Implementing oral cancer screening within these settings can contribute to early detection and treatment.
- d. *Refugee and Immigrant Communities:* Refugees and immigrants often encounter challenges related to language, cultural differences and unfamiliarity with the local healthcare system. In a study conducted by Lucy L about betel nut usage among the refugees, 48 participants with betel nut familiarity were interviewed. Majority of them were south and Southeast Asians. This study illustrated that there were gaps in understanding about usage of betel nut and its consequence on health.¹⁹
- **8.** <u>Tele-dentistry and Telemedicine</u>: Advancements in telehealth have paved the way for remote oral cancer screening. Tele dentistry and telemedicine enable healthcare providers to conduct preliminary assessments and offer guidance to patients in real-time. A systematic

review by Estai et al. (2020) highlights the potential of tele dentistry in enhancing access to oral health services, particularly in rural and remote areas. While not a replacement for inperson examinations, telemedicine platforms can aid in triaging patients for further evaluation.²⁰

- **9.** National oral cancer screening program undertaken in Taiwan: Taiwan is the only country in the world to initiate a sustained national oral cancer screening program. Screening is currently offered to high-risk groups, that is, betel quid chewers (including ex-chewers) and smokers. This was the first study to use risk-stratification modeling to target high-risk patients.²¹
- **10. NP-NCD Program incorporating oral cavity screening in India:** National program for prevention and control of Non communicable diseases was launched in 2010 being implemented under National Health Mission (NHM). Operational guidelines have been laid for the year 2023-2030.⁴ The goal is to provide assistance for Program management and capacity building of health practitioners at all levels of primary and secondary healthcare. The Population-Based Screening (PBS) and Opportunistic screening of common NCDs and Common cancers including cancer of oral cavity was initiated in 2016, and was scaled up in a phased manner.

Oral cancer screening services are undertaken at the sub-centre level by Community health officers (CHOs) and appropriate referral system has been strengthened. Activities and interventions at various levels by individuals, Community level forums like Village Health Sanitation and Nutrition Committee (VHSNC)/ Mahila Aaarogya Samiti (MAS), Jan Aarogya Samiti (JAS), Self Help Groups (SHG) and local bodies in both rural and urban areas need to be strengthened and established as a platform for community awareness and promotive and preventive care activities. Frontline workers, ASHA, Multiple Purpose Workers/Auxiliary Nurse Midwife (MPW/ANM) need to develop skills for primary, basic diagnostic and community level preventive care for NCD related issues.

Oral cancer screening methods vary across healthcare settings, each with its advantages and limitations. While visual inspection remains a fundamental tool, adjunctive technologies are sometimes used in dental clinics; community outreach programs and telemedicine extends accessibility to screening.

Collaborative efforts between primary care physicians, dental professionals and community health workers are essential to ensure comprehensive oral cancer screening. Combining the strengths of these different approaches holds the promise of earlier detection, better patient outcomes and ultimately a reduction in the global burden of oral cancers.

Evidence and guidelines: The only RCT for oral cancer screening from India showed reduction in mortality from oral cancers among high-risk individuals 35 years and older when they received three rounds of screening by oral visual inspection (OVI) conducted by trained health workers at 3-year intervals. This trial suggests that OVI conducted by well trained health workers among individuals \geq 35 years and are tobacco and/ or alcohol users at three yearly interval is beneficial. ¹⁶

Under the current National Program for Prevention and Control of Non-communicable Diseases (NP-NCD, 2023) population-based screening of persons aged 30 years and above for oral cavity cancer by Community health officers (CHO) and associated team

(ANM/MPWs) at the Sub-centre/ Sub-health centre-Health and wellness centre (SHC-HWC) has been incorporated in the operational guidelines.

In the National Program for Prevention and Control of Non-communicable Diseases (NP-NCD, 2023) Community Health Officers (CHO) and associated team (ANMs/MPWs) would provide primary level care at the Health and Wellness Centres (HWC) in rural areas while a dedicated Medical Officer (MO) would be posted at Urban HWCs (UHWCs) to undertake screening for individuals ≥ 30 years at 5 yearly interval.⁴

According to the Cochrane review there is not enough evidence to decide whether screening by OVI reduces mortality due to oral cancers though there is some evidence that it might help reduce death rates in patients who use tobacco and alcohol and there is no evidence for other screening methods for oral cancers.²²

Based on all the above literature, oral cavity cancer screening is suggested at least for individuals using tobacco and/or alcohol and ≥ 30 years at three yearly interval, by any well trained medical or paramedical personnel.

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<u>CURRENT EVIDENCE ON ORAL CANCER - HEALTH ECONOMIC</u> <u>EVALUATION OF SCREENING TOOLS</u>

A recent review of economic evaluation of oral cancer screening programs¹ revealed that there is still limited evidence on population-based screening approaches and their cost-effectiveness which limits institutionalization of those measures at scale by the policy makers. The review of 6 studies included study designs randomized controlled study, retrospective observational study, decision analytic model and Markov state transition model and explored the initiation of screening population between the ages of 35 to 40 years. Some countries such as Taiwan has integrated the screening through biennial oral mucosa examination for its high- risk population within its public health care² whereas some countries like USA followed annual screening of high risk population.³

The programmatic cost components included training, recruitment, the screening process, administrative work, and the provision of educational messages in the randomized control study in India.⁴ Some studies included extensive direct and indirect medical costs.⁵ The total societal cost included research, diagnostics, treatment, and loss of patient productivity. The costing excluded the program development and management costs. The outcomes evaluated in these studies were over a year and also considering a lifetime horizon to assess the impact of screening initiatives on the variable malignant transformation rates (MTR) of OPMD to be established over the life span of patients. Another approach estimated the long-term outcomes by calculating the equivalent lives saved according to a 25-year life expectancy and changes in quality- adjusted life years (QALYs).⁶

Another recent study in India⁷ evaluated the cost-effectiveness of commonly used screening techniques, namely conventional oral examination (COE), toluidine blue staining (TBS), oral cytology (OC), and light-based detection (LBD) devices like Velscope, ViziLite plus in the Indian scenario through economic modelling of population (>30 years). The screening intervals considered were 3, 5 and 10 years for each screening strategy and compared with the no screening cohort. The cost of screening strategies was estimated using the time, salary cost and effort by auxiliary nurse midwifery, the number of screenings per day, and the cost of consumables used. Support activities costs included invitation and organization for the screening, administration, registration, training, supervision, and miscellaneous activities required for the screening process. The cost of diagnosis was estimated considering the standard protocol of oral examination, i.e., the cost of consultation during outpatient department visits and the biopsy cost.

The outcomes considered were incidence of oral cancer, oral cancer deaths averted, the total cost incurred, total QALYs gained, and ICER for various screening techniques and at different intervals. The results showed that mass-screening/ high-risk screening had a lesser number of oral cancer incident cases and oral cancer deaths as compared to no-screening. Among the screening strategies, it was observed that high-risk screening was cost-effective compared to the mass-screening at various intervals. The no-screening arm had the maximum number of new cases (5674) and deaths (1180). Mass-screening techniques (number of incident cases), namely LBD 3 years (3272) had the least number of incident cases, followed by OC 3 years (3277), and COE 3 years (3310) and averted deaths (450).

The no-screening arm incurred lifetime cost of 2,677,683.84 US\$ (per 100,000 population) while high-risk screening incurred lesser costs across all comparisons. Amongst various

screening techniques, COE HR 10 years incurred the least lifetime cost 2,292,779.25 US\$ and OC 3 years 7,284,185.66 US\$ incurred the maximum lifetime cost. OC and LBD at 3 year intervals also yielded an incremental QALY gain of 6679 QALYs. The high-risk screening was cost saving at all levels of screening coverage than mass screening which is cost saving only at 10% and above coverage. Among the techniques the high-risk screening by COE at ten years was the most cost-saving approach.

The budget impact analysis indicated that the "implementation of nationwide oral screening using conventional oral examination for high-risk population above 30 years of age at 10-year interval would account for only 0.03% of annual healthcare budget of India in the year 2022–2023". Hence for Indian setting at national scale conventional oral examination for high risk population above 30 years at 10 year interval is recommended as the screening strategy.

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<u>CURRENT STATUS OF INFRASTRUCTURE, FACILITIES, TECHNOLOGIES, POLICIES, PROGRAMS IN INDIA</u>

As per the recent reports of the Healthcare Access and Quality Index (HAQI) conducted in 2016, India ranked 145th out of 195 countries, trailing behind its neighbours Sri Lanka (71st) and Bangladesh (132nd).¹ The HAQI India rank indicates that a majority of country's population does not have access to high-quality or even acceptable standards of healthcare. Both access and quality of healthcare are essential components of achieving universal health coverage (UHC).² However, progress towards UHC in India is hampered due to a very high level of out-of-pocket expenditure (OOPE) on health, especially in cancer care,³ leading millions of people towards impoverishment.

The Current Treatment Modalities, technology and in frastructure system available in India

As per the Census of India – Sample Registration System (SRS 2017-2019), cancer is the fourth leading cause of death in India, contributing to 6.8% of overall mortality.⁴ There were nearly 1.3 million new cancer cases in 2020 with an expected doubling of incidence by 2040 based on accounting of demographic changes.⁵ Cancer care in India is concentrated at tertiary-care hospitals and at major cancer centers, primarily in urban areas.⁶ The COVID-19 pandemic further worsened care among cancer patients with infection control measures delaying diagnosis and treatment, personnel shifting to COVID-19 care, as well as causing worse COVID-19 outcomes for individuals with cancer. Specifically, in 2020, oncology in India had a 54% decline in new patient registrations, 37% reduction in outpatient chemotherapy and 25% in cancer screening activities.⁷

Oral cancer, the third most common cancer in the country, and one of the most devastating neoplasms among Indian males, is of immense public health concern. About 50% of oral cancer cases in India have a five-year survival rate, and this number has been shown to increase from 70 to 90% if detected early (in stages I and II).8 Several treatment modalities are available, however, oral cancer cure depends on the cancer stage when diagnosed and delay in starting treatment. Early detection and treatment is the key to lower mortality rates and better survival rates for cancer patients in the country.

Primary surgery is the preferred modality of treatment for vast majority of operable oral cancers. Radiotherapy (brachytherapy ± External Beam Radiotherapy (EBRT)) is an alternate for early stage oral cancers with comparable control rates to surgery. Recurrences occur in up to 2/3rd of patients with oral cancer. These are often detected late given the fact that patients have been extensively pre-treated and identifying recurrences in this setting is difficult.⁹

Govt of India policies and programs: Education, Awareness, Screening and Treatment

Awareness initiatives and programs providing the foundation stone for a tobacco-free Nation: A huge step towards this direction is the comprehensive tobacco control legislation (COTPA, 2003)¹⁰ and ratification of WHO Framework Convention on Tobacco Control (WHO FCTC) in 2004 by the government of India. The Ministry of Health and Family Welfare, Govt of India has prepared a universal and objective Operational Framework for Cancer Screening and Management that aims to promote, coordinate, and conduct research to better understand, detect, diagnose, and treat cancer. The framework makes it mandatory to perform screening of oral, cervix and breast cancer for males and females above the age of 30. It provides

guidance to the district cancer societies to conduct national awareness campaigns, education, detection and screening at all levels.¹¹

The National Cancer Control Programme (NCCP) has established regional cancer centres (RCCs) and the National Cancer Registry Programme (NCRP) that provides nationwide cancer statistics of India, including oral cancer statistics. It is also entrusted with the recognition of new Regional Cancer Centres (RCCs), Strengthening of existing RCCs, development of oncology wings with head and neck surgery specialization in medical colleges, and formulating District Cancer Control Programme to achieve the objective.¹²

The National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Disease and Stroke (NPCDCS) also focuses on screening, diagnosis, identification and addressing modifiable risk factors of oral cancer, referral of oral pre-cancerous conditions, and community level follow up.¹³

Other Independent initiatives by health care professionals, community NGOs and other multidisciplinary efforts by other agencies involved with cancer control aim to align research on oral cancer with societal needs.

Facilities and Infrastructure on Oral Cancer Care:

- a. Diagnosis and Treatment of Oral Cancer under Ayushman Bharat: Establishment of Ayushman Bharat Health and Wellness Centres (AB-HWCs) across the country was announced in February 2018. Screening of three common cancers i.e. oral, breast and cervical, along with other common Non-Communicable Diseases, is an integral part of service delivery under the AB-HWCs.¹⁴
- b. Treatment of oral cancer under the Pradhan Mantri Jan Arogya Yojana (launched in 2018) is one of the focus areas to safeguard the beneficiaries from catastrophic expenditure of oral cancer treatment. Health insurance cover of Rs. 5 lakhs per family per year is provided for secondary or tertiary care hospitalization to over 10.74 crore beneficiary families. Chemotherapy and Radiotherapy packages, along with surgical oral oncology are covered as part of cancer treatment in the empanelled hospitals under the scheme.¹⁵
- c. Focus on Oral Oncology in Pradhan Mantri Swasthya Suraksha Yojana (PMSSY): A significant focus on oncology including specialization in head and neck cancers has been ensured in the new AIIMS that are being established under the aegis of PMSSY (Bhopal, Bhubaneswar, Jodhpur, Patna, Raipur and Rishikesh). These institutes have been provided with state-of-art diagnostic, medical and surgical care facilities. ¹⁶ Oral Cancer treatment facilities have also been strengthened in thirteen State Government Medical Colleges, which have been taken up for upgradation under PMSSY.
- d. Enhancing Facilities for Tertiary Care: The Ministry of Health and Family Welfare is strengthening tertiary care of cancer with operationalization of 19 State Cancer Institute's (SCIs) and 20 Tertiary Care Cancer Centres (TCCCs) which also includes oral oncology services.
- e. Giving a boost to Oral Cancer Research: National Cancer Institute (NCI) at Jhajjar, a state- of-the-art Tertiary Cancer Institute is equipped with several facilities including surgical oncology, radiation oncology, medical oncology and approximately 700 patient

care beds, among others.¹⁷ As India's premier institute of cancer, NCI, Jhajjar is responsible for identifying priority areas for oral cancer research & carrying out basic and applied research in molecular biology, genomics, and cancer epidemiology. Another institute called Chittaranjan National Cancer Institute, Kolkata is also a key step in the same direction.¹⁸

- f. The National Institute of Cancer Prevention and Research (ICMR-NICPR) is a premier institute with the intention of collaborative research activities in cancer including oral cancer. The institute also houses the WHO Global Knowledge Hub on Smokeless Tobacco (GKH-SLT), which is responsible for carrying out research on smokeless tobacco and its impact on oral cancer.¹⁹
- g. National Cancer Grid (NCG) Initiatives: The following initiatives have already been started by the NCG to combat the problems in the delivery of cancer care, including oral cancer
 - i. Adoption of implementable resource stratified guidelines
 - ii. Systematic method of data capture at all centres as part of the grid
 - iii. A voluntary process of accreditation and peer review in Indian health-care providers for standardisation of cancer care in India
 - iv. Exchange of expertise and mentoring between member centres of NCG
 - v. Plan varying durations of training for physicians and paramedical staff to augment human resource
 - vi. To increase number of training opportunities for specialist and to have reservation for government-run and regional cancer centres to augment their trained manpower vii. To prioritise research and development of established research networks.
- h. There are more than 320 dental colleges in India, with a combined capacity intake of >28000 dental graduates each year in the country. This makes dental academic institutions a huge potential base for oral cancer treatment and care. This nation-wide spread dental infrastructure serves as a groundwork for oral cancer management in the country.
- i. Premier medical institutions such as various AIIMS, PGIMERs, Tata Memorial Hospital, and many public and private state medical colleges have now specialized cancer centers, with states now giving importance to oral cancer care and treatment under their oncology wings, and focusing upon oral cancer treatment as well as mentoring all Cancer related activities including research, treatment and palliative care, in their respective jurisdiction
- j. The top private cancer hospitals in India are equipped with state-of-the-art facilities and cutting-edge technology. These hospitals invest heavily in research and development as well to stay at the forefront of medical advancements.

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NATIONAL & INTERNATIONAL GUIDELINES FOR ORAL CANCER MANAGEMENT

Oral cancer accounts for 8.8% of all cancer-related deaths. Most of these cases, nearly 90%, are squamous cell carcinomas (SCCs). The choice of the treatment approach for oral cancer depends on the stage of the disease, and if diagnosed in early stages curative therapies such as surgery is preferred. Therefore, it's essential to diagnose early and stage precisely through a thorough physical examination and various imaging techniques. This evaluation process should involve a multidisciplinary team and should be thoroughly reviewed before settling on the final treatment plan.

Modern technology has introduced several imaging methods, including computed tomography (CT), magnetic resonance imaging (MRI), ultrasonography, and positron emission tomography (PET)-CT. Among these, CT and MRI are typically preferred for evaluating the local and regional extent of the disease. Furthermore, during the staging process, it's advisable to conduct an endoscopic examination of the upper digestive tract because approximately 7% of oral cancer patients are known to have a concurrent second primary lesion in this region.¹

Typically, the primary treatment for OSCC is surgery. The primary goal of surgical resection is to ensure complete removal of the tumor tissue. However, the potential negative impacts on appearance and functionality due to the extent of the disease and the necessary surgical removal stress the importance of using less invasive surgical methods, such as sentinel lymph node (SLN) biopsy, especially in early-stage cases, to reduce surgical-related complications. Additionally, for patients at high risk of the cancer returning, radiation therapy (RT) or a combination of chemotherapy and radiation therapy (chemoradiation or CRT) is often added as a adjuvant treatment.²

National Cancer Grid (NCG) Head and Neck Cancer Management Guidelines (2019)

In the management of oral cancer, it is crucial to conduct a thorough workup and assessment of the lesion through clinical examination, which should be followed by a biopsy. Additionally, imaging is performed to evaluate the primary site and neck involvement, as well as to exclude the presence of distant metastasis.

The American Joint Committee on Cancer (AJCC)/International Union Against Cancer (UICC) staging system is a tool which provides clinicians across the world with the ability to stage cancer prior to any treatment (cTNM), after surgical resection (pTNM), and at recurrence (rTNM). Staging stratifies patients into various prognostic groups and, guides in choosing appropriate management plan.

For early stage cancer (stage I and stage II)- - Surgical is preferred for primary Tumor: Wide local excision with a minimum of 1 cm gross margin to ensure a histological tumor-free margin of over 5 mm. This procedure should be accompanied by appropriate Neck Dissection and suitable reconstruction. For N0 Neck: Selective neck dissection targeting Level I-III, optionally Level IV. For N+ Neck: Modified neck dissection (Level I-V), with efforts to spare the XI nerve, internal jugular vein (IJV), and sternocleidomastoid (SCM) muscle whenever oncologically feasible. The recommended minimum number of lymph nodes to be included in a Selective Neck Dissection (SND) is greater than 10, and in a Modified Neck Dissection (MND), it should exceed 14 nodes.

Radiation Therapy is considered an optimal treatment option for early oral cancers, particularly for lip tumors and specific sub-sites. However, it's worth noting that tumors closely adjacent to the mandible pose a risk of osteoradionecrosis. Ideally, the treatment should incorporate brachytherapy as part of the approach.

For advanced stages: For stages III and IVa surgery is preferred along with adjuvant radiotherapy or chemotherapy. Indications for adjuvant post-operative radiotherapy include T3-T4 primary tumors, the presence of positive lymph nodes, perineural invasion, lymphovascular invasion, and poorly differentiated disease. Adjuvant post-operative concurrent chemo-radiation is recommended for patients with positive surgical margins and the presence of extranodal extension or extracapsular spread, as well as when there is nodal positivity involving two or more lymph nodes. The options for adjuvant concurrent chemotherapy include Cisplatin at a dosage of 100 mg/m2 (the optimal choice) or weekly cisplatin at a dose of 30-40 mg/m2. Audiometry assessment is preferred before administering cisplatin.

The use of Radiation Therapy (Rx) or Chemoradiation Therapy (Chemo Rx) for advanced tumors is limited to individuals who are medically unfit for surgery and those who decline it. Additionally, this approach is applicable only when the target volumes can be safely irradiated with a tumoricidal dose of 70 Gy. Patients with substantial mandibular erosion are at risk of developing osteoradionecrosis and are not suitable candidates for this treatment modality. Furthermore, tumors that are closely adjacent to the mandible or exhibit gross skin ulceration carry an increased risk of complications.

For stage IVb - Borderline Resectable - This scenario typically involves a primary tumor that is grossly removable, but there are significant concerns regarding the likelihood of obtaining a clear surgical margin or the potential for excessive surgical complications. The determination of borderline resectability should ideally be made by a surgeon, preferably as part of a multidisciplinary tumor board.

Situations that might be classified as borderline resectable include:

- 1. Presence of soft tissue swelling extending up to the zygoma in cases of Buccal Mucosa and gingivobuccal sulcus (BM-GBS) primaries.
- 2. Disease located in close proximity to the hyoid bone or valleculae in cases of Tongue primaries.
- 3. Certain instances featuring extensive skin infiltration and involvement of the supranotch region of the infratemporal fossa.

Neoadjuvant chemotherapy may be considered in select borderline cases after multidisciplinary tumor boards as evidence for neo-adjuvant chemotherapy in oral cavity cancers has not shown survival benefit. Following chemotherapy options can be used depending on the functional status of the patient:

- 1. DCF- Docetaxel 75 mg/m2 D1-D5, Cisplatin 75 mg/m2 D1 or Carboplatin AUC 5-6 on D1, 5FU 750 mg/m2 Continuous infusion of 24 hours D1-D5- 3 weekly
- 2. DC- Docetaxel 75 mg/m2 D1-D5, Cisplatin 75 mg/m2 D1 or Carboplatin AUC 5-6 on D1- 3 weekly
- 3. CF- Cisplatin 100 mg/m2 D1 or Carboplatin AUC 5-6 on D1, 5FU 10000 mg/m2 Continuous infusion of 24 hours D1-D4- 3 weekly
- 4. PC- Paclitaxel 175 mg/m2 D1-D5, Cisplatin 75 mg/m2 D1 or Carboplatin AUC 5-6 on D1- 3 weekly
- 5. PC weekly—Paclitaxel v60-80 mg/m2 D1-D5, Carboplatin AUC 1.5-2 on D1- weekly.

In the case of a favorable response, either complete or partial, a reassessment is warranted to determine eligibility for curative treatment, which typically involves a combination of surgery followed by adjuvant radiotherapy or chemo-radiotherapy. In cases of an insufficient response, whether the disease remains stable or progresses, the recommended course of action aligns with the algorithm designed for managing unresectable oral cancer.

For unresectable tumors, palliative therapy is given. Options for first line palliative chemotherapy depends on performance status (PS). If patient has ECOG PS of upto 2 may benefit from palliative systemic therapy if fits to poor PS of 3 or 4 only best supportive care is offered. Preferred systemic therapy options include Cytotoxic chemotherapy (single agent or combination) with either immunotherapy (pembrolizumab) or targeted therapy (cetuximab). Other options in resource limited settings include metronomic chemotherapy consisting of weekly methotrexate-celecoxib with or without erlotinib (Methotrexate 9 -15 mg/m2 weekly, Celecoxib 200 mg twice daily with or without Erlotinib 150 mg daily); Options for second line or beyond chemotherapy include- Triple metronomic choethmerapy (b) or single agent chemotherapy (b), or nivolumab or its altered schedules (c) or Pembrolizumab or its altered schedules (c).

<u>Indian clinical practice consensus guidelines for the management of oral cavity cancer</u> T1-T2, N0

In the initial stages of disease, a single treatment approach is typically employed. In India, due to the limited availability of brachytherapy facilities, surgery is the preferred method for treating oral cancers. Additionally, surgery, which can be completed in a single day, offers the option of using radiation therapy for addressing potential second primary tumors. Elective neck dissection is more advantageous in early oral cancers with clinically negative lymph nodes than therapeutic neck dissection, as it is associated with lower rates of relapse and improved survival rates. For patients with T1N0 or T2N0 stage oral squamous cell carcinoma (OCC), two surgical options are available: resection of itmhearyprtumor site with or without ipsilateral/bilateral neck dissection and resection of the primary tumor site with or without sentinel lymph node (SLN) biopsy. In early OCC cases, SLN biopsy is recommended to detect any hidden metastatic disease. Following surgery, in the presence of adverse features, adjuvant chemoradiotherapy (CTRT)/radiation therapy (RT) is strongly recommended (EL 1; Grade A).

Definitive Radiation Therapy (RT)

For patients who are medically unfit for surgery or choose not to undergo it, an alternative option is definitive RT. This approach may involve conventional fractionation, with a dose ranging from 66 Gy (2.2 Gy per fraction) to 70 Gy (2.0 Gy per fraction) administered daily from Monday to Friday over 6 to 7 weeks (Grade A; EL 1). Another option is concomitant boost accelerated RT, which delivers a total dose of 72 Gy over 6 weeks (1.8 Gy per fraction for the large field, with a 1.5 Gy boost as the second daily fraction during the last 12 treatment days) (EL 1; Grade A). Locally Advanced Oral Squamous Cell Carcinoma (OCC) (T3, N0; T1–3, N1–3; T4a, N0–3).

Surgery

Research findings indicate that patients who undergo surgery in combination with concurrent radiation therapy (RT) and chemotherapy (CT) experience improved outcomes. Therefore, individuals with operable cancer lesions should receive a comprehensive approach involving a combination of surgery followed by either RT or chemoradiotherapy (CTRT).

Adjuvant Treatment

The selection of adjuvant treatment should hinge on the identification of adverse features following surgery or neck dissection. For patients exhibiting extranodal extension, the recommended course is chemoradiation. In cases where positive margins are detected, a reresection followed by radiation therapy (RT) is advisable if feasible; otherwise, chemoradiotherapy (CTRT) is the preferred option. Furthermore, in patients presenting with other risk factors such as pT3/pT4 stages, N2/N3 involvement, affected nodes at levels IV or V, perineural invasion, lymphatic invasion, or vasrcuelambolism, either RT or CTRT is recommended. In instances where a higher nodal disease burden is evident (involving two or more positive lymph nodes), CTRT is the favored approach. There is a growing interest and access to immunotherapy, especially low dose that has been found to be effective in oral cancer management.

Medically Inoperable Conditions

In cases of medically inoperable conditions, such as edema extending up to the zygoma, involvement of the vallecula, disease in proximity to the hyoid, or affecting the upper infratemporal fossa above the sigmoid notch, neoadjuvant chemotherapy stands as the preferred treatment choice. Patients who respond well to this treatment can subsequently consider surgery followed by chemoradiotherapy (CTRT). In cases where there is no response to neoadjuvant chemotherapy, options such as CTRT, radiation therapy (RT), or palliative care can be considered. Please refer to Figure 1 for the algorithm outlining the management of Oral Squamous Cell Carcinoma (OCC). For a concise summary of clinical evidence related to OCC, please consult Appendix 1.

NCCN guidelines of Buccal mucosa, floor of mouth, oral tongue, alveolar ridge, retromolar trigone, hard palate

Workup

- History and physical examination including a complete head and neck exam; mirror and
 fiberoptic examination as clinically indicated. It should also include documentation and
 quantification (pack years smoked) of tobacco use history. All patients who currently
 smoke should be advised to quit smoking, and those who formerly smoked should be
 advised to remain abstinent from smoking.
- Biopsy- Image-guided (ultrasound [US] or CT) needle biopsy of cystic neck nodes may offer better diagnostic yield than fine-needle aspiration (FNA) by palpation alone for initial diagnosis in this setting.
- As clinically indicated:
 - Chest CT (with or without contrast)
 - CT with contrast and/or MRI with contrast of primary and neck
 - Consider FDG-PET/CT
 - Examination under anesthesia (EUA) with endoscopy
 - Paranesthesia studies
 - Dental/prosthodontic evaluation, including Panorex or dental CT without contraste
 - Nutrition, speech and swallowing evaluation/therapy
 - Smoking cessation counseling
 - Fertility/reproductive counselling
 - Multidisciplinary consultation as clinically indicated

The choice of the main treatment approach for oral cancer depends on the stage of the disease, and surgical intervention remains the cornerstone of a comprehensive treatment

strategy. Therefore, it's essential to precisely determine the stage through a thorough physical examination and various imaging techniques. This evaluation process should involve a multidisciplinary team and should be thoroughly reviewed before settling on the final treatment plan. In many nations, surgical intervention continues to be the primary choice for addressing oral cancer.

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ORAL CANCER IN NATIONAL PROGRAM FOR NCD IN CONTEXT OF ORAL CANCER: CHALLENGES AND BARRIERS

India is experiencing a rapid health transition with a rising burden of Non-communicable Diseases (NCDs). According to a WHO report (2002), cardiovascular diseases (CVDs) will be the largest cause of death and disability in India by 2020. Overall, NCDs are emerging as the leading cause of deaths in India accounting for over 42% of all deaths (Registrar General of India). NCDs cause significant morbidity and mortality both in urban and rural population, with considerable loss in potentially productive years (aged 35–64 years) of life. There are an estimated 25 Lakh cancer cases in India. According to the National Commission on Macroeconomics and Health (NCMH) Report (2005), the Crude Incidence Rate (CIR) for Oral cancer is 11.8 (among both men and women) per 100,000 populations.¹

The Government of India launched the National Cancer Control Program (NCCP) in 1975, and revised the strategies during 1984-1985 which stressed on primary prevention and early detection of cancer. In order to prevent and control major NCDs, the National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) was launched in 2010 with focus on strengthening infrastructure, human resource development, health promotion, early diagnosis, management and referral.

During the period 2010-2012, the program was implemented in 100 districts across 21 States. The implementation strategies are as following:

- Health promotion through behavior change with involvement of community.
- Outreach Camps for opportunistic screening at all levels in the health care delivery system. Management of chronic Non-Communicable diseases, especially Cancer through early diagnosis, treatment and follow up.
- Build capacity at various levels of health care for prevention, early diagnosis, treatment, IEC/BCC, operational research and rehabilitation.
- Provide support for diagnosis and cost-effective treatment at primary, secondary and tertiary levels of health care.
- Provide support for development of database of NCDs through a robust Surveillance System and to monitor NCD morbidity, mortality and risk factors.²

However, the key challenges are with availability of trained human resources for the screening of the NCDs essential for early detection, low budget allocation and utilization, lack of access to diagnostics and regular supply of essential medicines. There is also poor focus on health promotion, with lack of multisectoral participation, surveillance, regular supervision, monitoring and evaluation of the Program at different levels of health care delivery. Kedar et al., in their study on views of health personnel regarding the cancerscreening programs, also reported that lack of human resources and increased workload on existing labor was considered a challenge in the implementation of the cancer screening program. Also, examination of the oral cavity for the screening of oral cancers requires an extra of 7-10 minutes, which can be challenging in the already overburdened public health facilities.^{3,4}

A study conducted in the southern India showed that the most important missing link in program implementation is the unavailability of medical officers and other relevant staffs.⁵ The need for training for effective implementation of cancer screening programs was emphasized by Patil et al., who in their study among health care providers in tribal areas of

Maharashtra, reported that lack of training was perceived as a major barrier. Many secondary care facilities; lacks provision for biopsy and diagnostics.⁶ Another challenge encountered is streamlining referrals and their follow-up. Meena et al., in their study conducted in two rural health facilities of Jodhpur, reported that complete treatment and assistance could not be provided to the patient who was found to have cancerous or pre-cancerous lesions, due to resource constraints.⁷

As per Ramani VK, Jayanna K, Naik R. and Shah et al. have identified four key priority areas which promote health services for cancer control:

- Capacity building in oncology related health service research in LMIC, the relevant policy and planning,
- Developing high quality sources of health data (eg: population based cancer registries) which can identify the process and outcomes of cancer management for achieving quality cancer control,
- Oncology related economic evaluation of screening, training, treatment as well as rehabilitative services.
- Explore high quality models of cancer control.8-11

The unique challenges posed by the rise in NCD morbidity, requires horizontal as well as vertical integration of the health systems with new services focused on oral cancer control. It is important to focus on understanding the implementation and its barriers so that these challenges are met timely.

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CAPACITY BUILDING AND TRAINING INITIATIVES IN ORAL CANCER

Oral cancer ranks among the top twenty most widespread cancer types globally, contributing to elevated rates of both mortality and morbidity. A great increase in new cases is projected in developing countries (China, India and Brazil), considering the period 2020 through 2040, ranging from 80.1% to 97.8%.

Unmet needs: A comprehensive review encompassing studies conducted in both developed and developing nations pinpointed the primary reasons behind delayed oral cancer diagnosis in patients. These were the challenge of visualizing or identifying oral lesions, coupled with absence of symptoms in the initial stages of these lesions.³ This may be due to limited awareness within the population regarding oral cancer, its associated risk factors and its distinctive attributes. Such lack of awareness might cause individuals to overlook the initial indications and symptoms, thus amplifying delay in search of specialized care.⁴

Roughly 50% of oral cancer patients are reported to consult a healthcare provider (HCP) within 1–2 months upon recognizing symptoms, however, an estimated 20–30% of patients postpone seeking assistance for over 3 months.⁵

The time between a patients' first awareness of symptoms of oral cancer and their first consultation with a health care professional (HCP) regarding those symptoms is considered to be the duration of patient delay.¹ This is distinct from 'professional delay' (time from first consultation with a HCP regarding a sign/symptom to definitive diagnosis) and 'total delay' (time from first awareness of a sign or symptom to definitive diagnosis).⁵

Capacity building: involves empowering individuals and organizations with the skills, knowledge, and resources² necessary to address complex health issues such as oral cancer. This aids in improving their competence in prevention, early detection and its management including supportive care. The four approaches of capacity building:⁶

- 1. **Top-down organizational approach:** Begins with changing agency policies or practices. Top-managements involvement in the change program helps establish a sense of urgency in change.⁷
- 2. **Bottom-up organizational approach:** e.g. provision of skills to staff. Bottom-up policy implementation theory states that managers make meaning of top-down reforms. The conditions in which the staff work, their own experience, discretion and tacit use of knowledge transforms policy into practice.⁸
- 3. **Partnerships approach:** Comprises strengthening the relationships between organizations. Regardless of one's area of specialty and background, members of partnership passionately reduce inequalities in health and social circumstances, thus improving the community's quality of life.⁹
- 4. **Community organizing approach:** Individual community members are drawn to forming new organizations or linking up with the existing ones to improve the health of community members. Moreover, community engagement can enhance linguistically and culturally appropriate measures and field piloting.¹⁰

Training Initiatives and Strategies:

• **Dental Professional Training:** Dentists play a crucial role in oral cancer detection and referral. Capacity building initiatives focus on training dentists to conduct thorough oral

examinations, identify potential early signs of cancer, and provide appropriate referrals to specialists for further evaluation and treatment. Improve existing dental health services for children and youth; promote brief interventions on tobacco, alcohol, and recreational drugs through these services and measure their efficacy.¹¹

- **Multidisciplinary Workshops:** Collaborative workshops involving oral and maxillofacial surgeons, oncologists, radiologists, epidemiologists, public health professionals, behavioral scientists, governments, and non-governmental organizations (NGOs) provide a platform for knowledge exchange and skill enhancement. These workshops foster interdisciplinary collaboration, enabling a holistic approach to oral cancer management. Effective continuous education programs on diagnosis of potentially malignant disorders and early cancer for all primary care providers are essential.¹²
- **Community Outreach:** Capacity building extends beyond healthcare professionals to community health workers and volunteers. Training programs equip them with basic knowledge about oral cancer risk factors, symptoms, and the importance of regular screenings. This grassroots approach facilitates early detection in underserved areas.
- **Telemedicine and E-Learning:** India's vast geographical expanse presents challenges in reaching remote areas. Telemedicine and e-learning platforms bridge this gap by providing online training modules, webinars, and teleconsultations, ensuring continuous education for healthcare providers across the country.¹³
- **Awareness Campaigns**: Public awareness campaigns raise awareness about oral cancer's risk factors and the importance of regular screenings. These initiatives empower individuals to seek timely medical attention and contribute to reducing the stigma associated with oral cancer.¹⁴
- **Registries:** are needed for potentially malignant disorders to facilitate studies on natural history, including systemic, clinical, histological and whole genome tracking of molecular abnormalities, and on the efficacy of habit interventions and of treatments (surgical, chemopreventive, and chemotherapeutic).¹⁵
- **Effective workforce models:** Likely involving a mix of dentists, midlevel oral health care providers, community-based health workers and other relevant health providers such as primary care physicians and nurses. This helps improve quality of care by enabling a population- and patient-centred, team-based health workforce that can flexibly respond to changing population needs at all levels.¹⁶
- **Research:** Advocacy research for tobacco control, Communication research to measure retention of messages on oral health, clinical research and social research on prevention of oral cancers targeting at-risk groups will substantially add to the knowledge and subsequently build effect strategies for oral cancer control.¹⁷

A study conducted in Southern India showed that the most important missing link in National Program for Prevention and Control of Non-Communicable Diseases (NP-NCD), previously known as National Program for prevention and control of cancer, diabetes, cardiovascular diseases and stroke (NPCDCS) implementation is the unavailability of Medical Officers and other relevant staffs. Many posts are vacant and Medical Officers (MOs) who are present are

often on contractual basis. As per the revised NPCDCS operational guidelines, the District NCD cell comprises of one Program Officer, Coordinator, Finance cum Logistics Consultant and a Data Entry Operator.¹⁸

The National Cancer Grid (NCG) was formed in August 2012 with the aim of linking cancer centers (existing and future major centers) across India.^{19,20} Creation of trained human resource is a prime activity of NCG including the exchange of expertise and mentoring. The NCG Education Portal aims to build courses catering to all sections of oncology staff comprising of the basic and advanced training and updates on cancer.

Handbooks are available on NCG portal in three languages to train paramedical staff in common cancer awareness, screening and in tobacco control and cessation. Video based tutorials on the portal aid paramedical staff in delivering standardized cancer awareness programs. The NCG provides an opportunity for research with the creation of network. Research emphasis is on multicentric studies in basic, translational and clinical cancer research, with a focus on common cancers of India.

A modest initiative, which originally had 14 cancer centers,²⁰ has rapidly grown now to include 306 major cancer centers.²¹ It is one of the largest virtual cancer networks in the world. Funded by the Government of India through the Department of Atomic Energy, the NCG has the primary mandate of working towards uniform standards of care across India by adopting evidence-based management guidelines, which are implementable across these centers.

EQuIP-India is now one of the central strategies of the NCG to build capacity and competencies of member teams to use Quality Improvement tools, identify and analyse quality concerns through experiential learning within their clinical settings, with the aim of improving the experience and outcomes of cancer and survivorship care.²²

In India, capacity building and training initiatives are vital to combating the challenges posed by oral cancer. By equipping healthcare professionals and community workers with the necessary skills and knowledge, these initiatives contribute to early detection, timely treatment and improved patient outcomes. Through interdisciplinary collaboration, telemedicine and community engagement, India is making strides toward effective oral cancer management and prevention.

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BUDGET FOR VARIOUS ORAL CANCER INITIATIVES IN INDIA

Oral cancer imposes a significant fiscal burden on a national, institutional and individual level. Funding of cancer care in India is a complex mixture of state and government accountabilities, with the government shouldering most of the responsibility. Oral cancer as such has not been given a separate budget in India. But it has been covered under various facilities of the Government, schemes and programs for Cancer. The allocation also has not been clear regarding the distribution of funds for cancer care and cancer research.

Assuming the Centre and State governments spend 30% and 70% of total government spending on health care, respectively, in 2023-24, the combined budgeted expenditure on the health sector would be 1.18% of GDP. The Budget estimate for 2023-24 is given in the below Table 12.1. The combined budgeted expenditure on the health sector by the Centre and State government has increased from 2020-21.^{1,2} Cancer-specific spending in India has increased from INR 115 million in the sixth plan (1980–1985) to INR 28,719 million and INR 60,000 million in eleventh and twelfth five-year plan, respectively.³⁻⁵ This increasing trend of GDP may also impact the increase on the budget allocation for various programs and schemes for Cancer.

Table 12.1: Budget estimate for Ministry of Health and Family Welfare (2023-24)

Sl. no	Ministry Demand	Budget Estimate 2023-24 (in crores)		
		Revenue	Capital	Total
1.	Department of Health and Family Welfare	83853.86	5301.14	89155.00
2.	Department of Health Research	80874.66	5300.34	86175.00

Oral Cancer

1. **Treatment:** India spent approximately USD 322 million (Rs. 2,386 crores) in 2020 on oral cancer treatment, paid for by insurance schemes, government and private sector spending, out of pocket payments and charitable donations or a combination of these.^{7,8} A significant portion of the healthcare budget allocation the government made is not linear to the Oral cancer treatment independent report (Mouth cancer treatment cost in India ranges from INR 60,574 (USD 758) to INR 5,04,893 (USD 6318) with an average of INR 2,80,096 (USD 3505) as shown in Figure 12.1.⁹

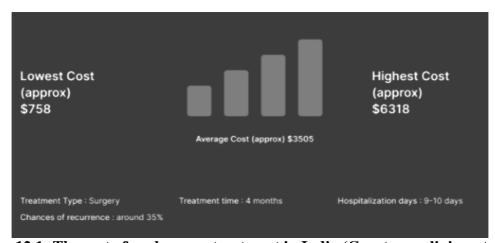


Figure 12.1: The cost of oral cancer treatment in India (Courtesy - clinicspots.com)

There also has been observation of varying trends in the rates for cancer treatments from one scheme to another scheme in 20083 and these rates are lower than the cost incurred by patients in a study done at PGIMER, Chandigarh (2018).⁶

Under **CGHS and DGHS** the cost of biopsies to surgeries for head and neck cancers (Rs. 5750/- to Rs. 47,610/-), radiotherapy (Rs. 5621/ to Rs. 169068/-) and chemotherapy (Rs 992/- to Rs. 1058/-) has been provided.¹⁰

Under **PMJAY** scheme the drug cost in Medical oncology ranges from Rs. 2600/- to Rs. 18,900, Rs. 5,500/- to Rs. 1,17,000/- for various radiation oncology procedures, palliative medicine therapy costs Rs. 2300/- to 10,300/- per day for various services and different OMFS surgeries cost varies from Rs. 2700/- to Rs. 18,00/-. (Annexure 2)

- **2. Screening:** Budget impact analysis showed that oral screening using Conventional Oral Examination for high-risk population at 10-year intervals costs lower than the annual healthcare budget of India for the year 2022–2023 (0.03% of annual healthcare budget of India (862,006.5 million).8 First year Rs. 25,727,541,030.81/- and Second-year Rs. 28,300,295,133.90 INR.
- 3. National Health Programs/Schemes for Cancer in India: No separate budget for oral cancer has been given by various schemes and programs in India. But oral cancers have been considered under the non-communicable diseases and cancer category for funding. National Cancer Control Program (NCCP) (now under NP-NCD) in India has also seen a modest rise in spending during the past decade from 48×10⁷ rupees (US\$7·7 million) to more than 140×10⁷ rupees (US\$22·6 million) in 2004-05¹².

Existing Schemes under National Cancer Control Program (NCCP) as on 1st June 2008 {w.e.f 1st January 2005}:

- 1. Recognition of New Regional Cancer Centers (RCCs): A one-time grant of Rs. 5.00 crores was provided for New RCC's.
- 2. Strengthening of existing Regional Cancer Centers: A one-time grant of Rs.3.00 crores was provided to the existing Regional Cancer Centers to further strengthen the cancer care services. 3. Development of Oncology Wing: Government Hospitals and Government Medical Colleges are provided with a grant of Rs. 3.00 crores for the development of Oncology Wing.
- 3. District Cancer Control Program: A grant-in-aid of Rs. 90.00 lakhs spread over a period of 5 years was provided per DCCP proposal.
- 4. Decentralized NGO Scheme: A grant of Rs. 8000/- per camp was provided to the NGOs for IEC activities.

National Health Mission (NHM): Under the NHM budget 22,094.57 Crores allocated for 2023-24 covers the National tobacco control program, National Oral Health Program and Non communicable Disease Program.¹⁴⁻¹⁶

- 1. National Program for prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS): program or now known as National Program for Non- communicable Diseases (NP-NCD)17-19 Total cost of the Program for period 2012-2017 was Rs. 8,096 crore (share of Government of India is Rs. 6,535 crore and that of State Governments is Rs. 1,561 crore).
 - For the Cancer component, there is the Tertiary Care Cancer Centers (TCCC) scheme, which aims at setting up/strengthening of 20 State Cancer Institutes (SCI)

and 50 TCCCs for providing comprehensive cancer care in the country. Under the scheme there is provision for giving a 'one time grant' of Rs. 120 crore per SCI and Rs. 45 crore per TCCC, to be used for building construction and procurement of equipment, with the Centre to State share in the ratio of 60:40 (except for North-Eastern and Hilly States, where the share is 90:10).¹²

- Earlier (approx.) before 2 years 15 to 20 lakhs per district were allocated under equipment head for the three cancers (Breast, cervical and oral).
- A total of 50 lakhs per district per year Cancer care for equipment of three cancers (Breast, cervical, oral). 25 lakhs per district per year for drugs for three cancers
- 2. **National Tobacco Control Program (NTCP):** NTCP was to 400 districts across India with a budget allocation of INR 650million (US\$8.8million) for the year 2018–2019.²⁰
- 3. **National Oral Health Program (NOHP)**²¹: A total approval of Rs 25.13 Crore for 26 states/UTs has been given to support proposed activities of NOHP. Grants have been released to the states/UTs under Health System Strengthening (HSS) of Mission flexipool under NHM. The oral cancer has been one of the major components of NOHP.
- 4. **Ayushman Bharat**: Pradhan Mantri Jan Arogya Yojana (AB PMJAY)14-16 Has been allotted Rs. 7200/- Crores for the FY 2023-24.Rs 761 Crores was spent in 2021-22.¹⁵ Surgical oncology, Radiation oncology for oral and maxillofacial region has been included in the list of services.
- 5. **Others:** Furthermore, since 2007, a large amount of money has been pooled towards cancer care by the Government of India through various publicly sponsored health insurance schemes (Rashtriya Swasthya Bima Yojana, Rajiv Gandhi Jeevandayee Arogya Yojana, Rajiv Aarogyasri Health Insurance Scheme). Also, certain states such as Punjab provide cashless cancer treatment in various public and private sector hospitals.
 - The Chief Minister's Comprehensive Health Insurance Scheme in Tamil Nadu- 400 000 rupees for 4 years in a recognised cancer centre.
 - The Vajpayee Arogyashree Scheme is a state insurance scheme that was introduced in Karnataka state A maximum limit of 150 000 rupees is set for a family of five per year in 7 streams including cancer.
 - Affordable Medicines and Reliable Implants for Treatment (AMRIT)
 - Rashtriya Arogya Nidhi (RAN)
 - Ayushman Bharat Arogya Karnataka scheme (ABArK)

Systems – The systems where budget is allocated in for cancer care are below:

- AIIMS National Cancer Institute, ICMR, National Institute of Communicable Disease (NCDC) Delhi 32.69 crores in 2021-22, The National Cancer Grid (NCG) Funded by the Government of India through the Department of Atomic Energy, Tata Memorial trust, etc.
- Cancer projects supported by The Department of Biotechnology (DBT) (2011–2019) Out of the total cancer project supported bad DBT 11.39% were for oral cancers and 1.27% were for tongue cancers. A total of 24043.01 lakhs was spent on cancer research by DBT from 2011-2019.²⁵

The funds allocation for oral cancer care and research is not separate in India and has been given under the budget for cancer care and research under various programs and schemes.

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KEY ISSUES/GAPS IDENTIFIED IN CURRENT SITUATION AND CONTEXT OF ORAL CANCER IN INDIA

The Indian subcontinent, especially India itself because of its large population and widespread tobacco use, has long been regarded as the global epicentre of oral cancer. A recent study concluded India has the highest incidence rates of mouth and oral tongue cancer in both males and females among 185 countries.¹

Diverse factors influence oral cancer development in India. The primary risk factor encompasses tobacco use (smoking and smokeless varieties), which is linked to nearly 90% of all oral cancers.² The other key risk factors are heavy alcohol consumption, betel quid and areca nut chewing, poor oral hygiene, HPV infection (especially HPV-16 and HPV-18), inadequate dietary habits, genetic predisposition (especially with a family history), prolonged UV radiation exposure (particularly in outdoor occupations), occupational exposure to wood dust, asbestos, and certain chemicals, and regional variations influenced by socioeconomic status, healthcare access, and cultural practices.³ In India, areca chewing without tobacco is associated with a threefold increased risk of HNSCC (head and neck squamous cell carcinoma), while combining areca chewing with tobacco resulted in an eightfold risk, with reported positive dose–response curves.⁴

Despite the fact that the above risk factors, oral cancer and its consequences, can be prevented, treated, and controlled, there exists a significant implementation gap in India. Though many efforts have been made till now to combat the risk factors and disease, the burden it imposes, in terms of incidence, mortality, survival and the determinants of disease, as well as the limited health care resources, creates significant gaps in control of these cancers.

The gaps are discussed under the broad headings of (Figure 13.1)

- I. PREVENTION- Health promotion, screening, registries and programs etc.
- II. MANAGEMENT
- III. PATIENT PERSPECTIVES
- IV. RESEARCH

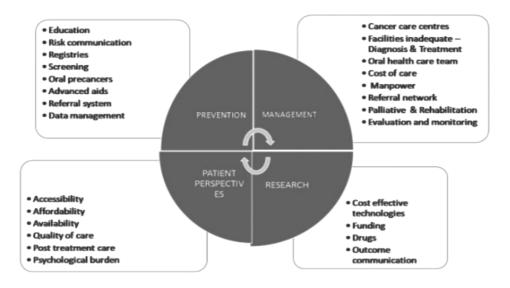


Figure 13.1: Gaps in oral cancer care in India

I. Prevention

1) Health Promotion⁵⁻⁸:

- a) There is a need for an increase regarding oral cancer, tobacco, areca nut, and related awareness among the masses.
- b) Communication strategies for behavioural change need strengthening to meet evidence-based, theoretical, and robust standards. Both population and high-risk approaches require a focused approach, and there's a need to leverage mass media, social media platforms and social marketing strategies.
- c) Evidence on the long-term impacts of engaging primary healthcare professionals is limited as the approach focuses mainly on population-based rather than high-risk groups.
- d) Robust cancer registries with broader coverage are urgently needed in India, with an increase in the number to cover the maximum population. The population and hospital- based cancer registries set up four decades ago have so far been able to cover only 10% of the population of the country with several states such as Madhya Pradesh, Andhra Pradesh, Rajasthan, Telangana and Orissa still not being covered.
- e) A system of registries for recording OPMD cases is needed in the country.
- f) National Tobacco Control Programme is predominantly confined to information, education and communication campaigns, establishing tobacco testing laboratories to build regulatory capacity, and mainstreaming programme components under the National Rural Health Mission. However, these initiatives so far have low visibility.⁷
- g) India was an early signatory in 2004 to the Framework Convention on Tobacco Control. However, legislation requires further strengthening and the need to prevent tobacco industry lobbying influence, which has, for example, delayed the implementation of regulations to mandate the printing of pictorial warnings on tobacco packages. State government bans against smokeless tobacco require strengthened implementation.⁸
- h) While advancements and focus have been on tertiary care, which has relatively improved patient survival rates, it is crucial to implement comprehensive public health interventions at the primary level with a focus on identifying risk factors, especially tobacco, alcohol, and areca nut use, and promoting and facilitating cessation of these habits through education.

2) Screening 9-14:

Screening coverage is currently inadequate in India, regardless of several schemes, programs, and facilities that call for precision prevention to supplement these population-level approaches.

- a) Cancer screening participation in India is inadequate and calls for the immediate attention of national and state governments. Across cancers being screened under the National Programme for Non-communicable Diseases (NP-NCD), screening coverage is less than 5% of the population.
- b) The issue of high disease burden is compounded by late-stage detection, caused mainly due a lack of awareness and low penetration of screening programs. India has a poor cancer detection rate of 29%, with a small percentage of breast, lung and cervical cancers being diagnosed in stages 1 and 2, which is significantly lesser than that in China, the UK and the US.
- c) Screening participation is scarce in places where the cancer burden is very high.
- d) NFHS-5 report reveals that screening guidelines for NP-NCD have not been appropriately utilized and effectively implemented in the country.

- e) Lack of integration of program activities at the health system level and use of etechnology for screening and detecting oral cancers.
- f) Capacity constraints in terms of physical infrastructure and workforce, lack of training in the methods for cancer screening among healthcare workers and deficiencies in referral mechanism and follow-up are key roadblocks to the success of the programme.
- g) Oral Visual Inspection cannot discriminate between potentially premalignant lesions and non-progressive lesions.
- h) There is currently limited evidence to support the use of vital tissue staining (toluidine blue, Methylene blue), visualization adjuncts (ViziLite Plus with TBlue, ViziLite, Microlux DL, Orascoptic DK, VELscope, etc.), as a screening tool to reduce oral cancer mortality. Cytology is most promising, but not widely available.

Lack of data capture to maintain longitudinal health records of the population, right from the screening stage and ensuring tracking and follow-up with patients for effective referrals is a key deterrent in the expansion and penetration of screening programs.

II. Management 6,15:

More advanced staging of disease at diagnosis and treatment can also result in significant functional impairment as well as disfigurement, with consequent impact on the quality of life of patients.

- a) Infrastructure- Only ~175 districts in the country covering 40-45% of the population have Comprehensive Cancer Centers (CCCs). Of the 470 to 480 CCs available in the country, ~40% are concentrated in metros and state capitals. A severe gap continues in access to radiotherapy (RT) treatment in the country with RT per million population of 0.4 vis-à-vis WHO recommendation of 1 RT per million population. Low penetration of PET-CT facilities (0.25 PET Scanners per million population). Diagnostic and treatment advances are costly and unavailable in all Centers).
- b) Lack of workforce and training There is a huge demand-supply gap in workforce in India for medical, surgical and radiation oncologists (EY report 2022) (Table 13.1). Health care workers (~1,17,000 as of Sep 2021 compared to the aspired target of 1,50,000), Vacancy of ~2 to 9% female ANMs, shortfall of 4% MOs exists in centres at Orissa, Karnataka, and Chhattisgarh. 23% of the staff deployed at HWCs are untrained.

Table 13.1: Demand-Supply gap of Manpower in India

Manpower	Demand and Supply Gap (Demand/Supply)		
	2022	2030	
Medical Oncologists	2.6	2.8	
Surgical Oncologists	1.4	1.6	
Radiation Oncologists	1.0	1.1	
Medical Physicists	1.3	2.5	

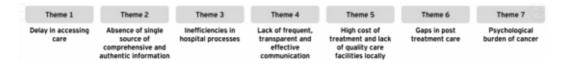
(Courtesy - EY Report 2022)

c) Treatment cost for cancer care is financially prohibitive and is almost 3x that of other non-communicable diseases (NCD). Additionally, treatment costs have been increasing, with the cost of a single cancer hospitalization (in a public or private

- facility) exceeding the average annual expenditure of 80% of the population in 2017 vis-à-vis 60% of the population in 2014.
- d) General surgeons can perform cancer surgeries, but oral cancer requires specialized training. The number of specialists in India is increasing, but these are far too few to meet the needs of most of the population.
- e) Lacks intersectoral coordination- More involvement of Dentists, community nursing personnel and community pharmacists should be there with referral pathways in place and strengthening linkages to follow-up needs.
- f) Technologies to be made more affordable and accessible.
- g) Pain control and palliative care Trained staff and facilities for caring for terminally ill patients and their families are required across the nation. A few such organizations already exist, provided by the government and non-governmental organizations, but their availability is patchy.
- h) Evaluation & Monitoring It is ideal to have more detailed sections on the number of times each person has been screened, the time gap between each screening, and the outcome of screening, such as screen positivity, diagnostic confirmation, follow-up details, etc., in the upcoming NFHS surveys.
- i) The COVID-19 pandemic has disrupted cancer care services, including palliative care, exposing vulnerabilities for those with cancer and increasing the risk of severe outcomes. It underscores the importance of preparedness for such emergent conditions.

III. Patients perspectives¹⁶:

The challenges in the current system of cancer management in the country have been further corroborated by a survey carried out with 154 cancer patients and caregivers. Gaps in the patient journey were characterized by seven key themes which need to be addressed to improve the experience and satisfaction of cancer patients in the country:



Differences in sociodemographic, cultural and urban- rural divide have a huge influence in the utilization of facilities.

IV. RESEARCH 17,18:

Present initiatives largely focus on strengthening treatment facilities, with comparatively less emphasis on generating country-specific evidence for effective prevention, early detection, access, survivorship, and palliation. Prioritizing quality and value in these areas is crucial. Public engagement in research is notably low in India, possibly due to limited awareness of the significance of biomedical research and lack of research communication to the public. Inadequate funding poses a significant obstacle, which could be addressed by increasing government spending on research, seeking philanthropic support, offering tax incentives for donations, and fostering public—private partnerships. The research in India under a leadership program can be focused on the following areas:

- a) Reducing the burden of patients with advanced disease
- b) Improving access and affordability
- c) Outcomes of cancer treatment
- d) Value-based care and health economics

- e) Quality improvement and implementation research
- f) And leveraging technology to improve cancer control measures

Addressing these gaps and challenges is crucial for enhancing solutions to the oral cancer problem. This includes strengthening access to primary health care and referral systems for early detection and treatment, improving the quality of data for prevention and early detection of oral cancer, and implementing targeted interventions in the high-risk regions.

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RECOMMENDATIONS TO BRIDGE THE CRITICAL GAPS/ DEFICIENCIES IN TREATMENT, MANAGEMENT INCLUDING PALLIATIVE CARE IN ORAL CANCER

Oral cancer is predominantly a regional disease that tends to infiltrate adjacent bone and soft tissues and spreads to the regional lymph nodes in the neck. Given the skills, expertise, and infrastructure required for staging and treatment with minimal physical, functional, and cosmetic morbidity, oral cancer treatment is usually provided in specialized cancer hospitals, such as comprehensive cancer centers, or in hospitals at the highest level of health services.

Treatment of Early-Stage Oral Cancer (Stages I and II)

Surgery and radiotherapy are widely used for the treatment of early oral cancer, either as single modalities or in combination. The choice of modality depends on the location of the tumor, cosmetic and functional outcomes, age of the patients, associated illnesses, patient's preference, and the availability of expertise.¹

Treatment of Locally Advanced Tumors of the Oral Cavity (Stages III and IV):

Locally advanced tumors are aggressive, and locoregional treatment failure rates are high. A combined modality approach integrating surgery, radiotherapy with or without chemotherapy, and planned and executed by a multidisciplinary team is always preferred. Appropriate importance should be given to factors such as functional and cosmetic outcomes and the available expertise. Surgery followed by postoperative radiotherapy is the preferred modality for patients with deep infiltrative tumors and those with bone infiltration.²

Side Effects of Radiotherapy

Side effects may occur during or immediately following radiotherapy—acute reactions—or months to years after treatment. Acute reactions are self-limiting and generally resolve within two to three weeks. These reactions are caused by the inflammation of tissues within the radiotherapy treatment field. Alteration of taste, pain, difficulty in eating, mucosal ulceration of the oral cavity, bacterial and fungal infections, increased thickness of saliva, discoloration and peeling of the overlying skin, loss of hair within the field of treatment, and edema of the skin are the major side effects. Maintenance of good oral hygiene, frequent cleaning of the oral cavity with soda-saline solution, analgesics, and control of infection are recommended for conservative management of these side effects. Good hydration, a high-calorie diet, and avoidance of spicy and hot food are recommended.²

Post-treatment Follow-Up

Patients with oral cancer are at risk for developing loco-regional recurrences and second malignancies. After completion of the treatment, patients should be followed up at regular intervals to detect any signs of recurrence. Patients should be encouraged to give up tobacco and alcohol and know the signs and symptoms of recurrence.

Future recommendations

Primary prevention, especially smoking cessation, and secondary prevention, focused on high-risk individuals, are likely to be cost-effective and affordable in LMICs. Additional studies are required to assess the costeffectiveness and budget implications of visual screening for oral cancers in LMICs. These studies should focus on the screening delivery structure to identify the most cost-effective approach to provide oral cancer screening to high-risk individuals.

When cancer-screening policies are implemented, the success of the program will depend on participation by the target population. Even when screening and follow-up care are free of charge, patients may not be able to afford to lose a day's wages to attend screening clinics or travel to health centers to receive follow-up diagnostic testing or treatments. The indirect costs borne by the patients may be particularly challenging among those in the lower socioeconomic strata.³

These are the very individuals likely to be at higher risk for developing oral cancers; it is, therefore, vital that identifying approaches to encourage and sustain participation among this potentially hard-to-reach, high-risk population be given high priority.

A multifaceted approach that integrates health education, tobacco and alcohol control, early detection, and early treatment is needed to reduce the burden of this eminently preventable cancer. How to accomplish this is known; astonishingly, it has not been applied in most countries, and not at all in the high-burden countries. Improving awareness among the general public and primary care practitioners, investing in health services to provide screening and early diagnosis services for tobacco and alcohol users, and providing adequate treatment for those diagnosed with invasive cancer are critically important oral cancer control measures.⁴

Imaging, histopathology, cancer surgery and radiotherapy infrastructure and services, trained professionals, and the availability of chemotherapeutic agents are inadequate in many LMICs, seriously compromising early detection and optimum treatment. As this chapter has demonstrated, however, these interventions are affordable and cost-effective.

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KEY GAPS IDENTIFIED IN CURRENT INFRASTRUCTURE, HEALTHCARE FACILITIES, HUMAN RESOURCES, TECHNOLOGIES, POLICIES, PROGRAMS IN ORAL CANCER

Oral cancer, a significant health concern in India, presents a daunting challenge for public health systems. Despite concerted efforts, several substantial gaps persist across infrastructure, facilities, human resources, technologies, policies, and programs with regard to oral cancer management.

1. Infrastructure: In India, has a 3-tier health care delivery system consisting of primary, secondary, and tertiary levels was established to provide basic health care services accessible at a grass-root level. Health and Wellness Centers (HandWC), Primary Health Centers (PHC), Community Health Centers (CHC), and District Hospitals are the cornerstone of healthcare delivery. Unfortunately, they often lack specialized resources for early detection, diagnosis, and treatment of oral cancer. Deficiencies in oral cancer screening tools, biopsy facilities, and radiotherapy equipment hinder effective intervention.¹⁻²

A case study from Maharashtra suggested that the CHCs have been under radar of criticism with regard to their inability to deliver quality services as per the Indian Public Health Standards (IPHS) Standards. The main reasons are the lack of proper human resources, inadequate infrastructure, and facilities.³

- **2. Human Resources:** A dearth of adequately skilled healthcare professionals well-versed in oral cancer management is a pressing concern. The shortage extends to oral maxillofacial surgeons, oral medicine and radiologists, oral pathologists and public health dentists all are essential for accurate diagnosis and treatment. Furthermore, empowering healthcare workers across all levels with oral health education is pivotal in identifying and referring potential cases.⁴⁻⁵
- **3. Technologies:** Cutting-edge technologies, like AI-driven diagnostic tools, teledentistry for remote consultations and telemedicine for expert opinions offer promise in bridging gaps in oral cancer care, especially in remote areas where the prevalence remains high but goes unnoticed. Nonetheless, integrating these technologies into the healthcare system faces challenges due to awareness gaps, infrastructure and regulatory limitations.
- **4. Policies and Programs:** While broader cancer policies exist in India, targeted policies addressing oral cancer's prevention, early detection, and treatment are often absent. Tailored programs aimed at high-risk groups, such as tobacco and alcohol users and work-place based screening are instrumental in reducing oral cancer incidence. A comprehensive, multi-sectoral approach involving health, education, labour and other stakeholders is the need of the hour.⁶

Hence addressing these gaps necessitates collaborative efforts between government bodies, healthcare institutions, non-governmental organizations, and international agencies. Partnerships can facilitate funding, capacity building, and knowledge enhancement, ultimately improving the overall oral cancer care ecosystem. In conclusion, the challenges in oral cancer management in India are multifaceted and require a comprehensive and holistic approach. By addressing these gaps in infrastructure, human resources, education, policies,

and collaborative efforts, India can make significant strides in reducing the overall burden of oral cancer and ultimately improving public health.

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RECOMMENDATIONS TO BRIDGE THE CRITICAL GAPS/ DEFICIENCIES INFRASTRUCTURE, FACILITIES, TECHNOLOGIES, POLICIES, PROGRAMS IN ORAL CANCER

Generally, death rates for oral cancer exceed those of many other cancers; only half of all patients survive the first five years after diagnosis. 5-year survival rate for Stage I oral cancer of approximately 80%, while the corresponding value for patients with advanced disease (Stages III/IV) is approximately 20%. Despite advances in diagnosis and treatment, this number has not changed in the past decades. In addition, the impacts of oral cancer, even after treatment, result in severely reduced quality of life for those who survive (FDI, 2015). Only 0.2% of populations are screened for oral cancer in India. (NHFS-5).

The programs in India for oral cancer reflect the recognition of the need to collect cancer related data and prioritizing the management of various cancers; there are various lacunae that exist while addressing the menace of oral cancer in India.

The recommendations to bridge these lacunae's are discussed at three levels of approach - (Figure 16.1.)

- i. Macro (Policy & Programs)
- ii. Meso (Systems & Research)
- iii. Micro (Patients and Care provider)

i. Macro (Policy and Programs):

1) The political priority and will should be oriented to end the menace of oral cancer in India considering its high mortality and morbidity.

2) Policy & Programs:

 Fiscal, macro-economic, social-welfare and trade policies oriented to target risk factors of oral cancer (Tobacco, Arecanut, Alcohol etc) need to be revisited and made robust.

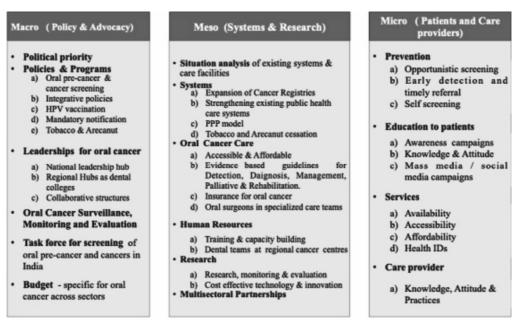


Figure 16.1: Recommendation to bridge the gap of for Oral precancer and Cancer Care in India

- There should be Integrative policies to address the areas like Risk factors (tobacco, alcohol, arecanut & HPV); Determinants; Inequalities; Education programs; Dentistry and other health care systems.
- Enabling inclusion of HPV vaccination in the National Immunisation Program for all: Despite achieving major milestones in indigenous HPV vaccine launch (2023), India is still to include the HPV vaccine as part of its Universal Immunization Program and presently girls are covered under this program.
- Oral cancer and pre-cancers should be declared by Indian Government as a notifiable disease, applicable across India, which will help strengthen the data availability through wider coverage with limited resources and funding.
- Tobacco control policy Existing tobacco control policies needs to be further augmented and strengthened along with effective implementation.
- Unlike tobacco, for which the WHO FCTC provides evidence-based policies, no global policy exists for the regulation and control of areca nut consumption and its cessation. Arecanut related policies and programs needs to be initiated in India.⁵
- 3) National leadership hub for oral cancer and oral pre-cancer should be initiated which coordinates with the state level hubs and other agencies/ bodies working for cancer. Dental colleges in India with existing infrastructure and manpower can function as hubs. The national hub can act as main advisory body for oral pre-cancer and oral cancer related policies/programs development, implementation, monitoring and evaluation as well as to set research priorities.
- 4) Oral pre-cancer and oral cancer Surveillance & Monitoring system needs to be created with the 2 other major cancers (breast and cervical) in India. The existing systems should be made robust and linked electronically with single data center for data management.
- 5) Task force of Screening of oral pre-cancers and oral cancers should be set up to look into the present evidence of screening and its effectiveness and further lay guidelines for screening programs in India as there is still limited evidence on population-based screening approaches and their cost-effectiveness in India.
- 6) A separate budget for oral cancer and oral pre-cancer has to be assigned for programs, research and health care systems. The cost effectiveness of opportunistic screening has been proven hence, specific funding of screening programs is imperative for country like India with huge population and diversity.

ii. Meso (Systems & Research)

1) **Situation analysis** of the existing health care systems, budget and research for oral precancer and oral cancer need to be carried out. The existing data is sparse and is mainly merged with the other cancers. In order to plan and provide administrative and financial forecasts, an urgent evaluation is required of the existing infrastructure and manpower under the NCCP.

2) Health care systems:

- Improving infrastructure to deliver quality services as per the Indian Public Health Standards (IPHS) Standards. This includes increasing the number of specialized cancer treatment centers, equipping them with state-of-the-art diagnostic and treatment equipment, and ensuring access to specialists in oral oncology.
- A 4 tier health care delivery system for cancer care with Multisectoral approach and PPP model is proposed in Figure 16.2.
- Expansion of Cancer Registries and strengthening of existing registries in India is imperative as only 38 Population Based Cancer Registries and 268 Hospital Based Cancer Registries under NCDIR –NCRP are covering only 10% of the population. These registries also need to set up in the existing dental colleges and hospitals with linkages to respective state registries.

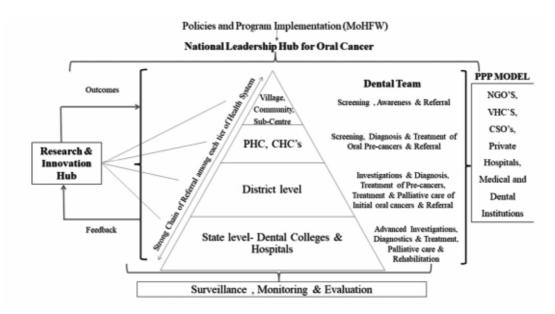


Figure 16.2: Proposed Oral cancer care in India

- Dental Colleges and Hospitals can also become a centre for comprehensive oral care and act as an early detector of OPMD'S and oral cancer.
- There is a pressing need to strengthen the existing public health care systems. The infrastructure, manpower and facilities to screen, diagnose and manage the patients in effective manner.
- Data should be captured to maintain longitudinal health records of population right from screening stage and ensuring tracking and follow up with patients for effective referrals. Digitalization of the facilities in terms of patient details entry, treatment and follow-up will facilitate the easy access and flow of information between databases during referral. Mandatory notification of data on from all health care systems in India should be implemented. Use of mhealth and robust data collection software or apps will also empower the ASHAs, ANMs, MOs and specialists with data regarding the patient

- The availability of screening, diagnostic and treatment support equipment, such as CT and PETCT, is also highly underpenetrated in India requiring significant ramp up.⁶
- With availability ~640 Radiotherapy (RT) installations in the country currently, there is a requirement of ~850 to 900 additional RT installations in the current state but the need will increase with increasing incidence of oral cancer. Public Private Partnerships can help to reduce the load on public health care systems.
- Tobacco and arecanut use cessation counselling capacity needs to further penetrate all the areas of country to reduce gaps. Dentists and dental organizations are actively to be involved.
- Referral and networking of centers to be strengthened.

3) Oral cancer care (Treatment, palliative and Rehabilitation)

- Developing the 4 tier care delivery systems for oral cancer will help to reduce the cancer care access in rural areas and reduce the cost of care.
- Provision of support for diagnosis, accessibility and cost-effective treatment at all levels of health care or oral pre-cancer and cancer.⁷
- Histopathological diagnosis being the gold standard for oral cancer detection can be
 a boon for early diagnosis and help in treatment planning, hence should be made
 more accessible to the rural population.
- The cost of care for many patients has come down due to some form of insurance/ government sponsored health coverage programs (54%) but the gaps in the coverage of different states needs to be minimized.⁸ The out-of-pocket expenditure on drugs and diagnostics can be reduced by Public Private Partnership (PPP) model of care and increasing the coverage of insurance for effective treatments. Include PET-CT as a separate procedure for reimbursement across the entire state government scheme.
- Evidence based Detection, Diagnosis, Management, Palliative & Rehabilitation should be emphasized. Guidelines and SOP's should be framed and circulated for uniform training and implementation.
- Emphasis on early diagnosis of OPMD lesions and Oral Cancer. More facilities should be enhanced in every health care system for early diagnosis. Training should be done for doctors and Para medical staff for earlier lesions of oral cancer. Encouraging technology driven tools like AI, Apps and early screening detection kits.⁹
- Focus on improving palliative care services for oral cancer patients, including pain management, psychological support, and rehabilitation programs. Collaborate with healthcare professionals and organizations specialized in palliative care to ensure comprehensive support for patients throughout their cancer journey.

- Guidelines for risk factor assessment and predictive analysis for OPMD and Oral cancer should be developed.
- Telemedicine, electronic patient records, robotics, AI-backed upskilling methods, daycare chemo, home care etc., are some of the strategies that are already in some places to address these care gaps but needs to be implemented throughout India.

4) Human Resources

- More oncologists should be deployed at cancer care centers. To meet the demand of oncologists, oral surgeons should be deployed at centers. Measures to be taken to increase the availability of oral health care team (oral and maxillofacial surgeons, oral medicine and diagnostic specialists, oral pathologists, and public health dentists) at all levels of health care settings including community settings.
- Adequate workforce planning and timely recruitment at CHC and DH will help meet gaps in the workforce.
- Sensitization, capacity building and training of all health care personnel involved in oral cancer care on regular basis with evaluations and feedbacks should be carried out.
- Training of paramedical staff, auxiliary nurses and ASHA workers for screening and to provide counseling to oral cancer patients, thus facilitating early diagnosis and prompt treatment to increase survival rates and reducing economic implications.

5) Research

- Research priorities to be identified, laid down and circulated based on situation analysis.
- Support collaborative efforts between government institutions, research organizations, and private industry to develop innovative approaches, technologies, and therapies.
- The evidence generated should be communicated among all stake holders including the general population.
- Cost effective technology & innovation should be encouraged for research and adopted for screening, diagnosis, management and rehabilitation of patients.
- Biomarkers both diagnostic and prognostics; Biosensors; Targeted therapy & immunotherapy areas need to researched more.

6) Multisectoral Partnerships (Collaboration and Partnerships)

• Foster collaborations between government bodies, healthcare providers, NGOs, and international organizations to pool resources and expertise in addressing the challenges associated with oral cancer. Encourage public-private partnerships to accelerate progress in research, prevention, and treatment initiatives.

- All organizations and agencies working for Oral cancer partner with the dental colleges and hospitals.
- Empower General Practitioner's and up skill specialists (dentists, ENT, etc.) to play an effective role as gatekeepers.
- Oral cancer should be part of healthy and safe schools, work places and public institutions & health facilities.

iii. Micro (Patients and care provider)

1) Prevention:

- Opportunistic screening should be done by all dentists and health care professionals to detect the lesions at the earliest. This saves the diagnostic delay and there will be timely referral which leads to increased prognosis of diseases.9 Screening also could be done by Grass root level workers who are more acceptable in society. Conventional oral examination for high-risk populations above 30s yaetar10-year intervals is recommended as the screening strategy. Estimates indicate that with expectations of improvement in early diagnosis of cancers, in 2030 the projected reported incidence will reach 40 to 45 lakhs (crude rate: 250 to 280 per lakh population) with 50 to 60% of cases being diagnosed in stage 1 and 2.6
- The National Cancer Registry Programme can be strengthened further, to include oral pre-cancers to facilitate early diagnosis and prompt treatment.
- Self-screening of the cavity can be taught to all patients and high risk groups for early detection of oral cavity for signs and symptoms of oral precancer lesion and conditions.

2) Education to patients (Awareness)

- Reduce the gap of knowledge existing among people. 10-12 Develop and implement comprehensive awareness and education campaigns to increase public knowledge of OPMD's and Oral Cancer -
 - Risk factors,
 - Screening,
 - HPV vaccination & other preventive measures
 - Treatment options and availability.
- These programs should have both whole population approach and high risk approach (tobacco, Arecanut and alcohol users etc) which is well implemented with standard operating procedures across the country to ensure maximum participation.
- Mass media / social media campaigns Sustained mass media campaign on social media platforms can be a powerful means to spread awareness about cancer screening, early detection, and prevention on a large scale. The mass media can be:
 - Information-based campaigns (mass-media information campaigns)
 - Written materials (pamphlets, labelling)
 - Campaigns reliant on people taking the initiative to opt in
 - Campaigns/messages designed for the whole population/risk groups
 - Approaches which involve significant price or other barriers.

3) Services

- Provision of adequate infrastructure, manpower, drugs and equipments in all centers to increase availability, accessibility of services.
- Insurance coverage to be penetrated to socio-economically disadvantaged populations and uniform throughout all places.
- Currently, the cancer registry only captures incidence data basis confirmed diagnosis. With the introduction of unique health ID or ABHA number, wellintegrated systems can enable linking of screening data to overall personal health records of an individual.

4) Care provider

- Bridge the gap between care provider and patients by knowledge dissemination. ¹³
- Sensitization and incentivization for work.

By focusing on these recommendations, India can make significant strides in addressing oral cancer, reducing its incidence and mortality rates, and improving the quality of life for those affected by this disease.

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ONLINE MEETING PROCEEDINGS OF THE TASKFORCE TEAM









ANNEXURES

Annexure-1: Chapter 4: Socio-cultural and Economic attributes of Oral Cancer in India

Table 1: Studies confirming the association of tobacco types and alcohol with oral cancer as per the literature reported from Indian studies:

				Smokel	ess form				Smo	oked form	
Study	Tobacco	Mishri	Paan	Gutka	Supari	Betel quid	Khaini	Zarda	Bidi	Cigarette	Alcohol
Madani et al (2012)	✓	✓	√	✓	✓	✓					
Nethan et al (2022)				✓			✓		√	√	✓
Iype et al (2001)	✓								√	✓	√
Sharma et al (2018)	✓										
Ajay et al (2018)	√								√	✓	✓
Vishma et al (2016)	√									✓	√
Jeeragyal et al (2017)	√								√	✓	
Prasad et al (2019)	✓									✓	
Balaram et al (2002)			√						√	✓	
Bhattacharjee et al (2006)	✓		√						√	✓	
Singla et al (2022)	✓										
Joshi et al (2022)									√	✓	√
Ken Russell Coelho (2012)		✓	✓				✓	✓	√	✓	
Aruna et al (2011)						✓					
Gangane et al (2007)						✓	✓		✓	✓	

Annexure-2: Chapter 12: Budget for various Oral Cancer Initiatives in India (prices are approximate, may vary across different healthcare institutions)

Speciality	Cross	AB PM-JAY	AB PM-JAY	Procedure	Tier 3	Tier 2	Tier 1	Implant Mapped
Medical Oncology	NA	CT for CA Head & Neck	Cisplatin + Docetaxel Docetaxel: 75 mg/m2, D1 Cisplatin: 75 mg/m2, D1 every 21 days	MO024A	13,700.00	15,500.00	16,200.00	NA
Medical Oncology	A A	CT for CA Head & Neck	Cisplatin Cisplatin: 100 mg/m2, every 21 days	MO024B	10,800.00	12,300.00	12,800.00	NA
Medical Oncology	NA	CT for CA Head & Neck	Carboplatin + Gemcitabine Gemcitabine: 1000 mg/m2, D1 D8 Carboplatin: AUC 5-6, D1 every 21 days	MO024C	15,300.00	17,400.00	17,400.00	NA
Medical Oncology	NA	CT for CA Head & Neck	Docetaxel + Cisplatin + 5 FU Docetaxel: 75 mg/m2, D1 Cisplatin: 75 mg/m2, D1 5 FU: 750 mg/m2, D1-D5 every 21 days	MO024D	16,000.00	18,200.00	18,900.00	NA
Medical Oncology	NA	CT for CA Head & Neck	Docetaxel Docetaxel: 20mg/m2, every week	MO024E	3,600.00	4,000.00	4,200.00	V V
Medical Oncology	NA	CT for CA Head & Neck	Docetaxel Docetaxel: 75 mg/m2, D1 every 21 days	MO024F	9,400.00	10,700.00	11,100.00	NA
Medical Oncology	NA	CT for CA Head & Neck	Etoposide + Carboplatin Etoposide: 100mg/m2, D1 - D3 Carboplatin: AUC 5-6, D1 every 21 days	MO024G	8,500.00	9,700.00	9,700.00	NA
Medical Oncology	NA	CT for CA Head & Neck	Etoposide + Cisplatin Etoposide: 100mg/m2, D1 - D3 Cisplatin: 75-100 mg/m2, D1 every 21 days	MO024H	10,200.00	11,600.00	11,600.00	NA
Medical Oncology	NA	CT for CA Head & Neck	Gemcitabine Gemcitabine: 1000 mg/m2, D1 D8 every 21 days	MO024I	9,900.00	11,300.00	11,300.00	NA
Medical Oncology	NA	CT for CA Head & Neck	Gemcitabine + Cisplatin Gemcitabine: 1000 mg/m2, D1 D8 Cisplatin: 75 mg/m2, D1 every 21 days	MO024J	13,400.00	15,200.00	15,200.00	NA
Medical Oncology	NA	CT for CA Head & Neck	Paclitaxel + Carboplatin Paclitaxel: 80mg/m2, D1 Carboplatin: AUC 2, D1 every week	MO024K	8,500.00	9,700.00	9,700.00	NA
Medical Oncology	NA	CT for CA Head & Neck	Paclitaxel + Carboplatin Paclitaxel: 175mg/m2, every 21 days	MO024L	16,000.00	18,200.00	18,200.00	NA
Medical Oncology	NA	CT for CA Head & Neck	Paclitaxel Paclitaxel: 80mg/m2, every week	MO024M	6,600.00	7,500.00	7,500.00	NA
Medical Oncology	NA	CT for CA Head & Neck	Paclitaxel Paclitaxel: 175mg/m2, every 21 days	MO024N	13,000.00	14,800.00	15,400.00	NA
Medical Oncology	NA	CT for CA Head & Neck	Carboplatin Carboplatin: AUC 2, every week	MO0240	3,000.00	3,400.00	3,600.00	NA
Medical Oncology	NA	CT for CA Head & Neck	Cisplatin Cisplatin: 40mg/m2, every week	MO024P	2,600.00	3,000.00	3,100.00	NA

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MR006A	MR006B	MR006C	MR006D	MR007A	MR007B	MR007C
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MR009B	MR009C	MR009D	MR010A	MR010B	PM002A	PM003A	PM004A	PM009A
Adjuvant	Neoadjuvant	Additional fractions - Max up to 18 (Every Additional Fraction at Rs. 2500)	SRT/SBRT with IGRT (Stereotactic Radiotherapy)	Additional fractions - Max up to 4 (Every Additional Fraction at Rs. 11,000)	Management of Bleeding in Haemostatic Surgery in Advance Malignant Head and Cancer Patient / Haemostatic Neck/Inguinal Lesions Radiotherapy	Transarterial Embolisation	Osteoradionecrosis - Surgical intervention	Osteoradionecrosis - Conservative
Linear Accelerator External Beam Radiotherapy IGRT (Image Guided Radiotherapy) with 3D CRT or IMRT (6 Fractions) (Inclusive of Simulation & Planning Costs)	Linear Accelerator External Beam Radiotherapy (BRT (image Guided Radiotherapy) with 3D CRT or IMRT (6 Fractions) (inclusive of Simulation & Planning Costs)	Linear Accelerator External Beam Radiotherapy (BRT (Image Guided Radiotherapy) with 3D CRT or IMRT (6 Fractions) (Inclusive of Simulation & Planning Costs)	SRT/SBRT with IGRT (Stereotactic Radiotherapy) (4 Fractions) (Inclusive of Simulation & Planning Costs)	SRT/SBRT with IGRT (Stereotactic Radiotherapy) (4 Fractions) (Inclusive of Simulation & Planning Costs)	Management of Bleeding in Malignant Head and Neck/Inguinal Lesions	Management of Bleeding in Malignant Head and Neck/Inguinal Lesions	Palliative Care Management of Osteoradionecrosis - Surgical Intervention	Palliative Care Management of Osteoradionecrosis - Conservative Management
A A	NA	NA	NA	NA	NA	NA	NA	N A
Radiation Oncology	Radiation Oncology	Radiation Oncology	Radiation Oncology	Radiation Oncology	Palliative Medicine	Palliative Medicine	Palliative Medicine	Palliative Medicine

AN	NA	NA	NA	NA
GW - Rs. 2,400/- per day HDU - 3,800/- per HDU - 3,800/- per Cot (without Ventilator) - Rs. 9,700/- per day (ICU (with Ventilator) - Rs. 10,350/- per day Rs. 10,350/- per day	GW - Rs. 2,400/- per day HDU - 3,800/- per day (ICU (without Ventilator) - Rs. 9,700/- per day (ICU (with Ventilator) - Rs. 10,350/- per day Rs. 10,350/- per day	GW - Rs. 2,400/- per day - S.2,400/- per HDU - 3,800/- per day ICU (without Ventilator) - Rs. 9,700/- per day ICU (with Ventilator) - Rs. 10,350/- per day	GW - Rs. 2,400/- per day - Rs. 2,400/- per HDU - 3,800/- per day iCU (without Ventilator) - Rs. 9,700/- per day iCU (with Ventilator) - Rs. 10,350/- per day	GW - Rs. 2,400/- per day - Rs. 2,400/- per HDU - 3,800/- per day (ICU (with out Ventilator) - Rs. 9,700/- per day (ICU (with Ventilator) - Rs. 10,350/- per day
GW - Rs. 2,400/- per day HDU - 3,800/- per day ICU (without Ventilator) - Rs. 9,700/- per day ICU (with Ventilator) - Rs.	GW - Rs. 2,400/- per day HDU - 3,800/- per day ICU (without Ventilator) - Rs. 9,700/- per day 10,350/- per day	GW - Rs. 2,400/- per day HDU - 3,800/- per day ICU (without Ventilator) - Rs. 9,700/- per day ICU (with Ventilator) - Rs.	GW - Rs. 2,400/- per day HDU - 3,800/- per day ICU (without Ventilator) - Rs. 9,700/- per day ICU (with Ventilator) - Rs.	GW - Rs. 2,400/- per day HDU - 3,800/- per day ICU (without Ventilator) - Rs. 9,700/- per day 10,350/- per day
GW - Rs. 2,300/- per day hDU - Rs. 3,630/- per day ICU (without Ventilator) - Rs. 9,350/- per day ICU (with Ventilator) - Rs. 9,900/- per day	GW - Rs. 2,300/- per day HDU - Rs. 3,630/- per day ICU (without Ventilator) - Rs. 9,350/- per day ICU (with Ventilator) - Rs. 9,900/- per day	GW - Rs. 2,300/- per day HDU - Rs. 3,630/- per day ICU (without Ventilator) - Rs. 9,350/- per day ICU (with Ventilator) - Rs. 9,900/- per day	GW - Rs. 2,300/- per day HDU - Rs. 3,630/- per day ICU (without Ventilator) - Rs. 9,350/- per day ICU (with Ventilator) - Rs. 9,900/- per day	GW - Rs. 2,300/- per day HDU - Rs. 3,630/- per day ICU (without Ventilator) - Rs. 9,350/- per day ICU (with Ventilator) - Rs. 9,900/- per day
PM010A	PM012A	PM020A	PM021A	PM022A
Communications - Terminal Stage/End-of-Life Care - Conservative	Cancer Pain Management	Palliative care in Trismus Mucositis	ıf Bleeding in Conservative Management of d and Fatal Bleeding in Cancer Patients -esions	Fatigue in Palliative Care
Communications in Advanced Chronic Diseases/Terminal Stage of illness, for Patient and Family Members with Discussions on Goals of Care and Facilitate Shared Decision Making	Palliative Care Management of Pain for Treating Pain Crisis, Analgesic Titration	Palliative Care Management of Trismus, Mucositis in Advanced Cancer Patient	Management of Terminal/Fatal Bleeding in Malignant Head and Neck/Inguinal Lesions	Palliative Care Management of Symptom Cluster – Fatigue in Advanced Cancer Patients
NA	NA	NA	NA	NA
Palliative Medicine	Palliative Medicine	Palliative Medicine	Palliative Medicine	Palliative Medicine

ΝΑ	ΝΑ	ΥV	ΥV	NA	(1) Plate @ Rs. 10,000/- (1) Mega Prosthesis @ Rs 1,00,000/-	A A	NA	NA	NA:	A A	NA
GW - Rs. 2,400/- per day the U-3,800/- per day iCU (without Ventilator) - Rs. 9,700/- per day iCU (with Ventilator) - Rs. 10,350/- per day	GW - Rs. 2,400/- per day HDU - 3,800/- per day ICD (without Ventilator) - Rs. 9,700/- per day 10,00 (with Ventilator) - Rs. 10,350/- per day	GW - Rs. 2,400/- per day HDU - 3,800/- per day ICU (without Ventilator) - Rs. 9,700/- per day ICU (with Ventilator) - Rs. 10,350/- per day	GW - Rs. 2,400/- per day HDU - 3,800/- per day ICU (without Ventilator) - Rs. 9,700/- per day 9,700/- per day Rs. 10,350/- per day	9,800.00	45,000.00	105,900.00	67,600.00	77,200.00	91,200.00	83,900.00	65,600.00
GW - Rs. 2,400/- per day HDU - 3,800/- per day ICU (without Ventilator) - Rs. 9,700/- per day 10,20 (with Ventilator) - Rs.	GW - Rs. 2,400/- per day HDU - 3,800/- per day ICU (without Ventilator) - Rs. 9,700/- per day 10,20 (with Ventilator) - Rs. 10,350/- per day	GW - Rs. 2,400/- per day HDU - 3,800/- per day ICU (without Ventilator) - Rs. 9,700/- per day 10,20 (with Ventilator) - Rs. 10,350/- per day	GW - Rs. 2,400/- per day HDU - 3,800/- per day ICU (without Ventilator) - Rs. 9,700/- per day 10,200 (with Ventilator) - Rs. 10,350/- per day	9,400.00	42,600.00	100,300.00	64,000.00	73,100.00	86,300.00	83,900.00	62,100.00
GW - Rs. 2,300/- per day HDU - Rs. 3,630/- per day ICU (without Vertilator) - Rs. 9,530/- per day ICU (with Vertilator) - Rs. 9,900/- per day	GW - Rs. 2,300/- per day HDU - Rs. 3,630/- per day ICU (without Ventilator) - Rs. 9,350/- per day ICU (with Ventilator) - Rs. 9,360/- per day Rs. 9,900/- per day	GW - Rs. 2,300/- per day HDU - Rs. 3,630/- per day ICU (without Ventilator) - Rs. 9,350/- per day ICU (with Ventilator) - Rs. 9,900/- per day	GW - Rs. 2,300/- per day HDU - Rs. 3,630/- per day ICU (without Ventilator) - Rs. 9,350/- per day ICU (with Ventilator) - Rs. 9,900/- per day	8,300.00	37,500.00	88,300.00	56,	64,	76,000.	67,200.	54,600.00
PM028A	PM037A	PM038A	PM039A	PM040A	SB041A	SC001A SC00	SC002A	SC002B	SC003A	SC003B SC003C	SC004A
Palliative Wound Conservative Management	Palliative Care in Nausea and Vomiting	Palliative Care in Diarrhoea	Palliative care end stage disease	Cancer pain interventions	Bone Tumour Excision + Reconstruction	Hemiglossectomy Total Glassectomy	Soft palate	Hard palate	Partial	Radical	Composite Resection (Oral Cavity)
Palliative Care Approach for Malignant Wound - Conservative Management using Drugs and Dressings including Special Dressings.	Palliative Care Management of Nausea & Vomiting in Cancer Patients - Conservative Management	Management of Diarrhea in Cancer Patients - Conservative Management	Palliative and Supportive Care for Non-Malignant Disease at Advanced or End-Stage	Spinal/Epidural/Regional Nerve Block, Radiofrequency Ablation (RFA) for Analgesia	Surgical Oncolo Reconstruction	Glossectomy 1B	Palatectomy 400.00	Palatectomy 400.00	~	Maxillectomy 00 Maxillectomy	Composite Resection (Oral Cavity)
AN	NA	NA	NA	NA	Surgical Oncolo	NA NA				Δ Δ	
Palliative Medicine	Palliative Medicine	Palliative Medicine	Palliative Medicine	Palliative Medicine	Orthopaedics	Surgical Oncology Surgical Oncology	Surgical Oncology	Surgical Oncology	Surgical Oncology	Surgical Oncology Surgical Oncology	Surgical Oncology

Surgical Oncology	NA	Neck Dissection - Comprehensive	Neck Dissection - Comprehensive	SC065A	33,300.00	37,800.00	39,900.00	NA
Surgical Oncology	NA		Benign Soft Tissue Tumour - Excision	SC066A	19,300.00	21,900.00	23,200.00	NA
Surgical Oncology	NA	0	Malignant Soft Tissue Tumour - Excision	SC067A	51,000.00	57,900.00	61,200.00	NA
Surgical Oncology	Orthopaedics	Soft Is:	Bone Tumours / Soft Tissue Sarcomas: Surgery	SC070A	52,800.00	60,000.00	63,400.00	NA
Surgical Oncology	NA	Wide Excision - Oral Cavity Malignancy	Wide Excision - Oral Cavity Malignancy	SC082A	49,000.00	55,700.00	58,800.00	NA
General Surgery	Surgical Oncolo		Estlander Operation (Lip)5061A	S 18,500.00	00:00	21,000.00	22,200.00	NA
General Surgery	Surgical Oncolo	Carcinoma	Wedge Excision	SG062A	25,100.00	28,500.00	30,100.00	NA
General Surgery	Surgical Oncolo Lip	Operation for Carcinoma Lip	Wedge Excision and Vermilionectomy	SG062B	37,500.00	42,600.00	45,000.00	NA
General Surgery	Surgical Oncolo	Surgical Oncolo Lip	Cheek Advancement	SG062C	37,500.00	42,600.00	45,000.00	NA
General Surgery	Paediatric Surgery Surgical Oncology	>	Complete Excision of Growth from Tongue only (Inclusive of Histopathology)	SG063A	20,900.00	23,700.00	25,000.00	NA
General Surgery	Surgical Oncolo	Excision of Growth from Surgical Oncold Tongue with Neck Node Dissection	Excision of Growth from Tongue with Neck Node Dissection	SG064A	39,200.00	44,500.00	47,000.00	NA
General Surgery	Surgical Oncolo Excision	Submandibular Mass Excision	Submandibular Mass Excision	SG066A	25,000.00	28,400.00	30,000.00	NA
General Surgery	ENT Surgical Oncology	Radical Neck Dissection	Radical Neck Dissection	SG067A	33,700.00	38,300.00	40,400.00	NA
General Surgery	Surgical Oncolo	Excision of Tumour of Oral Carlty / Paranasal Surgical Oncolo Sinus / Laryngopharynx with or without Reconstruction	Excision of Tumour of Oral Cavity / Paranasal Sinus / Laryngopharynx without Reconstruction	SL020A	12,500.00	14,200.00	15,000.00	(1) Implant @ Rs. 20,000/-
General Surgery	Surgical Oncolo	Excision of Tumour of Oral Cartity / Paranasal Surgical Oncolo Sinus / Laryngopharynx with or without Reconstruction	Excision of Tumour of Oral Cavity / Paranasal Sinus / Laryngopharynx with Pedicled Flap Reconstruction	SL020B	45,700.00	51,900.00	54,800.00	NA
General Surgery	Surgical Oncolo	Excision of Tumour of Oral Cavity / Paranasal Surgical Oncolo Sinus / Laryngopharynx with or without Reconstruction	Excision of Tumour of Oral Cavity / Paranasal Sinus / Laryngopharynx with Free Flap Reconstruction	SL020C	31,300.00	35,500.00	37,500.00	37,500.00 (1) Implant @ Rs. 20,000/-
ENT	General Surgery Surgical Oncology	Parotidectomy	Total Parotidectomy	SL021A	28,200.00	33,000.00	35,300.00	NA
ENT	General Surgery Surgical Oncology	Parotidectomy	Superficial Parotidectomy 00	SL021B	23,800.	27,900.00	29,800.00	NA
OMFS	NA	Surgery for Cyst & Tumour of Maxilla/Mandible	Enucleation/Excision of Cyst/Tumour of Jaws under LA + Cost of Implant	SM005A	2,700.00	3,100.00	3,300.00	NA

	:	Surgery for Cyst &	Enucleation/Excision of					:
OMFS	¥ Z	Tumour of	Cvst/Tumour of Jaws under GA	SM005B	2,500.00	6,400.00	6,800.00	ΑΝ
		Maxilla/Mandible						
		Mandible Tumour	Mandible Tumour					
OMES	ΔN	Resection and	Mandible Tumour Resection and	SMOORA	13 500 00	15 800 00	16 900 00	ΔN
	<u>{</u>	Reconstruction (Cancer	Reconstruction (Cancer Surgery)		00000	000000	00.000,0	<u> </u>
		Surgery)						
		Octoboropic	Osteoradionecrosis of Jaws -					
OMFS	Ϋ́	Management by Excision	Management by Excision under	SM014A	2,000.00	5,900.00	6,300.00	ΑΝ
		manuagement by Excision	LA					
			Osteoradionecrosis of Jaws -					
SIMO	Š	Osteoradionecrosis	Management by Excision and/or	00000	00000	00 001 21	100000	V
0	<u> </u>	Management by Excision	lanagement by Excision Reconstruction under GA	24-10/10	00.000,0	00.001,	0,000,0	5
			including Implant					

