National Guidelines for Management of Oral Potentially Malignant Disorders for Medical and Dental Practitioners

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Cancer is the second most common cause of mortality in Sri Lanka. Lip, oral cavity and pharyngeal cancer are the leading cancers identified among males in Sri Lanka and account for approximately one fourth of all male cancers. These cancers are predominantly preventable through modification of life style and habits.

Detection of Oral Potentially Malignant Disorders is one of the key strategies used for prevention and control of oral cancers. At the same time, early detection of oral cancer will vastly improve the outcome of treatment and greatly improve the quality of life of patients.

Developing and updating the ‘Guidelines for management of Oral Potentially Malignant Disorders’ will improve the knowledge and practice in the detection of Oral Potentially Malignant Disorders by Dental and Medical practitioners. It will facilitate in reducing the oral cancer burden in Sri Lanka.

I hope Dental Surgeons and Medical Officers would make maximum use of this guidelines and improve the quality of health care provided to the public.

Dr. Anil Jasinghe
Director General of Health Services
Message from the Deputy Director General (Non Communicable Disease Bureau)
Ministry of Health, Nutrition and Indigenous Medicine

It is with great pleasure I am sending this message to the third edition of the ‘Guidelines for Management of Oral Potentially Malignant Disorders’.

Cancer is a non-communicable disease predicted to be an important cause of morbidity and mortality all over the world as well as in Sri Lanka. Epidemiological evidence points towards an increasing trend in the low and middle income countries in the world where more than 70% of all cancer deaths occur.

The need of a guidelines for healthcare providers on screening, diagnosis and management of these disorders including the criteria for referral for specialist care has been correctly identified by the National Cancer Control Programme. Therefore, I hope this guidelines will contribute to improve competency of detection of Oral Potentially Malignant Disorders among Dental Surgeons and Medical Officers which improves the overall early detection of Oral Potentially Malignant Disorders and oral cancer in Sri Lanka.

I would like to appreciate the contributions of resource personnel in developing and updating this guidelines and the coordinating role of the National Cancer Control Programme.

Dr. (Mrs.) S. C. Wickramasinghe
Deputy Director General (Non - Communicable Disease Bureau)
Cancers in the lip, oral cavity and pharynx, commonly called as ‘oral cancer’ are a group of cancers largely preventable and also can be cured if detected early. Oral cancers are preceded by the condition called as ‘Oral Potentially Malignant Disorders’ and is detectable by routine screening.

Despite this conducive environment for prevention and early detection, oral cancer ranks high in Sri Lanka. Sri Lanka is one of the few countries where the oral cancer is the leading cause of cancer among men. On average, one in every fourth cancer among men and one in seventh of all cancers (in men and women) in Sri Lanka is an oral cancer. Furthermore, each day, 3 to 4 people in Sri Lanka are dying of oral cancer. Majority of oral cancers presenting to the healthcare system in Sri Lanka are at advanced stages preventing better outcome.

This sad status of affairs reflect the need for more and more high-risk individuals referring and screening for Oral Potentially Malignant Disorders at primary care level and strengthening the available services at all levels. Dental Surgeons and Medical Officers at primary care level need proper guidance for the screening and early detection of Oral Potentially Malignant Disorders.

The National Cancer Control Programme, having understood this need, has developed this guidelines in 2013 and pleased to publish the revised third edition.

I am very much thankful to Dr. Prasanna Jayasekara, Consultant in Community Dentistry, National Cancer Control Programme for taking the lead role and guiding his team for preparing the third edition of the publication. I also very much appreciate, Dr. Hemantha Amarasinghe, Consultant in Community Dentistry who has taken the lead role in drafting the first edition of this publication and actively contributing for the development of subsequent editions. The active contribution provided by Dr. Eshani Fernando, former Acting Director and Deputy Director of the National Cancer Control Programme is also very much appreciated. I am also very much thankful to all the members of the Editorial Committee for their excellent contribution provided.

It is my sincere wish that the Dental Surgeons and Medical Officers at the primary care level will use the ‘Guidelines for Management of Oral Potentially Malignant Disorders’ for screening and early detection of Oral Potentially Malignant Disorders and oral cancers thereby reducing the burden of oral cancer in Sri Lanka.

Dr. Sudath Samarakweera,
Director,
National Cancer Control Programme.
Chapter 1
Introduction

Oral cancer is the commonest malignancy among males in Sri Lanka and the seventh most common cancer among females. Malignancies of the lip, tongue and mouth are estimated to account for 11.1% of all reported cancers among the Sri Lankan population. The age standardized incidence of lip, tongue and mouth cancers among Sri Lankans in 2011 was reported as 16.4 and 4.1 per 100,000 among males and females respectively (National Cancer Control Programme Sri Lanka, 2018).

More than 90% of oral cancers are Squamous Cell Carcinomas (SCC) (Moore et al, 2000). In most instances in South Asia, oral SCC is preceded by clinically recognizable disorders appearing on the oral mucosa such as leukoplakia, erythroplakia, oral sub mucous fibrosis and oral lichen planus. These diseases that precede the appearance of oral cancer are collectively referred to as Oral Potentially Malignant Disorders (OPMDs) (Warnakulasuriya et al, 2007). Summary of the genetic alterations that are observed at the different stages of oral carcinogenesis is depicted in Fig 1. The molecular changes that are associated with dysplasia grade and transformation to OSCC are shown in this figure.

Fig 1: Summary of the genetic alterations that are observed at the different stages of oral carcinogenesis (Dionne et al., 2015)
These main OPMDs, except oral lichen planus, are usually associated with the habits such as betel quid chewing, chewing tobacco, smoking, snuff dipping, areca nut chewing and alcohol intake (Shiu and Chen, 2004; Tilakaratne et al, 2006). Smokeless tobacco in the form of betel quid, oral snuff, and betel quid substitutes (locally called guktha, nass, naswar, khaini, mawa, mishri, and gudaku) increases the risk of oral precancerous lesions and oral cancer between 2-fold and 15-fold (Gupta et al, 2013).

Tobacco chewing, smoking and consumption of alcohol have been shown to act synergistically with the combined risk being considerably increased in comparison to when the individual factor is found alone. Combination of risk factors also can act as a promoter in the malignant transformation from OPMDs to oral cancer. Smoking and alcohol consumption have been shown to act synergistically with the combined risk being considerably increased in comparison to when the individual factor is found alone (Kadashetti et al, 2017). Smokeless tobacco use among young people is increasing in South Asia, with the marketing of conveniently packaged products made from areca nut and tobacco; as a consequence, oral precancerous conditions in young adults have increased significantly (Gupta et al, 2011). Only a portion of OPMDs necessarily undergo malignant transformation.

A systematic review of observational studies revealed that the estimated overall (mean) malignant transformation rate for oral leukoplakia was 3.5%, with a wide range from 0.13% to 34% (Warnakulasuriya and Ariyawardana, 2016). This article reported that the features that stand out as significant determinants contributing to malignant potential of oral leukoplakia include advanced age, sex, leukoplakia exceeding 200 mm², non-homogenous type (eg.erythroleukoplakia) and higher grades of dysplasia.

OPMD prevalence has been reported to be as low as 0.2% and as high as 11.3% with multiple estimates falling in between these extremes. The worldwide prevalence of leukoplakia has been estimated at 2%. Although the worldwide prevalence is unknown for other types of OPMDs, erythroplakia prevalence among populations in Malaysia and India is estimated at 0.02% (Dionne et al,2015).

To reduce the risk of malignant transformation, efforts should be made to eliminate modifiable risk habits, and patients should be appropriately counselled at the earliest opportunity. As these patients remain at risk for malignant transformation, they should be followed-up at regular intervals. Currently, follow-up intervals are not evidence-based and are entirely based on clinicians’ subjective assessment of clinical appearance and reported dysplasia in the specimens. The occurrence of malignant transformation is likely greatest within the first 2 years, and thereafter an estimated 1% may transform annually. However, patients should remain on regular follow-up and clinically suspicious areas should be re-biopsied by an experienced clinician if clinically indicated (Dionne et al,2015).

According to the National Oral Health Survey of Sri Lanka 2015/2016, leukoplakia and oral submucous fibrosis were the most prevalent OPMDs among 35-44 and 65-74 year old age
groups (prevalence of leukoplakia was 1.06% and 0.97% in the respective age groups and prevalence of oral sub mucous fibrosis was 0.45% and 1.07% in the respective age groups. The same survey had revealed the prevalence of oral cancer among 65-74 year old age group was 0.05 % (Ministry of Health Sri Lanka, 2018). However, higher prevalence of OPMDs were reported among certain population sub group in Sri Lanka. A study done among labourers employed in tea estate plantations in Sri Lanka revealed that the prevalence of leukoplakia and oral sub mucous fibrosis was 4.61% and 1.64% (Ariyawardana et al, 2007).

As most of the risk factors stated above are related to life styles of individuals, it is evident that most oral cancers are preventable. Moreover, oral cavity can be easily examined without the need for any sophisticated equipment. Primary and secondary prevention of oral cancer are thus relatively easily attainable if healthcare providers such as dental surgeons and medical officers have adequate knowledge on risk factors and skills in the recognition of OPMDs and whenever opportunity arises, perform a thorough examination of the mouths of their patients to detect OPMDs. Such routine examination of the mouth would also facilitate the detection of oral cancer in its early stages, which would in turn lead to prompt referral of the patients for relatively less complicated and less mutilating treatment.

This documents consists of three sections.

1. Screening
2. Diagnosis and management of OPMDs
3. Surveillance
Chapter 2

Screening Guidelines

2.1 Introduction

Screening

Screening is defined as the presumptive identification of unrecognized disease in an apparently healthy, asymptomatic population by means of tests, examinations or other procedures that can be applied rapidly and easily to the target population. A screening programme must include all core components in the screening process from inviting the target population to accessing the effective treatment for individuals diagnosed with disease (World Health Organization, 2018).

An effective screening programme should meet the following criteria:

- Mechanisms for systematic invitation and follow-up for individuals identified by the screening test as having an abnormal finding (call and recall mechanisms);
- Participation of over 70% of the target population to be screened;
- Necessary infrastructure and resources to offer the test periodically and to adequately diagnose and treat those found to have cancer or a precancerous lesion, and;
- Robust monitoring and evaluation framework to assure quality

Concept of Screening

In order to understand the screening process, it is necessary to consider the different stages in the development of a cancer. Screening differs from early diagnosis in that an entire target population is examined for unrecognized cancer or precancerous lesions and the majority of individuals tested will not have the tested disease (World Health Organization, 2017). Figure 2 shows the different stages of the disease with reference to screening and early diagnosis.
Fig 2:  Natural history of OPMD and oral cancer (Modified from World Health Organization, 2017)

**Biological onset of the disease (Epithelial dysplasia)**

The time at which a disease or condition first appears, but yet to cause any clinical signs.

E.g.: In case of oral cancer this would be the development of the first cancerous cell or a clone of transformed cells.

**Latent period (Carcinoma in-situ)**

The period of time between the biological onset of disease and the development of clinical signs.

E.g.: In the case of oral cancer, this would be the duration between the development of the first cancerous cell and the time at which an oral lesion is seen.

Screening should be done during the asymptomatic stages of the disease.
The core assumption in oral cancer screening

Diagnosis and treatment in the asymptomatic stage will lead to better outcomes than diagnosis and treatment following the presentation of symptoms. Oral cancer is a disease which fulfills most of the criteria for screening. It is considered to be one of the most cost effective approaches for control of oral cancer in a high risk country. The screening test for oral cancer might be affordable, easy to use, accurate and effective in controlling oral cancer. Employing such a screening test will increase treatment demand. However, the level of health service development and available resources should be considered before the decision to introduce population based screening. The target population for oral cancer screening which includes of those age 30 years and older who use tobacco and/or alcohol be considered as a better approach. (Sankaranarayanan et al, 2015)

Visual screening of the oral cavity has been widely evaluated for its feasibility, safety, acceptability, accuracy to detect OPMDs and cancer, and efficacy and cost-effectiveness in reducing oral cancer mortality (Johnson et al, 2011; Sankaranarayanan et al, 2005; Sankaranarayanan et al, 2013).

Visual screening involves systematic visual and physical examination of the intraoral mucosa under bright light for signs of OPMDs, as well as early oral cancer, followed by careful inspection and digital palpation of the neck for any enlarged lymph nodes.

Since the performance of oral visual screening in detecting lesions varies among providers, the providers should have comprehensive knowledge of the oral anatomy, the natural history of oral carcinogenesis, and clinico-pathological features of OPMDs and preclinical cancer (Sankaranarayanan et al, 2015).

2.2 Screening strategies

There are two main strategies used for screening of OPMDs / oral cancer

1. Risk strategy

   There are two screening types using risk strategy
   
   I. Targeted screening for high risk individuals
   II. Targeted screening for population sub groups who are at risk

   This risk strategy used for screening for OPMDs/oral cancer could be performed even by primary health care workers. Feasibility of this approach was demonstrated in a study conducted in Sri Lanka in early 80s. (Warnakulasuriya et. al, 1984)

2. Opportunistic screening in the dental / medical clinics

   This could be done when patients who are attending a health care provider for another purpose are examined for clinical signs of OPMDs/ oral cancer.
Although above screening strategies are implemented in Sri Lanka, there are problems in identifying the target groups, coverage and sustainability of these programmes. These reasons may contribute towards increased number of patients presenting to hospitals with advanced stages of oral cancer which are often in the incurable stage.

The main obstacles for effective OPMD / oral cancer screening in Sri Lanka are:

- Lack of an established referral system
- Difficulty in allocating time for oral cancer screening due to routine activities of primary health care (PHC) staff namely MCH (Maternal and Child Health) and other vertical preventive programmes devolved to the grass root level
- Inadequate number of continuous education programmes for PHC staff and dental surgeons to update the knowledge
- Lack of monitoring and evaluation of healthcare workers
- Lack of comprehensive surveillance system for OPMDs / oral cancer

To detect high risk individuals during screening programmes three criteria are developed (Table 1). These are based on the Risk Factor Model (RFM) developed by Amarasinghe et al in 2010.

Table 1: Criteria to identify individuals at higher risk for OPMDs and oral cancer

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<tr>
<td>1</td>
<td>Those who chew betel quid three or more times a day</td>
</tr>
<tr>
<td>2</td>
<td>Those who chew betel quid less than three times a day and additionally smoke and / or consume alcohol habitually</td>
</tr>
<tr>
<td>3</td>
<td>Those who habitually consume smokeless tobacco and areca nut products (Babul beeda, Pan parag, Mawa etc.)</td>
</tr>
</tbody>
</table>
Screening and referral pathway

Individuals are referred to dental clinics for clinical oral examinations and the referral pathway is mentioned in figure 3.

Targeted screening of population sub groups who are at risk (estate workers, three - wheel drivers, labourers etc) - conducted by dental surgeons

Those individuals having increased self-awareness due to social marketing campaigns / awareness programmes

Screening of high risk individuals for risk factors carried out by Medical Officers of OPD/ Healthy Lifestyle Centres/ Private medical clinics and Primary Health Care Staff

Triad of criteria
- Those who chew betel quid three or more times a day.
- Those who chew betel quid less than three times a day and additionally smoke and /or consume alcohol habitually
- Those who habitually consume smokeless tobacco and areca nut products (Babul beeda, Pan Parag, Mawa etc.).

Government Dental Clinic

Opportunistic screening of all patients attending government / private dental clinics

Screening Positive for further investigations
- Habit intervention
- Oral hygiene improvement
- Should be managed according to the guidelines for management of Oral Potentially Malignant Disorders

Screening Negative
- Habit intervention
- Oral hygiene improvement
- Review in 12 months

Fig 3: Screening and referral pathway
Chapter 3

Benign oral mucosal abnormalities identified through an oral examination

Frictional keratosis
A whitish or grayish patch or line, the location of which corresponds to the site for a readily recognizable physical trauma (Fig. 4).

Denture stomatitis
Denture Stomatitis is described as an inflammation of the mucous membranes of the mouth in the denture bearing zone of the people wearing dentures due to irritation and most commonly due to oral candidiasis (Fig. 5).

Smoker’s palate (Stomatitis nicotina palati)
Specific whitish lesion of the palate in pipe & cigar smokers (Fig. 6). At initial stage the palatal mucosa shows erythematous changes followed by keratinization. Subsequently red dots surrounded by white keratotic rings appear. The red dots represent the inflamed ducts of the minor salivary glands.

Angular cheilitis
Angular cheilitis clinically present as cracking/fissuring of the corners of the mouth with some erythema and superficial ulceration (Fig 7). Angular cheilitis often represents an opportunistic infection of fungi and/or bacteria with multiple local and systemic predisposing factors such as over closer of the mouth, nutritional deficiencies, dry mouth, immune suppression, drooling and wearing of poorly fitting dentures.
Aphthous ulcers (also known as aphthous stomatitis)

Aphthous ulcers are benign, non-contagious, single or multiple ulcerations of the oral mucosa; usually self-limiting, painful, or recurrent. Minor aphthous ulcers are round to ovoid ulcers no larger than 2–5 mm in diameter with well-defined erythematous margins. Site of occurrence is usually non-keratinized oral mucosa. It usually heals within two weeks with no scarring. Major aphthous ulcers, which are painful, round to ovoid ulcers larger than 10 mm in diameter. These ulcers usually heal within 2-8 weeks with scarring. Site of occurrence can be either keratinized and non-keratinized oral mucosa.

Leukoedema

Leukoedema appears as a white opalescence of the buccal mucosa that disappears when the mucosa is stretched and reappears upon relaxation. This is a normal anatomical variation, which is more common in people with dark skin and especially in smokers (Fig 9 & 10).
Chewer’s mucosa

Yellowish or reddish–brown wrinkled incrustation on the oral mucosa that can be scraped off, leaving behind non-elevated mucosal alterations such as a wrinkled surface due to direct action of the quid or traumatic effect of chewing or both (Fig 11).

Quid induced lichenoid lesion

It resembles oral lichen planus. This condition is characterized by the presence of fine, white, wavy, parallel non-elevated lines that do not overlap or crisscross, and some instances these lines radiate from a central erythematous area. These should be reviewed annually (Fig 12).
Diagnosis and Management of Oral Potentially Malignant Disorders

National guidelines for Management of OPMDs is intended to provide evidence-based management which include diagnostic information on OPMDs for:

A. Dental surgeons at primary care dental clinics located at state and non-state institutions and practices.

B. Oral and Maxillo-Facial surgeons in secondary and tertiary care hospitals.

The above-mentioned categories of the staff would be inter-dependent in the management of the OPMDs.

Although the primary target audience is the staff categories listed above, other health professionals including medical officers also would find the guidelines useful

Oral Potentially Malignant Disorders

Table 2 shows the disorders that are considered as OPMDs (Warnakulasuriya et al., 2007; Amagasa et al., 2011). However, only four most important disorders (leukoplakia, erythroplakia, oral submucous fibrosis and oral lichen planus) are described in this book.

<table>
<thead>
<tr>
<th>Table 2: Oral Potentially Malignant Disorders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leukoplakia</td>
</tr>
<tr>
<td>Erythroplakia</td>
</tr>
<tr>
<td>Oral submucous fibrosis</td>
</tr>
<tr>
<td>Oral lichen planus</td>
</tr>
<tr>
<td>Palatal changes due to reverse smoking</td>
</tr>
<tr>
<td>Discoid lupus erythematosus</td>
</tr>
<tr>
<td>Actinic keratosis</td>
</tr>
<tr>
<td>Inherited disorders</td>
</tr>
<tr>
<td>Dyskeratosis congenita</td>
</tr>
<tr>
<td>Epidermolysis</td>
</tr>
<tr>
<td>Bullosa xeroderma pigmentosum</td>
</tr>
<tr>
<td>Fanconi’s anaemia</td>
</tr>
</tbody>
</table>

4.1 Leukoplakia

Leukoplakia is generally defined as a predominantly white lesion of the oral mucosa that cannot be clinically or histopathologically characterized as any other definable lesion (Pindborg et al., 1997; Pindborg et al., 2012; Batsakis et al., 1999; Warnakulasuriya et al., 2007; Feller and Lemmer, 2012). Leukoplakia is the most common potentially malignant lesion of the oral mucosa (Feller and Lemmer, 2012). The term leukoplakia is a clinical descriptor only (Bouquot, 2006). The terms keratosis and dyskeratosis are histological features and should not be used as clinical terms. On the basis of the following clinical features a provisional diagnosis of leukoplakia is made when the lesion cannot be clearly diagnosed as any other disease of the oral mucosa with a white appearance.
Clinical features

Leukoplakia is usually a solitary white patch with a clear border/margin. It may appear on any site of the oral cavity. But the most common sites for leukoplakia are buccal mucosa, alveolar mucosa, floor of the mouth, tongue, lips and palate (Reibel, 2009).

Generally, two clinical types of leukoplakia are recognized: homogenous and non-homogenous, which can be co-exist (Warnakulasuriya et al, 2007).

1. Homogenous leukoplakia

Homogenous leukoplakia is defined as a predominantly white lesion of uniform flat and thin appearance that may exhibit shallow cracks and that has a smooth, wrinkled surface with a consistent texture throughout (Warnakulasuriya et al, 2007). This type is usually asymptomatic (Fig 13).

2. Non-homogenous leukoplakia

Non-homogenous leukoplakia is defined as a predominantly white and red lesion (erythroleukoplakia) that may be either irregularly flat (speckled) or nodular. (van der Waal, 2009).

Types of non-homogenous leukoplakia

- Verrucous leukoplakia (Fig 14)
- Nodular leukoplakia (Fig 15)
- Ulcerated leukoplakia (Fig. 16)

Verrucous leukoplakia is a type of non-homogenous leukoplakia usually has a uniformed white appearance and its verrucous texture is the distinguishing feature from homogenous leukoplakia. These types of leukoplakia are often associated with mild complaints of localized pain or discomfort. Proliferative verrucous leukoplakia is an aggressive type of verrucous leukoplakia that almost invariably develops into malignancy (Feller and Lemmer, 2012; Batsakis et al, 1999). This type is characterized by widespread and multifocal appearance, often in patients without known risk factors (Batsakis et al, 1999, van der Waal, 2009).
In general, non-homogenous leukoplakia has a higher malignant transformation rate, but oral carcinoma may develop from any leukoplakia (Batsakis et al, 1999).

**Diagnosis**

Diagnosis Clinical diagnosis of leukoplakia is based on approaches mentioned in Fig 17 (Van der Waal, 2009). Clinical differential diagnosis includes the disorders mentioned in Table 3.

**Provisional clinical diagnosis:** It is based on clinical features stated above using examination and palpation as the only diagnostic measures (van der Waal, 2009).

**Definitive clinical diagnosis:** It is based on clinical evidence obtained by lack of changes after identifying and eliminating suspected aetiologic factors during a follow-up period of 2-6 weeks (In some cases the time may be longer) (van der Waal, 2009).

**Histopathologically proven diagnosis:** Definitive clinical diagnosis complemented by biopsy in which, histopathologically, no other definable lesion is observed.

See Fig. 17 and Fig 18 for flow charts for the diagnosis and management of leukoplakia.

Fig. 16: Ulcerated leukoplakia on right commissure and buccal mucosa
Table 3: Oral disorders that resemble leukoplakia and need to be excluded (Adapted from Warnakulasuriya et al 2007) (See in conjunction with Fig 17)

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Diagnostic features</th>
<th>Biopsy /Other investigations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lichen planus (plaque type)</td>
<td>Other forms of lichen planus (reticular) found in association</td>
<td>Biopsy consistent with lichen planus</td>
</tr>
<tr>
<td>Lichenoid reaction</td>
<td>Drug history, e.g. close to an amalgam restoration</td>
<td>Biopsy consistent with lichen planus or lichenoid reaction</td>
</tr>
<tr>
<td>Discoid lupus erythematosus</td>
<td>Circumscribed lesion with central erythema, white lines radiating</td>
<td>Biopsy consistent with DLE supported by immunofluorescence and other investigations</td>
</tr>
<tr>
<td>Leukoedema</td>
<td>Bilateral on buccal mucosa, could be made to disappear on stretching (retracting), racial</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Acute pseudomembranous Candidiasis</td>
<td>The membrane can be scraped off leaving an erythematous raw surface</td>
<td>Swab for culture</td>
</tr>
<tr>
<td>White sponge nevus</td>
<td>Noted in early life, family history, large areas involved, genital mucosa may be affected</td>
<td>Biopsy not indicated</td>
</tr>
<tr>
<td>Frictional keratosis</td>
<td>History of trauma, mostly along the occlusal plane, an etiological cause apparent, mostly reversible on removing the cause</td>
<td>Biopsy not indicated</td>
</tr>
<tr>
<td>Morsicatio buccarum (Chronic cheek biting)</td>
<td>Habitual cheek – lip biting known, irregular whitish flakes with jagged out line</td>
<td>Biopsy not indicated</td>
</tr>
<tr>
<td>Leukokeratosis nicotina palate (smoker’s palate)</td>
<td>Smoking history, greyish white palate</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Chemical injury</td>
<td>Known history, site of lesion corresponds to chemical injury, painful, resolves rapidly</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Skin graft</td>
<td>Known history</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Hairy leukoplakia</td>
<td>Bilateral tongue keratosis. Specific histopathology with koilocytosis</td>
<td>EBV demonstrable on in situ hybridization</td>
</tr>
</tbody>
</table>
White lesion in the mouth that cannot be rubbed off

Exclude oral disorders those resemble leukoplakia as mentioned in Table 3

Provisional clinical diagnosis of leukoplakia

 Exclude /Eliminate possible aetiological factors (mainly chronic mechanical irritation to the site)

Observe for 2-6 weeks (may be longer if appropriate)

- Source of friction/ cheek biting identified
- History of chemical injury, site of lesion corresponds to the source of injury
- Contact with amalgam restoration identified
- Lichenogenic drug intake recognized
- Smoking in case of palatal keratosis

Lesion persists

Lesion disappears or begin to fade out

Definitive clinical diagnosis of leukoplakia

See Fig 18: for subsequent activity

Fig 17: Flow chart for the clinical diagnosis of leukoplakia
†-Taking into consideration patient factors such as medical/social etc
* - No treatment method including surgical excision is shown to prevent development of SCC (Holmstrup et al., 2006)

Fig 18: Flow chart for the management of Leukoplakia
4.2 Erythroplakia

Oral Erythroplakia (OE) is considered a rare potentially malignant disorder of the oral mucosa and is classically defined as “fiery red patch of the oral mucosa that cannot be characterized clinically or pathologically as any other definable disease” (Pindborg et al, 2012). It must be noted that in case of a mixture of red and white changes, such lesion is usually categorized as non-homogenous leukoplakia (Erythroleukoplakia) (Fig. 19). A new approach to perceive the lesion is proposed based on the clinical features of a fiery red, sharply demarcated lesion situated at a slightly lower level than the surrounding mucosa. Such a definition would help clinicians distinguish erythroplakia from other red lesions of the oral mucosa. Although the course of such lesions vary, a significant proportion will develop into malignant condition, which is why they should be followed up at short intervals (Holmstrup, 2018; Reichart and Philipsen, 2005).

Aetiology:
Tobacco and alcohol use are considered important aetiologic factors. The possible role of *candida albicans* is at present still unclear. The etiology of OE reveals a strong association with tobacco consumption and the use of alcohol (Pindborg et al, 2012).

Epidemiology:
Prevalence figures for erythroplakia are only available from studies conducted in South-and Southeast Asia and vary between 0.02% and 0.83% (Reichart and Philipsen, 2005).
OE is predominantly seen in the middle aged and elderly (Scully, 2004). There is no distinct sex preponderance. A study in India has shown a female: male ratio of 1:1.04. (Hashibe et al, 2000).

Clinical features:
Lesions of OE are typically less than 1.5 cm in diameter but lesions larger than 4cm in diameter have been reported (Bouquot and Ephros, 1995). The clinical appearance may be flat or with a smooth or granular surface (Reichart and Philipsen, 2005). The surface of OE is often depressed below the level of the surrounding mucosa (Cawson et al, 1996). Any site of the oral cavity and oropharynx may become involved, usually in a solitary fashion. This solitary presentation is often helpful in clinically distinguishing erythroplakia from several other erythematous lesions affecting the oral mucosa, since these other lesions occur almost always in a bilateral, more or less symmetrical pattern (van der Waal, 2010). (See table 4 and Fig 20 for differential diagnosis and management of OE). OE is soft to palpation and does not become indurated or hard until an invasive carcinoma develops in it. The soft palate, the floor of the mouth and the buccal mucosa are most commonly affected by OE (Reichart and Philipsen, 2005). The tongue is rarely affected (Pindborg et al, 2012).

Oral Erythroplakia is diagnosed by exclusion. The term OE does not carry a histopathological connotation. As for oral leukoplakia, the principle of provisional diagnosis and definitive diagnosis is also suggested for OE.

Provisional clinical diagnosis:
“A provisional diagnosis of OE is made when a lesion at clinical examination cannot be clearly diagnosed as any other disease of the oral mucosa with red appearance”.


**Definitive clinical diagnosis:**

“A definitive diagnosis of OE is made as based on identification, and if possible elimination, of suspected aetiological factors and in the case of persistent lesions, histopathological examination”. OE is seldom multicentric and rarely covers extensive areas of the mouth (van der Waal, 2010).

**Histopathologically proven diagnosis:**

The term erythroplakia is regarded as a clinical term with no specific histopathological connotations. However, most cases of erythroplakia appear to harbor some degree of epithelial dysplasia/ carcinoma in situ or frank carcinoma (Holmstrup 2018).

Since the malignant transformation rates are very high (vary from 14% to 50%) it needs to be treated expeditiously (Yardimci et al, 2014). Malignant transformation rates are considered to be the highest among all OPMDs. Surgical excision is the treatment of choice (Reichart and Philipsen, 2005).

**Prognosis and treatment**

In general, OE needs to be treated because of its high risk of malignant transformation. Besides, most erythroplakias are symptomatic. Surgery or by laser, is the recommended treatment modality. As for excision of leukoplakia, no guidelines are available with regard to the width of the surgical margins. There are no data from the literature about the recurrence rate after excision of erythroplakia (van der Waal, 2010).

![Fig 19: Erythroplakia- red patch on the right buccal mucosa with white areas posteriorly](image)
Table 4: Red lesions that need to be considered in the differential diagnosis of Oral Erythroplakia  
(adapted from Reichart and Philipsen 2005 and Warnakulasuriya et al., 2007)

<table>
<thead>
<tr>
<th>Nature of lesion</th>
<th>Lesion/ condition</th>
<th>Diagnostic features</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inflammatory/ immune disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Desquamative gingivitis</td>
<td></td>
<td>Associated with erosive lesions in other areas of the oral cavity</td>
</tr>
<tr>
<td>Erosive/atrophic lichen planus</td>
<td></td>
<td>Reticular lesion/striae may be seen in peripheral areas; multiple sites</td>
</tr>
<tr>
<td>Discoid lupus erythematosus</td>
<td></td>
<td>Circumscribed lesion with central erythema, with radiating white lines</td>
</tr>
<tr>
<td>Pemphigus, Pemphigoid</td>
<td></td>
<td>History of bullous eruption and rupture, wider &amp; multiple areas involved</td>
</tr>
<tr>
<td>Hypersensitivity reactions</td>
<td></td>
<td>History of exposure to allergen; wider area affected</td>
</tr>
<tr>
<td><strong>Infections</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reiter’s disease</td>
<td></td>
<td>Non gonococcal urethritis, arthritis</td>
</tr>
<tr>
<td>Acute erythematous candidiasis</td>
<td></td>
<td>History of chronic antibiotic usage</td>
</tr>
<tr>
<td>Denture induced stomatitis</td>
<td></td>
<td>Found on palate and under denture</td>
</tr>
<tr>
<td>Histoplasmosis</td>
<td></td>
<td>Raised /ulcerated lesion</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td></td>
<td>Usually ulcerative stellate appearance</td>
</tr>
<tr>
<td><strong>Hamartomas/ Neoplasms</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemangioma</td>
<td></td>
<td>Blanching on pressure</td>
</tr>
<tr>
<td>Lingual varices</td>
<td></td>
<td>Ventral aspect of tongue, symmetrical</td>
</tr>
<tr>
<td>Telangiectasia</td>
<td></td>
<td>Multiple sites and skin involvement</td>
</tr>
<tr>
<td>Oral purpura</td>
<td></td>
<td>Bleeding diatheses present</td>
</tr>
<tr>
<td>Kaposi’s sarcoma</td>
<td></td>
<td>Seen mostly in HIV infected people</td>
</tr>
</tbody>
</table>
No epithelial dysplasia

Moderate to severe degree of dysplasia/carcinoma in situ/sq. cell carcinoma

Surgical excision at OMF clinic*

Biopsy

No epithelial dysplasia

Mild dysplasia

Monthly review. Repeat biopsy if clinical picture changes. If necessary, excise the lesion

Review in 3 months

Back referral

Biopsy indicated

Biopsy not indicated

Red lesion

Provisional clinical diagnosis of erythroplakia

Definitive clinical diagnosis of erythroplakia

OMF SURGEON AT OMF CLINIC

Dental Surgeon at Primary care clinic

Exclude lesions that mimic erythroplakia by history and clinical examination (See Table 4)

Eliminate possible causative factors for red lesions and observe for 2-4 weeks

Red lesion disappears or begin to fade out

† Follow separate guidelines – National Guidelines for Management of Oral Cancer;
* No treatment method including surgical excision is shown to prevent development of SCC (Holmstrup et al., 2006) Constructed on model advocated by Isaac van der Wall 2010 and modification of model suggested by Warnakulasooriya et al., 2007, Hashibe et al., 2000)

Fig 20: Flow chart for the management of Erythroplakia
4.3 Oral submucous fibrosis

Unlike other potentially malignant disorders, Oral Submucous Fibrosis (OSF) is insidious in origin and is not amenable to reverse at any stage of the disease either spontaneously or with cessation of habit. The condition may remain either stationary or become severe, leaving an individual challenged both physically and psychologically (Bari et al, 2017)

This condition is associated with burning sensation in the oral mucosa from the early stages and with a significant risk for malignancy. It is a chronic disease with progressive fibrosis in the sub mucosal tissues leading to restriction in opening the mouth with the advancement of the disease (Tilakaratne et al, 2006; Kerr et al, 2011). Fibrosis initially affects the lamina propria of the oral mucosa and as the condition worsens, extends to the sub mucosa and the deeper tissues including oral musculature. Consequently the elasticity of the oral mucosa is progressively lost (Fig.21 and 22). Malignant transformation varies from 4.5% to 30 % (Arora et al., 2014; Ahmad et al., 2006; Ray et al., 2016 and Jayasinghe et al., 2015).

Aetiology
Based on the evaluation by the International Agency for Research on Cancer (IARC), conclusive evidence now exists that the disease is caused by the consumption of areca nut. The condition predominantly affects populations of the Indian subcontinent and South East Asia who chew areca nut in betel quid or in flavoured formulations of the areca nut. Although the disease mostly affects people older than 40 years of age, younger people are increasingly affected; particularly those who consume flavoured areca nut products alone (Tilakaratne et al, 2006). A study done in Sri Lanka revealed that five children aged 2-3 years who consumed betel quid with areca nut or areca nut alone has developed depigmentation of lips, which appears to be one of the early features of OSF (Sitheeque et al, 2010).

Pathogenesis
Unlike other OPMDs, pathogenesis of OSF has been well elucidated. Although a detailed discussion of the pathogenesis of OSF is beyond the scope of this book, an understanding of this aspect of OSF is important. Fibrosis and hyalinization resulting from increased amount of collagen in the extra cellular matrix of sub epithelial tissues contribute to the important clinical features seen in this condition. It has been shown that either an increased collagen synthesis or reduced degradation of collagen may be responsible for the development of OSF. Alkaloids in areca nut, importantly, arecoline, have been implicated in stimulation of fibroblast proliferation while tannins in the nut appear to stabilize collagen structure that resists degradation by collagenases. Increased secretion of fibrogenic cytokines such as TGF beta and imbalance between Matrix Metallo Proteinases (MMPs) and Tissue Inhibitors of Matrix Metallo Proteinases (TIMMP) are responsible for the altered collagen metabolism leading to fibrosis. The disease is associated with certain genetic groups (Tilakaratne et al, 2006; Tilakaratne et al,2016).
Clinical features

Clinical features that are useful in the diagnosis include:

<table>
<thead>
<tr>
<th>Early disease</th>
<th>Late disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Burning sensation of the oral mucosa</td>
<td>• Palpable fibrous bands in cheeks, along the faucial pillars, soft palate and lips</td>
</tr>
<tr>
<td>• Blanching and stiffening of the oral mucosa leading to limitation in mouth opening</td>
<td>• Tightening of the lips with resultant lack of their elasticity</td>
</tr>
<tr>
<td>• Widespread pallor of the oral mucosa Depigmentation of the mucosa particularly noticeable on the vermillion border of the lips in a significant proportion of patients</td>
<td>• Depapillation of the dorsum of the tongue with restricted mobility of the tongue including protrusion</td>
</tr>
<tr>
<td>• Vesiculation of the oral mucosa is sometimes described but not often seen</td>
<td></td>
</tr>
</tbody>
</table>

Other Oral Potentially Malignant Disorders such as leukoplakia may be seen in long standing OSF.

Diagnosis of OSF

Diagnosis can be made easily in established OSF based on the above clinical features. In early stages, however, the diagnosis may be difficult to establish purely on clinical grounds and a biopsy may be necessary for the diagnosis. Biopsy is also necessary in advanced stages to determine the presence of epithelial dysplasia, if there are clinically suspicious features. The condition may need to be distinguished from other diseases that may exhibit fibrosis and may cause limitation in mouth opening such as epidermolysis bullosa, post-irradiation fibrosis, cicatricial pemphigoid, progressive systemic sclerosis etc (Fig 23).

Grading of OSF

Unlike other OPMDs, OSF is a disorder that is associated with a functional disability. Attempts have been made to grade OSF using mainly clinical / functional criteria (Haider et al, 2000; Kerr et al, 2011). A grading scheme proposed by Kerr et al, in 2011, is a useful one and is shown in Table 5.

Table 5: Disease Grading of Oral Submucous Fibrosis (Kerr et al., 2011)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Clinical and functional features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1 – Mild</td>
<td>Any feature of the disease triad for OSF ((burning sensation, depapillation, blanching or leathery mucosa) present + inter-incisal opening &gt;35 mm</td>
</tr>
<tr>
<td>Grade 2 – Moderate</td>
<td>Above features of OSF + inter-incisal limitation of opening 20–35 mm</td>
</tr>
<tr>
<td>Grade 3 – Severe</td>
<td>Above features of OSF + inter-incisal opening &lt;20 mm</td>
</tr>
<tr>
<td>Grade 4A</td>
<td>OSF + other potentially malignant disorder on clinical examination</td>
</tr>
<tr>
<td>Grade 4B</td>
<td>OSF with any grade of oral epithelial dysplasia on biopsy</td>
</tr>
<tr>
<td>Grade 5</td>
<td>OSF + oral squamous cell carcinoma (SCC)</td>
</tr>
</tbody>
</table>
Treatment of OSF

There is no single satisfactory and evidence-based treatment method for the disease. Cessation of areca nut consumption by regular users remains the most vital step in the management of OSF. Physical, medical, nutritional and surgical treatments have all been tried with claims of varying rates of success (Warnakulasuriya and Kerr, 2016). Physical methods such as stretching exercises aimed at increasing mouth opening and medical treatments such as nutrients, antioxidants, tropical and intra-lesional corticosteroids, intra-lesional enzymes and peripheral vasodilators have been reported (Warnakulasuriya and Kerr, 2016). Intra lesional steroid (for example methyl prednisolone) injection is the widely practiced treatment (Ariyawardana et al, 2005; Warnakulasuriya and Kerr, 2016) in most centers, especially for symptomatic cases with developing limitation in mouth opening associated with burning sensation. As nutritional supplements, patients are advised to have a diet rich in fresh fruits and vegetables.

Initial stage of OSF should be included counselling of patients along with anti-oxidants (lycopene, spirulina, curcumin), multivitamins and minerals. Moderate stages of OSF should be treated with intra-lesional steroids and peripheral vasodilator (pentoxifylline), whereas advanced stages should be treated surgically (Chole and Patil, 2016). A full blood count is recommended for every patient when the diagnosis of OSF is made. When deficiencies are detected, treatment must be instituted to correct them.

Fig 21: Oral Submucous Fibrosis - diffuse blanching on the right buccal mucosa, with severe blanching in the retro-molar area

Fig 22: Oral Submucous Fibrosis - blanching on the lower labial mucosa
Dental Surgeon at Primary care clinic

Patient with burning sensation of oral mucosa

Restricted mouth opening

Yes

Presence of pallor/blanching of mucosa or depapillation of tongue or leathery texture of mucosa

No

Investigate for other causes of restricted mouth opening with burning sensation, if necessary by referral

Yes

Provisional diagnosis of OSF

Refer

OMF SURGEON AT OMF CLINIC

Biopsy

OSF confirmed

OSF not confirmed

Investigate further

Identify nutritional deficiencies if any and correct them Educate and motivate patient to stop areca nut (and tobacco) chewing habits

No

Presence of pallor/blanching of mucosa or depapillation of tongue or leathery texture of mucosa

Doubtful

Yes

Provisional diagnosis of early OSF (Grade 1)

Further management at Primary care clinic by education and habit cessation and 6 monthly review

No

Investigate for other causes of burning sensation, if necessary by referral

Review every 6 months and inspect for adverse changes

Grades 3, 4A and 4B – Review every 3 months [For cases with dysplasia see earlier guideline (Fig 18)]

Fig 23: Flow chart for the management of Oral Submucous Fibrosis
4.4 Lichen Planus
Oral lichen planus is a common chronic inflammatory mucocutaneous disorder that typically affects the skin and/or mouth (Warnakulasuriya et al., 2007; George et al., 2011)(Fig 24). Lichen planus can also affect other extra oral sites such as the genitals (Ahmad et al, 2006).

Clinical features
Oral lichen planus has a bilateral distribution (Al-Hashimi et al, 2007) that typically affects the buccal mucosa, dorsum and ventral surfaces of the tongue and/or gingiva (Napier, 2008). Other mucosal surfaces can be affected but palatal involvement is particularly rare. Oral lichen planus is often asymptomatic (Al-Hashimi et al, 2007; George, 2011) although when there are areas of erosion or ulceration, the patient may have variable amounts of discomfort, being particularly troublesome when eating spicy or acidic type of food. The variable clinical presentations of oral lichen planus comprise white patches, erosions, ulcers and very rarely, blisters (Al-Hashimi et al, 2007; George et al, 2011).

The clinical presentation of lichen planus can be classified as follows:

Reticular oral lichen planus
This is the most common presentation, manifesting as a network of plaque-like oral lichen planus. This manifests as areas of homogenous whiteness. This typically arises on the buccal mucosa or on the dorsum of tongue and may be more prevalent amongst smokers.

Papular oral lichen planus
This manifests as small white raised areas approximately 1-2 mm in diameter. These again typically arise on the buccal mucosa and dorsum of tongue, although may also present on other mucosal surfaces.

Erosive oral lichen planus
This is sometimes termed atrophic oral lichen planus. In this form, there are areas of redness within the aforementioned white patches. Patients with this type of disease often complain of oral soreness.

Ulcerative lichen planus
There are frank ulcers within the areas of whiteness. Patients complain of continued soreness, this being particularly severe with spicy or acidic foods.

Bullous lichen planus
This rare presentation manifests as small vesicles or blisters (bullae) within the white patches.

Patients with disease involving the gingiva may have areas of white patches or striae superimposed upon redness of the gums. These lesions are often painless, although patients may complain of a slight roughness or dryness to the affected mucosal surfaces. The latter is often termed desquamative gingivitis and can be extremely painful. Around 30% of patients with oral lichen planus will have lesions in other parts of the body.
Diagnosis

The diagnosis of oral lichen planus is initially based on the clinical presentation of bilateral white patches with or without erosions, ulcers or blisters, typically affecting the buccal mucosa, dorsum of tongue and gingiva (Bombeccari et al, 2011).

Biopsy with subsequent histopathological examination of affected tissue is essential to exclude other disease that may mimic oral lichen planus – such as lupus erythematosus (Bombeccari et al, 2011).

In addition, it is advantageous to undertake a biopsy to identify possible areas of cellular atypia (dysplasia) within the involved tissue (Brennan et al, 2007).

Worldwide it is accepted that oral lichen planus has a malignant transformation rate of 0.4% to 5% over a period of observation from 6 months to 20 years and seems to be independent of the clinical types of OLP or the treatment used (Gonzalez- Moles et al, 2008).

Fig 24: Lichen planus
Chapter 5

Roles and Responsibilities of Health Care Facilities and Service Providers

5.1 Role of National Cancer Control Programme (NCCP)

- Ensure public awareness on OPMD and oral cancer and their risk factors through mass media and other communication channels.

- Training of Primary Health Care (PHC) staff: Training of Trainers (TOT) and ensure cascade training up to field level staff.

- Coordination of oral cancer prevention and early detection programme with Deputy Director General of Dental Services, Deputy Director General of Non-Communicable Disease Bureau, Director - Family Health Bureau, Director - Health Promotion Bureau, Director - Primary Care Services, Principal Public Health Inspector and other relevant authorities including provincial and district level staff of Ministry of Health and oral health professionals.

- Ensure overall oral cancer prevention and early detection programme in the country: planning, coordination, implementation and monitoring of programmes on prevention and early detection of oral cancer.

- Ensure receipt of data on cases referred for screening and number of cases diagnosed, compilation and data analysis.

- Ensure that supply chain management is properly functioning and relevant hospitals / Medical Officer of Health (MOH) areas receive required equipment and consumables.

5.2 Role of Provincial Director of Health Services (PDHS)

- Coordination of oral cancer prevention and early detection programme with district level staff of Ministry of Health including Regional Directors of Health Services, Provincial Consultant in Community Dentistry and Regional Dental Surgeons (RDSs).

- Monitoring and evaluation of the programme at provincial level.

5.3 Role of Regional Director of Health Services (RDHS)

- Coordination of oral cancer prevention and early detection programme with district level staff including Regional Dental Surgeon and Medical Officers of Health

- Implementing, monitoring and evaluation of the programme at district level.

- Provision of adequate resources for dental clinics facilitating screening activities.
5.4 Role of Provincial Consultant in Community Dentistry (CCD)

- Coordination of oral cancer prevention and early detection programme with district level staff of Ministry of Health including RDHS, Consultant Community Physicians, RDS, MO-NCD (Medical officer Non-Communicable diseases) and Medical Officers of Health.

- Coordination of training programmes on prevention and early detection of oral cancer for PHC staff in the province with NCCP and district level staff of Ministry of Health and ensure cascade training up to field staff.

- Ensure public awareness on OPMD and oral cancer and their risk factors within the province.

- Organize targeted awareness campaigns and screening programmes for high-risk individuals at district level with RDS, MOH, Dental Surgeons and PHC staff.

- Compile and analyze data on patients referred and diagnosed at provincial level. Coordinate with NCCP regarding the data of these patients

- Conduct surveys within the province to assess the prevalence of risk factors related to OPMDs and oral cancer.

- Monitoring and evaluation of the programme at provincial level.

5.5 Role of Regional Dental Surgeon (RDS)

- Implement the oral cancer prevention and early detection programme at district level.

- Coordination of oral cancer prevention and early detection programme with district level health staff including MOH.

- Coordinate with the Dental Surgeons of the area to ensure they screen the high-risk individuals referred by the PHC staff.

- Coordinate with MO – NCD of the district to ensure oral cancer prevention and early detection programme in the common Non Communicable Disease (NCD) screening programme.

- Coordinate training programmes for Dental Surgeons, Medical Officers, Registered Medical Officers and PHC staff.

- Ensure adequate supply of logistics including supply and distribution of referral forms, registers and returns at district level.

- Organize targeted awareness campaigns and screening programmes for high-risk individuals at district level with the coordination of Dental Surgeons and PHC staff.

- Compile the “Quarterly Return for Regional Dental Surgeons on new patients with Oral Potentially Malignant Disorders and oral cancer” (Annex V) based on the monthly return send by the government dental surgeons. This return needs to be sent to the Director, National Cancer Control Programme, on or before 25th day of the month subsequent to the end of quarter.
5.6 Role of Medical Officer of Health (MOH)

- Implement the oral cancer prevention and early detection programme at MOH area level.
- Coordination of oral cancer prevention and early detection programme with MOH staff.
- Coordinate with Regional Dental Surgeon and Dental Surgeons of the area to ensure that the Dental Surgeons screen high risk individuals referred by the PHC staff.
- Coordinate training programmes for Dental Surgeons, Medical Officers, Registered Medical Officers and PHC staff with the Regional Dental Surgeon.

5.7 Role of Public Health Nursing Sister (PHNS) / Supervisory Public Health Inspectors (SPHI)/ Supervisory Public Health Midwife (SPHM)

- Coordination of oral cancer prevention and early detection programme at MOH level with the Medical Officers of Health, Dental Surgeons and PHC staff.
- Monitor distribution of referral form booklets among the PHC staff at MOH level.
- Organizing targeted awareness campaigns and screening programmes for high-risk individuals at MOH area levels with the coordination of Regional Dental Surgeon.

5.8 Role of Public Health Midwives (PHM) and Public Health Inspectors (PHI)

- Promote oral cancer prevention programmes at PHM PHI area level.
- Identify individuals at risk of OPMD / oral cancer during their routine home / field visits, and refer them to the closest government Dental Surgeon by using the referral form (Annex I).
- PHC Staff is asked to refer high-risk individuals for screening between 10.30 a.m. to 11.30 a.m. on week days.
- Keep the duplicate copy of the referral form with PHM PHI.
- Educate the public on the importance of habit intervention and mouth self-examination.
- Trace the loss to follow up patients diagnosed with oral cancer.

5.9 Role of Dental Surgeons in Government Hospitals

- Opportunistic screening for OPMDs and oral cancer of all patients attending the dental clinic.
- Priority for screening should be given to persons referred by PHC staff and self-referred individuals (PHC staff is asked to refer high-risk individuals for screening between 10.30 a.m. to 11.30 a.m. on weekdays).
- Provide instructions to persons referred for screening of OPMDs / oral cancer by PHC staff and self-referred individuals to improve the oral hygiene and for habit intervention.
- Manage patients with OPMDs according to the ‘Guildlines for management of Oral Potentially Malignant Disorders’- Management will be either at clinic level or they will be referred to the Oral & Maxillo Facial Surgical (OMFS) units for further management using
the referral forms provided (Annex II). Keep the duplicate copy of the referral form in the dental clinic.

- In case of receipt of cases referred back, follow-up and improvement of oral health status should be done according to the treatment plan.

- Improvement of the oral health status of the patient with OPMDs is considered as the most important step in preventing malignant transformation. Therefore, the dental surgeons of the primary care institutions should improve the oral health status of the OPMD patients before starting any treatment or referring to OMFS units for further management.

- Should maintain the ‘Register for patients with oral cancer and Oral Potentially Malignant Disorders - OPD Dental Clinics / OMF units (Annex III) at the clinic.

- Should prepare the ‘Monthly return for dental Surgeons on new patients with oral Potentially Malignant Disorders and Oral cancer’ (Annex IV) using the above mentioned register and send to the RDS of the district on or before 5th day of the subsequent month.

- Monthly statistics on OPMDs should also be reported through the ‘Monthly Report of Hospital Dental Clinics’ (format H 1201) to the respective authorities.

- Dental Surgeon-in-charge of dental clinics not under administrative purview of Provincial Director of Health Services should also maintain all registers related to oral cancer and OPMD. The returns should be sent to the relevant authorities as mentioned above.

5.10 Role of Medical Officers (especially at HLCs /OPD)

- Identify high-risk individuals according to the developed triad of criteria (Table 1) and refer them to the nearest dental clinic in government hospital to carry out a proper clinical oral examination.


- Assist individuals having higher risk for OPMDs / Oral cancer for cessation of risk habits.

5.11 Role of Oral & Maxillo Facial Surgical (OMFS) Units

- Manage patients with OPMD’s and oral cancer at OMFS units.

- Patients with OPMD should be referred back to the dental clinic for improvement of oral health status and follow up (if the patient is referred by a dental surgeon back referral can be carried out using overleaf of the same form - Annex II).

- Liaise with Dental Public Health/ Preventive Oral Health units (if available) for habit intervention, counseling and improvement of oral hygiene of OPMD patients.

- Maintain the ‘Register for Oral Cancer Incidence Data’ at the OMFS units. Annual returns should be sent to the Director, National Cancer Control Programme, Public Health Complex, 555/5, Elvitigala Mawatha, Narahenpita according to the General Circular No:01-33/2012.
5.12 Role of Dental Surgeons and Medical Officers in private sector

- Opportunistic screening of all patients attending dental/ medical clinics for OPMDs and oral cancer.

- Refer those patients having OPMDs or oral cancer to the nearest OMFS units for further management.

- Provide instructions for high risk individuals on refrain from consuming betel quid or tobacco and areca nut products.
6.1 Introduction
Surveillance of OPMDs is a process of systematic, continuous collection, analysis, interpretation and dissemination of epidemiological information for action on OPMD cases occurring in a particular geographic area. Surveillance of OPMDs provides information about the occurrence (incidence), types (morphology / histology) and locations (site / topography), extent of OPMD at the time of diagnosis (disease stage) and the kind of treatment that patients receive.

6.2 Importance of Surveillance of Oral Potentially Malignant Disorders
- Incidence of OPMDs will provide the future burden of oral cancer
- Determine OPMD patterns in various sub populations
- Guide planning, implementation and evaluation of cancer control programmes (eg. determine whether prevention, screening and treatment efforts are making a difference)
- Help set priorities for allocating health resources
- Provide evidence for clinical, epidemiological and health services research

The majority of patients with OPMDs are diagnosed by dental surgeons and the identified cases of OPMDs are then referred to OMFS units in the government hospitals in the respective districts. The OMFS units provide further management and follow up of these patients. In addition some patients are managed in the private sector.

6.3 Process of Surveillance of Oral Potentially Malignant Disorders in Sri Lanka
The National Cancer Control Programme of Ministry of Health, Nutrition and Indigenous Medicine, Sri Lanka conducts surveillance for OPMDs and oral cancers in Sri Lanka. The General Circular No. 01- 33/2012, has been issued to establish the surveillance system for OPMD at first primary contact level.

Public Health Midwives and Public Health Inspectors either during their regular home visits or during other encounters with the community should identify high-risk individuals for OPMDs and oral cancer according to the three criteria mentioned in Table1.

Two simple formats are developed as booklets by the NCCP, one to be used by the PHC staff to refer high-risk individuals for OPMDs/ oral cancer to the dental surgeons (Annex I) and the other booklet to be used by the dental surgeons to refer patients to OMFS units (Annex II). Overleaf of the referral forms have been designed as feedback forms. By using these feedback forms, dental surgeons should provide a feedback to the PHM /PHI (Annex I) or dental surgeons working at OMFS units to the dental surgeons who refer individuals (Annex II).

According to General Circular No. 01- 33/2012, “Register for patients with oral cancer and Oral Potentially Malignant Disorders – OPD Dental Clinics” (Annex III) should be maintained by all government hospital dental clinics. Monthly return on data on OPMDs and oral cancer should be
complied by the dental surgeon and send the return to the RDS (Annex IV). Monthly statistics on OPMDs should also be reported through the Monthly Report of Hospital Dental Clinics (format H 1201).

Quarterly return of data on OPMDs and oral cancer (Annex V) should be complied by RDS and send the return to the NCCP using the monthly return sent by dental surgeons (Annex IV).

OMFS units should maintain “Register for patients with oral cancer and Oral Potentially Malignant Disorders” (Annex III). Information on patients with oral cancer should be maintained by OMFS units using “Register for Oral Cancer Incidence data”. An annual return of the “Register for Oral Cancer Incidence data” should be sent to the National Cancer Control Programme and this information will be used for the preparation of annual cancer incidence data of Sri Lanka.

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**Fig 25: Flow chart for the surveillance system of OPMDs and oral cancer**

- Monthly summary of data on OPMDs and oral cancer compiled by dental surgeon and sent to RDS
- Quarterly summary of data on OPMDs and oral cancer compiled by RDS and sent to NCCP
- Annual summary of data on OPMDs and oral cancer in Sri Lanka compiled by NCCP
References


### Summary of Annexes

<table>
<thead>
<tr>
<th>Annex No.</th>
<th>Name of the Return/ Record</th>
<th>Prepared by</th>
<th>Sent to</th>
<th>Source of information</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annex I</td>
<td>Referral Form for Primary Health Care Staff to refer high-risk individuals for OPMDs / Oral cancer to the Dental Surgeon and feedback form for the Dental Surgeon</td>
<td>Referral: PHM/ PHI</td>
<td>Dental Surgeon</td>
<td>-</td>
<td>When high-risk individuals are identified</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feedback: Dental Surgeon</td>
<td>PHM/PHI</td>
<td>-</td>
<td></td>
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<tr>
<td>Annex II</td>
<td>Referral form for the Dental Surgeons to refer patients to Oral &amp; Maxillo Facial Surgical units and feedback form for Dental Surgeons at OMFS Units</td>
<td>Referral: Dental Surgeon</td>
<td>Oral &amp; Maxillo Facial Surgical Unit</td>
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<td>When Patients are referred</td>
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<td></td>
<td>Feedback: OMF Surgeon/Dental Surgeon in OMFS Unit</td>
<td>Dental Surgeon</td>
<td>-</td>
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<tr>
<td>Annex III</td>
<td>Register for patients with oral cancer and Oral Potentially Malignant Disorders – OPD Dental Clinics</td>
<td>Dental Surgeon</td>
<td>-</td>
<td>-</td>
<td>On the Patients first visit</td>
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<tr>
<td>Annex IV</td>
<td>Monthly Return for Dental Surgeons on New Patients with Oral Potentially Malignant Disorders and oral cancer</td>
<td>Dental Surgeon</td>
<td>Regional Dental Surgeon</td>
<td>Register for patients with oral cancer and oral potentially malignant disorders - OPD Dental Clinics</td>
<td>On or before 5th day of the subsequent month</td>
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<tr>
<td>Annex V</td>
<td>Quarterly return for Regional Dental Surgeons on new patients with Oral Potentially Malignant Disorders and oral cancer</td>
<td>Regional Dental Surgeon</td>
<td>Director, National Cancer Control Programme</td>
<td>Monthly Return on New Patients with Oral Potentially Malignant Disorders and oral cancer by Dental Surgeons</td>
<td>On or before 25&lt;sup&gt;th&lt;/sup&gt; day of the month of the subsequent quarter</td>
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</tbody>
</table>
Annex I
Referral form for Primary Health Care Staff to refer high-risk individuals for OPMDs/oral cancer to Dental Surgeon and feedback form for the Dental Surgeon

Feedback form to be filled by the Dental Surgeon
Annex II

Referral form for Dental Surgeons to refer patients to Oral and Maxillo Facial Surgical Units and feedback form for Dental Surgeons at OMFS Unit

To be filled by the dental surgeon at OMF Surgical Unit (For feedback)

Diagnosis: .................................................................

Treatment plan: ............................................................

To be reviewed in: 3/12 □ 6/12 □ 1 year □

Any comment: .................................................................

Dental Surgeon’s Signature ........................................ Hospital ........................................ Date .................

Feedback form to be filled by the Dental Surgeon at OMFS unit

To be filled by the Dental Surgeon at OMF Surgical Unit (For feedback)

Diagnosis: .................................................................

Treatment plan: ............................................................

To be reviewed in: 3/12 □ 6/12 □ 1 year □

Any comment: .................................................................

Dental Surgeon’s Signature ........................................ Hospital ........................................ Date .................
## Annex III

**Register for patients with Oral Cancer and Oral Potentially Malignant Disorders — OPD Dental Clinics / OMF Units**

<table>
<thead>
<tr>
<th>Name of the Dental Surgeon</th>
<th>Year/Month</th>
<th>Institution</th>
<th>Management</th>
<th>Treatment</th>
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<tbody>
<tr>
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</table>

<table>
<thead>
<tr>
<th>Patient's Name</th>
<th>Age/ Sex</th>
<th>NIC No.</th>
<th>Site</th>
<th>Clinical diagnosis</th>
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<th>Address</th>
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</thead>
<tbody>
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</table>

| Date | Regd. No. | |
|------|------------||
Annex IV

Monthly Return for Dental Surgeons on New Patients with Oral Potentially Malignant Disorders and oral cancer

This monthly return should be compiled by the Dental Surgeon/ Dental Surgeon in charge and should be sent to the Regional Dental Surgeon (RDS) of the district on or before 5th day of the subsequent month.

<table>
<thead>
<tr>
<th>Year</th>
<th>Month</th>
<th>RDHS Division</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
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Name of the Institution

<table>
<thead>
<tr>
<th>Number of high-risk individuals referred by (based on the PHC referral booklet)</th>
<th>PHC staff</th>
<th>MO</th>
<th>Self-referral</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Number of high-risk individuals reported to the Dental Clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

Information on individuals with OPMDs/ suspected Oral Cancers

(Please refer the Register for patients with oral cancer and Oral Potentially Malignant Disorders – OPD Dental Clinics)

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<tr>
<th>Referred by</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td>Self-referral</td>
<td></td>
</tr>
<tr>
<td>PHC staff</td>
<td></td>
</tr>
<tr>
<td>GP</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total number of OPMDs detected at dental clinics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Total number of suspected oral cancers detected at dental clinics</th>
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<tbody>
<tr>
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</table>

Details of OPMDs and suspected oral cancer detected at the dental clinic

<table>
<thead>
<tr>
<th>Condition</th>
<th>Male</th>
<th>Female</th>
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</thead>
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<td></td>
<td></td>
</tr>
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<tr>
<td>5</td>
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</tbody>
</table>

Total number of OPMDs

Total number of suspected Oral Cancer
Annex V

Quarterly Return for Regional Dental Surgeons on new patients with Oral Potentially Malignant Disorders and oral cancer

This Quarterly Return should be compiled by the Regional Dental Surgeon based on the ‘Monthly Return on new patients with Oral Potentially Malignant Disorders and oral cancer by Dental Surgeons.

The quarterly Return should be sent to Director, National Cancer Control Programme, Public Health Complex, 555/5, Elvitigala Mawatha, Narahenpita on or before 25th day of the month subsequent to the quarter.

<table>
<thead>
<tr>
<th>Year</th>
<th>Quarter 1 (Jan-March)</th>
<th>Quarter 2 (April-June)</th>
<th>Quarter 3 (July Sept)</th>
<th>Quarter 4 (Oct-Dec)</th>
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<table>
<thead>
<tr>
<th>RDHS Division</th>
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<th>Line Ministry</th>
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<tbody>
<tr>
<td>No. of dental clinics in the District</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of dental clinics who send all 3 returns at the end of the quarter</td>
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Information on high-risk individuals

<table>
<thead>
<tr>
<th>Number of high risk individuals referred to the dental clinics by PHC staff during the quarter (Based on the PHC referral booklet)</th>
<th>PHC staff</th>
<th>MO</th>
<th>Self</th>
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</table>
Details of OPMD and suspected oral cancer detected at the Dental Clinic

<table>
<thead>
<tr>
<th>OPMD Type</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
<th>OPMD Type</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
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<tbody>
<tr>
<td>1 Leukoplakia</td>
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<td></td>
<td>5</td>
<td>5 Other OPMDs</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>2 Erythroplakia</td>
<td></td>
<td></td>
<td>6</td>
<td>6 Total No of OPMD’s</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Oral sub mucous fibrosis</td>
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<td></td>
<td>7</td>
<td>7 Total No of suspected oral cancer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 Oral lichen planus</td>
<td></td>
<td></td>
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</table>

(Please refer the Register for patients with Oral cancer and Oral Potentially Malignant Disorders – OPD Dental Clinics)

<table>
<thead>
<tr>
<th>Referred by</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self referral</td>
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<tr>
<td>PHC staff</td>
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<tr>
<td>MO</td>
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</tr>
<tr>
<td>Other</td>
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</tr>
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</table>

Total number of OPMDs detected at dental clinics

Total number of suspected oral cancers detected at dental clinics

Special Remarks:

Name of the RDS :  ..........................................................................................................

Date : ..........................................

Signature : .............................................