National Guidelines for Management of Oral Cancer Sri Lanka

National Cancer Control Programme
Ministry of Health
Sri Lanka
2020

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Message from Director General of Health Services

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. Comprehensive and quality treatment can improve the survival rate of the oral cancer patients as well as the quality of life of patients.

Clinicians have multiple options at every step in the comprehensive care for oral cancer from diagnosis, treatment, reconstruction, rehabilitation and surveillance. A guideline gives a generalized recommendation about the management.

Developing a “Guidelines for Management of Oral cancer” will guide the clinicians to choose specific management options with improved understanding according to the patient’s need. It will improve the survival rate and the quality of life of oral cancer patients.

I hope OMF surgeons and dental surgeons would make maximum use of this guideline and improve the quality of health care provided to the public.

Dr. Anil Jasinghe
Director General of Health Services

Message from Deputy Director General(Non Communicable Diseases)

It is with great pleasure I am sending this message to the first edition of the “Guidelines for Management of Oral cancer”.

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. Majority of the disease burden is localized to the low and middle income countries in the world where more than 70% of all cancer deaths occur. In Sri Lanka alone there are 2 to 3 cancer deaths per day due to oral cancer alone.

Developing guidelines for management of oral cancer is a timely necessity since treatment of oral cancer must be made uniform in order to maximize the treatment outcomes, quality of life of the patient and ultimately the quality of life of family members. It will also update the knowledge of the clinicians and dental surgeons setting the benchmark for excellence.

I would like to appreciate the contributions of resource personnel in developing and updating these guidelines and the coordinating role of the National Cancer Control Programme. My sincere wish is that the clinicians will take the maximum out of the guidelines for the betterment of oral cancer patients of the country.

Dr. (Mrs.) S.C. Wickramasinghe
Deputy Director General (Non Communicable Diseases)

Preface
Director - National Cancer Control Programme

It is with great pleasure I am sending this message to the first edition of the "Guidelines for Management of Oral Cancer".

Though classified as preventable and treatable, oral cancer is one of the most common cancers and has a high mortality. Oral tissues play an important role in the facial aesthetics and they are vital to maintain bodily functions. Cancer treatment of this region leads to aesthetical and functional difficulties which have a negative psychological impact of patients and their families. Additionally oral cancer is restricted mainly to people with poor socioeconomic status and prolonged multidisciplinary treatment will have a detrimental effect on the economy of these patients. Therefore the importance of developing evidence based management guidelines encompassing all specialties related to oral cancer treatment cannot be over emphasized. Standardized treatment will enable oral cancer patients all over the country to live longer, better lives with minimum physical, psychological and economic difficulties. Having such guidelines has never been so important since more and more cancer treatment centres are being established and are getting involved in the treatment of oral cancer.

I thank the eminent resource persons of various specialties for the role that they played in developing these guidelines over the years by providing technical inputs based on the latest knowledge in the management of oral cancer. The support given by previous Director and Consultant in Community Dentistry as well as the staff of the National Cancer Control Programme deserves a special word of mention.

I sincerely hope that all related health personnel will utilize these guidelines to uplift the lives of oral cancer patients of Sri Lanka.

Dr. Janaki Vidanapathirana
Acting Director, National Cancer Control Programme

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List of abbreviations

AJCC	American Joint Committee on Cancer
CT	Computerized Tomography
DOI	Depth of Invasion
DO	Development Officer
DS	Dental Surgeon
EBRT	External Beam Radiotherapy
ENE	Extra Nodal Extension
ECOG	Eastern Cooperative Oncology Group
EGFR	Epidermal Growth Factor Receptor
EUA	Examination Under Anaesthesia
HBCR	Hospital Based Cancer Registry
HPV	Human Papilloma Virus
ICD	International Classification of Diseases
ICD-O	International Classification of Diseases for Oncology
IOH	Institute of Oral Health
IMMR	Indoor Morbidity & Mortality Register
IMRT	Intensity Modulated Radiotherapy
LC	Cancers of the Lip
MDT	Multidisciplinary Team
MLT	Medical laboratory Technician
MRI	Magnetic Resonance Imaging
NCCP	National Cancer Control Programme
OC	Oral Cancer
OCC	Cancers of the Oral cavity
OMF	Oral and Maxillofacial
OPG	Orthopantomography
OPMD	Oral Potentially Malignant Disorder
PHC	Primary Health Care
PET	Positron Emission Tomography
RT	Radiotherapy
RDS	Regional Dental Surgeon
SCC	Squamous Cell Carcinoma
TNM	Tumour, Nodes and Metastases
UICC	International Union against Cancer
USS	Ultra Sound Scan

Chapter 1

Introduction

The term oro-pharyngeal cancer is usually taken to cover malignant neoplasms that develop in the lip, oral cavity and pharynx (International Classification of Diseases for Oncology (ICD-0): C00-C14) including lips, tongue, gum, floor of the mouth, palate and buccal mucosa (C00-06), salivary glands (C07-C08) and pharynx (C09-C14). However, this guideline only covers oral cavity cancers including lips, tongue, gingivae, floor of the mouth, palate and buccal mucosa (C00-C06) which hereafter will be referred as oral cancer (OC). Morphologically, most of the oral cancers are squamous cell carcinomas (SCC).

In Sri Lanka, cancers of the lip, oral cavity and pharynx are the most common cancers among males and ranks ninth among women, reported to account for 9.7% of total malignancies in the country[1]. The incidence of cancers of the lip, oral cavity and pharynx in Sri Lanka, standardized to the world standard population, in the year 2012, was 16.6 per 100,000 and 3.6 per 100,000 in males and females respectively[1]. In Sri Lanka, it is estimated that around 3 oral cancer related deaths occur every day[1].

OC is strongly associated with lifestyle and environmental risk factors; tobacco use (smoked and smokeless), alcohol consumption, poor oral hygiene, diets poor in antioxidants, vitamins and minerals, ultra violet rays from the sun, occupational hazards like exposures to radiation or chemical carcinogens and exposure to certain viruses, perhaps sexually transmitted, notably “high-risk” genotypes of the human papillomavirus family particularly Human Papilloma Virus (HPV) 16 and 18. There is a modest inherited susceptibility. Chronic inflammation is re-emerging as a significant co-factor[2]. In Sri Lanka, tobacco use, both smoked and smokeless, areca-nut chewing and excessive alcohol use found to be common causes for OC[3].

In addition to its effect on the affected individual and immediate family, OC has a significant health, economic and social impact to the country. OC has a greater impact on the quality of life of the individual. With reference to mean per capita income and National Gross Domestic

Product (GDP), the cost of management of oral cancer in Sri Lanka is extremely high giving negative impacts not only to healthcare system and economy of the country but also on individual families[4].

OC is curable if it is detected early, usually with some form of surgery. For more advanced lesions, surgery is usually accompanied by preceding or subsequent radiotherapy, with or without adjuvant chemotherapy.

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Chapter 2

Anatomical sub-sites and coding

The current document enumerates the anatomical sites and sub-sites of cancers of the oral cavity and the lip with codes allotted by the International Classification of Disease (ICD), version 11 released on 18th June 2018. Malignant tumours of the parotid gland (2B67), submandibular and sublingual glands (2B68), tonsils (2B69), oropharynx (2B6A) and malignant mesenchymal tumours (2B50-2B5Z) are excluded[1].

Table 2.1: Comparison of ICD codes 10 and 11: Malignant neoplasms of oral cavity

Anatomical sub-site	ICD 10	ICD 11
Lip	C00	2B60
Other or unspecified parts of tongue (dorsal surface, tip, ventral surface of anterior two thirds of the tongue)	C02	2B62
Gingivae (upper and lower)	C03	2B63
Floor of the mouth (anterior, lateral or overlapping lesions)	C04	2B64
Palate (hard palate, soft palate, uvula and overlapping lesions)	C05	2 B65
Other or unspecified parts of the mouth (cheek mucosa, vestibule, retromolar region and overlapping lesions)	C06	2B66

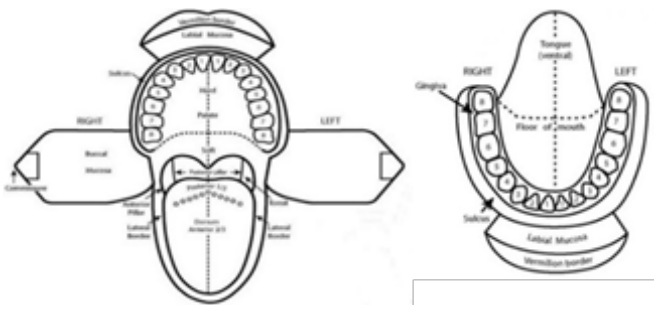

Figure 2.1: Diagrammatic presentation of oral cavity sub-sites

The oral cavity extends from the skin-vermilion junction of the lips to the junction of the hard and soft palate above and to the line of circumvallate papillae below and is divided into the following specific areas[2,3].

Mucosal lip: The lip begins at the junction of the vermilion border with the skin and includes only the vermilion surface or that portion of the lip that comes into contact with the opposing lip. It is well defined into an upper and lower lip joined at the commissures of the mouth.

Buccal mucosa: This includes all the membrane lining of the inner surface of the cheeks and lips from the line of contact of the opposing lips to the line of attachment of mucosa of the alveolar ridge (upper and lower) and pterygomandibular raphe.

Lower alveolar ridge: This refers to the mucosa overlying the alveolar process of the mandible which extends from the line of attachment of mucosa in the buccal gutter to the line of free mucosa of the floor of the mouth. Posteriorly, it extends to the ascending ramus of the mandible.

Upper alveolar ridge: This refers to the mucosa overlying the alveolar process of the maxilla which extends from the line of attachment of mucosa in the upper gingival buccal gutter to the junction of the hard palate. Its posterior margin is the upper end of the pterygopalatine arch.

Retromolar gingiva (retromolar trigone): This is the attached mucosa overlying the ascending ramus of the mandible from the level of the posterior surface of the last molar tooth to the apex superiorly, adjacent to the tuberosity of the maxilla.

The floor of the mouth: This is a semilunar space over the mylohyoid and hyoglossus muscles, extending from the inner surface of the lower alveolar ridge to the under-surface of the tongue. Its posterior boundary is the base of the anterior pillar of the tonsil. It is divided into two sides by the frenulum of the tongue and contains the ostia of the submaxillary and sublingual salivary glands.

Hard palate: This is the semilunar area between the upper alveolar ridge and the mucous membrane covering the palatine process of the maxillary palatine bones. It extends from the inner surface of the superior alveolar ridge to the posterior edge of the palatine bone.

Anterior two-thirds of the tongue (oral tongue): This is a freely mobile portion of the tongue that extends anteriorly from the line of circumvallate papillae to the under surface of the

tongue at the junction of the floor of the mouth. It is composed of four areas: the tip, the lateral borders, the dorsum and the under surface (non-villous ventral surface) of the tongue.

Regional lymph nodes: Mucosal cancers of the oral cavity may spread to the regional lymph node(s). Tumours of each anatomic site have their own predictable patterns of regional spread. The risk of regional metastasis generally relates to the T category and probably more importantly to the depth of infiltration of the primary tumours.

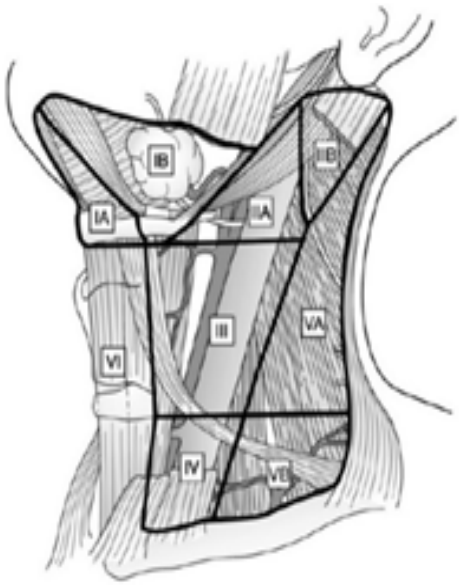

Figure 2.2: Neck levels[4]

Table 2.2: Description of lymph node levels[5]

Level I	Lymph nodes lie above the hyoid bone, below the mylohyoid muscle and anterior to a transverse line drawn on each axial image tangent to the posterior surface of the submandibular gland on each side of the neck.	**IA:** (Submental nodes) lie between the medial margins of the anterior bellies of the digastric muscles. **IB:** (Submandibular nodes) lie on each side lateral to the level IA nodes and anterior to the back of each submandibular gland.

Level II	Lymph nodes from level II (upper jugular nodes, deep cervical chain) extend from the skull base to the level of the bottom of the body of the hyoid bone. They are posterior to the back of the submandibular gland and anterior to the back of the sternocleidomastoid muscle.	**IIA:** anterior, lateral or medial to the vein or posterior to the internal jugular vein and inseparable from it. **IIB:** posterior to the internal jugular vein and have a flat plane separating the nodes and the vein (posterior-superior to the accessory nerve). **NB:** any nodes that lie medial to the internal carotid artery are retropharyngeal and not level II.
Level III	Lymph node from level III (middle jugular nodes) extend from the level of the bottom of the body of the hyoid bone to the level of the bottom of the cricoid arch. They are located around the middle third of the internal jugular vein. The anterior (medial) boundary is the lateral border of the sternohyoid muscle and the posterior (lateral) boundary is the posterior border of the sternocleidomastoid muscle (they also lie lateral to the medial margin of either the common carotid artery or the internal carotid artery, separating them from the level VI that is medial).	
Level IV	The level IV (Lower jugular nodes) extends from the level of the bottom of the cricoid arch to the level of the clavicle. Nodes lie anterior to a line connecting the back of the sternocleidomastoid muscle and the posterolateral margin of the anterior scalene muscle and are also lateral to the medial margin of carotid arteries.	
Level V	The nodes from level V (posterior cervical nodes) lie posterior to the back of the sternocleidomastoid muscle from the skull base to the level of the bottom of the cricoid arch and posterior to a line connecting the back of the sternocleidomastoid muscle and the posterolateral margin of the anterior scalene muscle from the level of the bottom of the cricoid arch to the level to the level of the clavicle. They also lie anterior to the anterior edge of the trapezius muscle.	**VA:** (Upper level V nodes) extend from the skull base to the level of the bottom of the cricoid arch. **VB:** (Lower level V nodes) extend from the level of the bottom of the cricoid arch to the level of the clavicle, as seen on each axial scan.

Level VI	The lymph nodes from level VI (anterior cervical node; superior visceral nodes; prelaryngeal; pretracheal; Delphian node) lie between the carotid arteries from the level of the bottom of the body of the hyoid bone to the level of the manubrium (or innominate vein). They are anterior to visceral space and anterior to levels III and IV.
Level VII	If the term level VII is to be used, it should refer to the extension of the chain of paratracheal nodes below the suprasternal notch (the dividing line between levels VI and VII) to the level of the innominate artery only. Alternatively, these nodes might be defined as the superior mediastinal lymph nodes above the level of the innominate artery.

Metastatic sites

The lungs are the commonest site of distant metastases; skeletal or hepatic metastases occur less often. Mediastinal lymph node metastases are considered distant metastases.

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Chapter 3

TNM classification, staging and prognostic indicators

Squamous cell carcinoma of the head and neck are a heterogenous disease. The Tumour, Nodes and Metastases (TNM) classification offers a reliable method for estimating the prognosis of patients with cancer based on certain characteristics of the tumor. It is also used in planning treatment and has helped to standardize the way the cancer is staged and treatment results are reported around the world. The American Joint Committee on Cancer (AJCC) / International Union against Cancer (UICC) staging system is used in this guideline as it is a major tool used worldwide currently for clinical (cTNM), pathological (pTNM) and recurrent disease (rTNM) staging. Therefore, TNM staging should be used when planning treatment and assessing the prognosis of oral cavity Squamous cell carcinomas[1,2].

Clinical staging

The assessment of the primary tumour is based upon inspection and palpation of the oral cavity and neck. Additional investigations may include Computerized Tomography (CT) scan or Magnetic Resonance Imaging (MRI). When imaging is utilized, one study will generally suffice to evaluate primary and nodal tumour extent. Clinical assessment of extent of mucosal involvement is more accurate than radiographic assessment. The radiographic estimate of deep tissue extent and regional lymph node involvement is usually more accurate than clinical assessment. MRI is generally more revealing of extent of soft tissue, perivascular and perineural spread, skull base involvement and intracranial tumour extension[3].

CT or MRI may be more useful in evaluation of advanced tumours for assessment of bone invasion (mandible or maxilla) and deep tissue invasion (deep extrinsic tongue muscles, midline tongue, soft tissues of neck). Clinical examination supplemented with dental films or Orthophantamographs (OPG) may be helpful in determining cortical bone involvement. If CT or MRI is undertaken for primary tumour evaluation, radiologic assessment of nodal involvement should also be done simultaneously. For advanced lesions, appropriate screening for distant metastases should be considered.

Ultrasonography may be helpful in assessment of major vascular invasion as an adjunctive test. The tumour must be confirmed histologically. All clinical, imaging and pathologic data available prior to first definitive treatment may be used for clinical staging.

Pathological staging

Complete resection of the primary site and/or regional nodal dissections followed by pathologic examination of the resected specimen(s) allow the use of this designation for pT and/or pN, respectively. Specimens that are resected after radiation or chemotherapy need to be identified and considered in context. pT is derived from the actual measurement of the unfixed tumour in the surgical specimen. It should be noted, however, that up to 30% shrinkage of soft tissues may occur in the resected specimen. Pathological staging represents additional and important information and should be included as such staging but it does not supplant clinical staging as the primary staging scheme.

TNM classification and staging for the lip and oral cavity cancers[2,3,4]

Following classification is in relation to squamous cell carcinoma of the oral cavity only and non-epithelial tumors such as those of lymphoid tissue, soft tissue, bone and cartilage are not considered.

Primary tumour

T - Primary Tumour

TX	Primary tumour cannot be assessed
T0	No evidence of primary tumour
Tis	Carcinoma in situ
T1	Tumour 2cm or less in greatest dimension and 5mm or less depth of invasion*
T2	Tumour 2cm or less in greatest dimension and more than 5mm but not more than 10mm depth of invasion or Tumour more than 2cm but not more than 4cm in greatest dimension and depth of invasion no more than 10mm
T3	Tumour invasion more than 4cm in greatest dimension or more than 10mm depth of invasion
T4a	(Lip) Tumour invades through cortical bone, inferior alveolar nerve, floor of mouth or skin (of the chin or nose)
T4a	(Oral cavity) Tumour invades through cortical bone of the mandible or maxillary sinus or invades skin of the face
T4b	(Lip and oral cavity) Tumour invades masticator space, pterygoid plates or skull base and/or encases internal carotid artery

Note: **Superficial erosion alone of bone / tooth socket by gingival primary is not sufficient to classify a tumour as T4a*

Regional lymph node involvement

N - Regional lymph nodes

NX Regional lymph nodes cannot be assessed

N0 No regional lymph node metastasis

N1 Metastasis in a single ipsilateral lymph node, 3cm or less in greatest dimension without extra nodal extension

N2 Metastasis described as:

- **N2a** Metastasis in a single ipsilateral lymph node, more than 3cm but not more than 6cm in greatest dimension, without extra nodal extension
- **N2b** Metastasis in multiple ipsilateral lymph nodes, none more than 6cm in greatest dimension, without extra nodal extension
- **N2c** Metastasis in bilateral or contralateral lymph nodes, none more than 6cm in greatest dimension, without extra nodal extension
- **N3a** Metastasis in a lymph node more than 6cm in greatest dimension without extra nodal extension

Note: *The presence of skin involvement or soft tissue invasion with deep fixation/ tethering to underlying muscle or adjacent structures or clinical signs of nerve involvement is classified as clinical extra nodal extension. Midline nodes are considered ipsilateral nodes.*

Status of metastasis

M - Distant metastasis

M0 No distant metastasis

M1 Distant metastasis

pTNM Pathological classification: The pT categories correspond to the clinical T categories.

pN - Regional lymph nodes: Histological examination of a selective neck dissection specimen will ordinarily include 10 or more lymph nodes. Histological examination of a radical or modified radical neck dissection ordinarily include 15 or more lymph nodes.

Lymph node levels should be properly identified in the neck specimen.

pNX	Regional lymph nodes cannot be assessed
pN0	No regional lymph node metastasis
pN1	Metastasis in a single ipsilateral lymph node, 3cm or less in greatest dimension without extra nodal extension
pN2	Metastasis described as:
pN2a	Metastasis in a single ipsilateral lymph node less than 3cm in greatest dimension with extra nodal extension or more than 3cm but not more than 6 cm in greatest dimension without extra nodal extension
pN2b	Metastasis in multiple ipsilateral lymph nodes, none more than 6cm in greatest dimension without extra nodal extension
pN2c	Metastasis in bilateral or contralateral lymph nodes none more than 6cm in greatest dimension without extra nodal extension
pN3a	Metastasis in a lymph node more than 6cm in greatest dimension without extra nodal extension
pN3b	Metastasis in a lymph node more than 3cm in greatest dimension with extra nodal extension or multiple ipsilateral or any contralateral or bilateral nodes with extra nodal extension
pM	Distant metastasis*
pM1	Distant metastasis microscopically confirmed

Note: **pM0 and pMX are not valid categories*

Table 3.1: Lip, oral cavity and p16 negative oropharynx stages

Stage	Tumour size (T)	Nodal status (N)	Metastasis (M)
Stage 0	Tis	N0	M0
Stage I	T1	N0	M0
Stage II	T2	N0	M0
Stage III	T1, T2	N1	M0
	T3	N0, N1	
Stage IVA	T1	N2	M0
	T2	N2	
	T3	N2	
	T4a	N0, N1, N2	
Stage IVB	Any T	N3	M0
	T4b	Any N	
Stage IVC	Any T	Any N	M1

Other prognostic factors of the cancers of the oral cavity and the lip

In addition to the importance of the TNM factors outlined previously, the overall health of these patients clearly influences outcome. Co-morbidity can be classified by more general measures, such as the Eastern Cooperative Oncology Group (ECOG) performance scale.

ECOG scale

Grade 0 Fully active, able to carry on all pre-disease performance without restriction

Grade 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g. light house work, office work

Grade 2 Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours

Grade 3 Capable of only limited self-care, confined to bed or chair more than 50% of waking hours

Grade 4 Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

Grade 5 Dead

Diagnosis and treatment of depression may also aid in symptom control and improved quality of life. Continued exposure to carcinogens, such as alcohol and tobacco also affects patient's outcome adversely.

The summary of prognostic factors is given in table 3.2

Table 3.2: Prognostic factors for carcinoma of the oral cavity

Prognostic factor	Tumour related	Host related	Environment related
Essential	T category, N category Extra nodal extension (ENE), Surgical excision margin	Performance status, Addictions (tobacco / areca nut /alcohol)	Dose of radiotherapy / chemo radiotherapy
Additional	Tumour volume, hypoxia	Age Comorbidity	Overall treatment / radiation treatment time interval from surgery to start of post-operative radiotherapy
New and promising	EGFR* expression, TP53 mutation, Bcl 2 ERCC1**	Swallowing related quality of life, global quality of life	

** Epidermal Growth Factor Receptor* *** Excision repair cross-complementing group 1*

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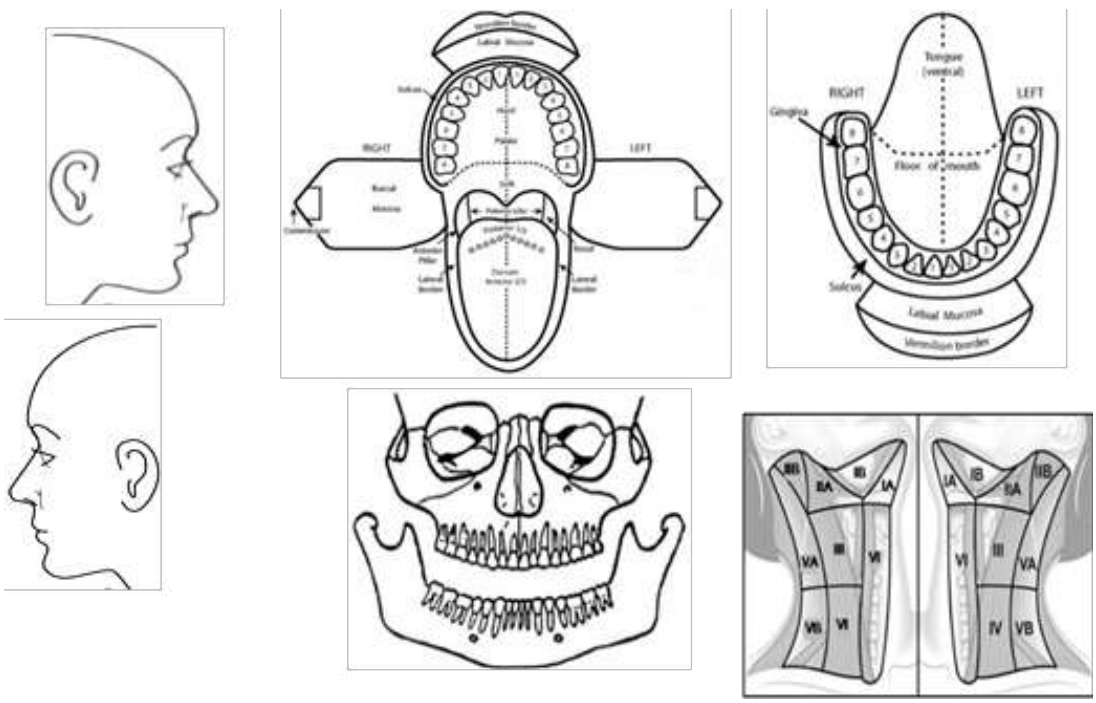
Chapter 4

Histopathological assessment of cancers of the oral cavity and the lip

Pathology report in oral squamous cell carcinoma specimens

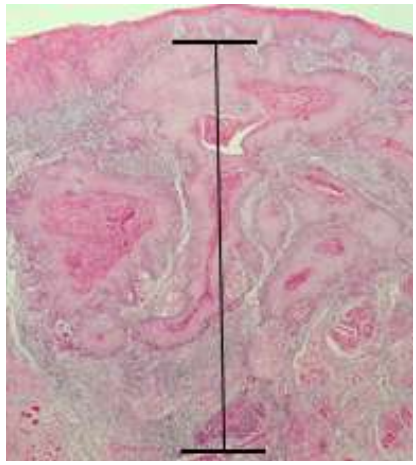
I. Gross pathology

1. Location of the tumour / lesion
2. Tumour dimensions (including tumour depth)
3. Extent of the lesion
4. Distance from the various margins of excision
5. Nodal dissection



Excision specimens should be oriented and labelled correctly before sending for Histopathology. If possible, lymph node levels should also be identified.

II. Microscopy



1. Histopathological sub type of the tumour
2. Level of differentiation
3. Pattern of invasion at the advancing front
4. Depth of invasion
5. Abnormal mitoses
6. Presence / absence of perineural invasion
7. Presence / Absence of lympho-vascular invasion
8. Bone / cartilage / skin / soft tissue involvement
9. Margins of excision should be clearly mentioned in millimetres (<1mm; Involved, 1-5mm; close >5mm; clear). Dysplasia at the margins should also be commented
10. Nodal status - number and size of nodes, extra capsular spread and level of nodes (extent of metastasis such as individual cells, micro metastasis or metastasis should be included)
11. Host immune response

III. Miscellaneous features

1. In radical neck dissection / modified neck dissection, status of the internal jugular vein
2. Presence of predisposing factors - HPV, leukoplakia, oral submucous fibrosis
3. Dysplasia / in situ elements
4. In tongue specimens - microscopic tumour thickness

Histologic confirmation of clinical diagnosis is required for treatment planning. Histopathology grading of SCC is recommended; the grade is subjective and uses a descriptive as well as numerical form, i.e. well differentiated, moderately differentiated and poorly differentiated, depending upon the degree of closeness to squamous epithelium or deviation from squamous epithelium in mucosal sites. Also recommend quantitative evaluation of depth of invasion of the primary tumour and the presence or absence of vascular invasion and perineural invasion[1-3].

Biopsy report should include degree of differentiation, pattern of invasion, depth of invasion, vascular and peri-neural invasion and host immune response.

Characteristics of tumours

Endophytic: The measurement using an ocular micrometer is taken perpendicular from the surface of the invasive squamous cell carcinoma (A) to the deepest area of involvement (B) and recorded in millimetres (distance between A to B). The measurement should not be done on tangential sections or in lesions without a clearly recognizable surface component[4].

Exophytic: The measurement which is better characterized as tumour thickness rather than depth of invasion, is taken from the mucosal surface (A) to the top-most area of the lesion (B). Distance between A to B is measured in millimetres.

Ulcerated: The measurement is taken from the ulcer base (A) to the deepest area (B) as well as from the surface of the most lateral extent of the invasive carcinoma (C) to the deepest area (D). Depth of tumour invasion (mm) should be recorded.

Although the grade of the tumour does not enter into staging of the tumour, it should be recorded. The pathologic description of any lymphadenectomy specimen should describe the size, number and position of involved lymph node(s) and the presence or absence of extra capsular extension[5].

(Annexure I and II contain details of the biopsy request form and histo-pathological details which should be included in biopsy report and in the minimum data set)

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Chapter 5

Clinical and radiological assessment of cancers of the oral cavity and the lip

Confirmation of diagnosis

Clinical examination is mandatory for the detection of new tumours and any recurrences. A systematic approach must be followed to include the primary site and neck, with the aim of assessing the tumour size and any potential invasion of local structures. The examination should be preceded by a focused history to elucidate any potential co-morbidities and social circumstances that may influence the choice of treatment[1,2].

Examination under anaesthesia (EUA), endoscopy and biopsy.

- Careful physical examination of the primary tumour and the neck is mandatory and has not been superseded by imaging. Examination findings may be aided with either fibre-optic or direct examination of pharynx, larynx and postnasal space.
- EUA could be performed where necessary - direct palpation under anaesthesia to adequately assess floor of the mouth, tongue and neck and could be combined with taking an incisional biopsy simultaneously.
- Pan-endoscopy for a second primary tumour, in those at high risk.
- Tumour sites and areas of field cancerisation should be carefully documented using standardized tumour maps in the biopsy request form.

Specific imaging

Once malignancy is confirmed, CT or MRI could be performed where necessary for staging of the tumour[3].

1. Superficial low-volume lesions may not require radiological assessment. If advanced radiological facilities are not readily available radiological assessment itself may contribute to treatment delay.

2. Deep invasion, mandibular invasion and nodal status may be assessed by CT or in selected cases by MRI. No single imaging modality exists with adequate sensitivity and specificity to accurately assess mandibular invasion. A variety of techniques including plain radiography, CT, MRI and radioisotope scans may be necessary to accurately assess neoplastic disease in the mandible.

3. All imaging methods, including dental films, may not show early mandibular invasion. The patient's dentition is evaluated by a combination of OPG and standard dental views.

Specific Investigations before definitive treatment

- Lat. Oblique Mandible / OPG / Dental Occlusal view for mandibular involvement.
- Ultra Sound Scan (USS) neck for clinically N0 neck when clinical suspicion is high and neck evaluation is difficult.
- CT scan as appropriate if recent onset trismus (Invasive Tumour Front involvement), suspected vascular / maxillary infiltration.
- MRI in selected cases to evaluate soft tissue extent e.g. Base of the tongue.
- Examination under anaesthesia for mapping of lesion where ever clinically indicated.

Table 5.1: Imaging check list for oral cavity tumours (other than nodal involvement)

(1) Lip Carcinoma

Bone erosion

Soft tissue invasion

(2) Floor of the Mouth Carcinoma

Extent of bone erosion

Deep invasion along the mylohyoid and hyoglossus muscles

Relationship to ipsilateral lingual neurovascular bundle

Extension across midline and relationship to contralateral neurovascular bundle

Tongue base invasion

Extension into the soft tissues of neck

Table 5.1: Imaging check list for oral cavity tumours (other than nodal involvement)
contd.

(3) Tongue carcinoma

Invasion of ipsilateral lingual neurovascular bundle

Extension across midline and relationship to contralateral neurovascular bundle

Invasion of floor of the mouth and associated bone erosion

(4) Buccal carcinoma

Sub mucosal extension

Bone erosion

(5) Gingival and hard palate carcinoma

Bone erosion

Perineural invasion of the incisive canal and greater and lesser palatine foramen

(6) Retromolar region carcinoma

Bone erosion

Sub mucosal spread

Perineural invasion

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Chapter 6

Principles of management for cancer of the oral cavity and the lip

The clinical behaviour of OC and prognosis will depend on the site of origin and aetiological factors. Staging of the disease is essential for treatment planning and outcome evaluation. It is based on clinical examination (preferably examination under anaesthesia) supported with radiological assessment[1]. The staging usually follow TNM classification.

The management of patients with oral cancer should be a multi-disciplinary approach[2]. Factors that influence the choice of treatment are tumour factors (site and extension of primary, TNM classification and staging of the disease) and patient factors (patients' age, compliance and co-morbid conditions). Goals in the management of oral cancer are; high locoregional control with preserved organ functions, improved survival rates, reduced probability of distant metastases and to ensure good quality of life. According to evidence-based data, single modality treatment with surgery or radiotherapy is recommended for majority of the patients who are with early stage disease (Stage 1-2)[1]. Combined modality of treatment for advanced stage disease will benefit with local control and survival improvement. Especially concurrent chemo-radiotherapy has shown 8% survival benefit compared to radiotherapy alone. Targeted therapy with Epidermal Growth Factor Receptor (EGFR) blockers has shown improvement in local control and also survival benefit. Which selected group is going to benefit is yet to be discovered in oral cancers[3].

Multidisciplinary Team Management (MDT Management)

Patients with a diagnosis of head and neck cancer are best seen in a multidisciplinary team meeting to allow adequate discussion of the case and appropriate decision-making as indicated[4].

Team members should include:

- Oncologist
- Surgeon with skills encompassing ablation and reconstruction
- MDT Coordinator preferably a trained nurse in cancer care

- Dental surgeon to assess the status of the dentition and make recommendations in relation to the dentition in respect of radiation therapy. The evaluating clinician should be aware of the treatment portals planned for radiotherapy.
- Pathologist
- Radiologist
- Specialists in internal medicine, cardiology, respiratory medicine or anaesthesia as needed to evaluate co-morbidities that may preclude or increase the risk of general anaesthesia[5].

Additionally:

- Prosthetic support may be required both perioperative and in the post-operative phase. An appropriately equipped and staffed oral & maxillofacial laboratory will be helpful.
- Support of speech therapists may be needed for pre-operative counselling regarding possible post-operative speech and swallowing rehabilitation[6].
- Assess nutritional status and decide the need for Neso-gastric / Gastrostomy / PEG feeding[4].
- Nutrition and psychiatric support.
- Betel chewing, smoking and alcohol cessation counselling need to be addressed.

The surgical management of the cancer of the oral cavity and the lip

The surgical treatment includes:

- The value of frozen section for evaluation of margins to ensure adequate resection is questionable[7].
- Tracheostomy at the discretion of the surgeon.
- Dental extractions if necessary (preferably oral hygiene improvement to be completed 2 weeks prior to commencement of radiotherapy).
- Insertion of a feeding tube or gastrostomy where necessary[4].

It is very important to orientate the primary and neck dissection specimen for the pathologist, by the surgeon[8].

Resection margins

The objective of surgical resection of a primary tumour is complete resection of tumour with histologically tumour free margins. For definition of adequate resection margins please refer chapter 4 (Histopathology). The details of resection margins should be included in the operative notes. The primary tumour should be marked in a fashion adequate for orientation by the surgical pathologist.

Reconstruction of the surgical defect should be performed using conventional techniques at the direction of the surgeon. Surgery may be more appropriate in young patients due to the high incidence of second primary and in lesions involving or close to bone to prevent osteoradionecrosis[8].

Radiotherapy is preferred over surgery as a single modality, where there could be severe impairment of function or cosmesis with surgery[1].

Criteria of unresectability

Tumour involvement of the following sites is associated with poor prognosis or function or with T4b cancer. (e.g. Unresectable based on technical ability to obtain clear margins). None of these sites of involvement is an absolute contraindication to resection in selected patients in whom total cancer removal is possible:

- Involvement of the pterygoid muscles, particularly when associated with severe trismus or pterygopalatine fossa involvement with cranial neuropathy
- Gross extension of tumour to the skull base (e.g. Erosion of the pterygoid plates or sphenoidal bone, widening of the foramen ovale
- Invasion (encasement) of the common or internal carotid artery
- Direct extension to the superior nasopharynx or deep extension in to the Eustachian tube and lateral nasopharyngeal walls
- Direct extension of neck disease to involve the external skin
- Direct extension to mediastinal structures, prevertebral fascia or cervical vertebrae
- Presence of subdermal metastases

Management of recurrences

Resectable recurrent cancers should be re-resected with curative intent if feasible and recurrences in a previously treated neck should undergo surgery as well. Neck dissection in

an untreated neck should be addressed by formal neck dissection or modification depending on the clinical situation. Non-surgical therapy may also be utilized as clinically appropriate[9].

Best managed with aggressive surgical resection with frozen section control. Elective neck dissection advocated as 25% have occult metastases. High success rate (75-85%) is observed in management of local recurrence.

Special surgical considerations

Mandible

A marginal/segmental mandibulectomy is carried out where invasion of the bone has occurred[1]. The key to a successful outcome is adequate assessment and accurate resection. We have to bear in mind that resection is done using existing imaging modalities. Therefore, both over and underestimations can occur[1].

- The use of smears from the resected mandible margins has a high predictive value in the assessment of tumour status[10].
- The surgeon must be aware of the patterns of tumour invasion, which differ between dentate and edentulous patients[11]. Previous radiotherapy alters the pattern of invasion. It is difficult for good functional results to be achieved after excision of the largest tumours.
- Dental rehabilitation should be considered for patients with mandibular reconstruction. This may include the use of osseo-integrated implants.

Reconstruction

Primary closure if possible is the method of choice but significant functional impairment may result from the overzealous use of this technique.

- The complex three dimensional and composite nature of many oral defects means that a variety of reconstructive techniques may be indicated[1,8].

These include:

- Skin grafts, local and regional flaps and vascularised free tissue transfer (including composite flaps)

- Reconstruction of the mandible can be carried out using a suitable plating system (for short lateral defects), non-vascular bone grafts for short lateral defects or free

tissue transfer for more extensive defects (including the anterior mandible)[1]. The most appropriate bone flaps for mandibular reconstruction include the fibula and deep circumflex iliac artery free flaps. Consideration should be given to the soft tissue defect when assessing the bone flap best suited to the defect. The composite radial free flap produces excellent soft tissue for mucosal reconstruction but has limitations in bone quantity and volume. There is an associated incidence of fracture of the osteotomised radius that may be reduced with the use of prophylactic plating. The best reconstruction may be achieved by the use of more than one flap but consideration must be given to the patient's general condition and the potential greater morbidity associated with this approach.

- The selection of a flap to be used for oral reconstruction must consider the type of defect to be encountered, the impact upon function of the reconstruction and the donor site morbidity. For oro-pharyngeal soft tissue defects requiring free tissue transfer the fascio-cutaneous radial forearm flap is a versatile, reliable and robust flap[11]. It enables a large volume of pliable thin soft tissue to be harvested with a long pedicle and good-sized vessels for anastomosis. It is suited to a two-team approach to surgery thus minimizing operative time and has a low donor site morbidity. Where more bulk is required the rectus abdominus flap and antero-lateral thigh flap provide abundant volume of skin and muscle or muscle only for reconstruction. Vessels are again of a good size with minimal donor site morbidity.

Treatment of the neck

- **N0 -** The incidence of occult metastasis in a N0 neck depends on many factors. The most predictable factors include depth of invasion (DOI), differentiation grade, size and the site of the tumour. An elective neck dissection is planned when the probability of metastasis to the neck nodes is considered higher than 20%. If not, a wait and see policy is advocated with regular monitoring. However recent literature suggests that necks becoming positive during a "wait and see policy" often do so at high pathological stage with poor salvage rates and shown a definitive survival benefit in patients with N0 neck who underwent prophylactic neck dissection[3].

- Elective radiotherapy may be used, but the advantage of surgery for the N0 neck is that the specimen is sent for histopathological examination, providing significant prognostic

information and objective assessment of adequacy of resection (elective selective staging neck dissection). This surgical staging of the N0 neck is preferable in T2 and non-infiltrating T3 tumours, high grade T1 lesions and low-grade T2 and T3 lesions.

- Because of lymphatic crossover and retrograde flow, especially with anterior lesions and those that are located at or near the mid-line, consideration should be given to treatment of the neck bilaterally, either with radiotherapy or selective neck dissection.

- Primary tongue lesions may have a different biological behaviour than other oral cavity sub sites, metastasising more frequently to levels II and III than level I. In addition to levels I to III, level IV has a significant risk of skip lesions from primary tongue tumours[7].

- Scattering of nodes at multiple levels may also occur in up to 10% of patients with primary lesions of the tongue. Therefore, a selective neck dissection, including levels I to IV, is the most appropriate type of neck dissection for tongue primary tumours[7].

- **The N+ Neck -** With palpable neck node involvement or evidence following imaging of the neck, surgical treatment is required which may be in the form of a modified comprehensive neck dissection, radical neck dissection or extended radical neck dissection. In most instances, post-operative irradiation is indicated[1].

Role of radiotherapy in cancer of lip and oral cavity

- Radical curative radiotherapy (alone or in combination with chemotherapy)
- Post-operative adjuvant radiotherapy
- Palliative radiotherapy

Radical curative radiotherapy (alone or in combination with chemotherapy)

Radiotherapy (RT) is preferred over surgery as a single modality, where there could be severe impairment of function or cosmetic concern with surgery[1].

As a radical single modality treatment, newer radiotherapy techniques like Intensity Modulated Radiotherapy (IMRT)/3D-CRT can reduce morbidity by more conformal dose distribution with steep dose gradient between tumour and risk organs[7]. Although interstitial

brachytherapy allows ideal conformal technique with increased dose intensity at the lesion and good dose reduction at high risk surrounding organs, it needs specialized expertise and also very regular specially planned facilities. At present in Sri Lanka this technique is not practiced on regular basis.

External beam radiotherapy is not usually recommended as the primary curative treatment in oral cavity tumours because the significant morbidity with severe mucositis, osteoradionecrosis of the mandible and xerostomia which limits radiation dose and therefore cure rates. Xerostomia is one of the most unpleasant permanent complications from RT of the oral cavity. Sparing of the salivary glands by intensity-modulated radiation therapy may improve toxicity without reduction in local control.

External beam radiotherapy alone can be used to treat the neck prophylactically after excision of a small primary without a neck dissection. The lower lip is one of the few ideal sites for orthovoltage therapy. Using a single anterior field a fractionated course of 50 Gy in 15 fractions over 3 weeks is administered. External beam radiotherapy using electrons or orthovoltage photons minimizes dose to the oral cavity so that mucositis occurs only on the treated lip.

Post-operative adjuvant radiotherapy

Criteria for post-operative radiotherapy is given below.

Criteria for post-operative radiotherapy

Primary Site

- Any stage with microscopically positive margins
- All T3 and T4 - irrespective of nodal status
- Peri-neural or intra-vascular invasion
- Poorly differentiated tumours

Radiation therapy should begin as soon as possible and not more than 6 weeks after surgery. It may include a brachytherapy boost when indicated by pathological findings such as unsatisfactory margins.

Palliative radiotherapy

In patients with incurable disease, a short course of palliative RT may help to improve local symptoms. Any palliative radiotherapy schedule with severe toxicities should be avoided.

Role of chemotherapy in cancer of lip and oral cavity

It is usually used in advanced oral cancers in combination with radiotherapy (sequential or concurrent). Choice of systemic therapy depends on performance status of patients and risk factors of the lesion.

In selected patients chemotherapy can be used for palliating symptoms[12]. Palliative chemotherapy with platinum-based drugs and 5FU or capecitabine can also be considered to help symptoms and quality of life.

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Chapter 7

Guidelines for management of cancers of the oral cavity and the lip

For management, OC are considered in two separate groups.

1. Cancer of the lip (LC)
2. Cancers of the oral cavity (OCC)

Cancers of the lip

Work up for cancer of the Lip

- History and physical examination including a complete head and neck examination: Mirror and/or fibre optic examination as clinically indicated
- Biopsy
- Dental evaluation
- As clinically indicated
    - Chest imaging
    - OPG
    - CT and/or MRI of primary and neck
- Preanaesthesia studies as clinically indicated
- Multidisciplinary consultation as indicated

Treatment pathways for the cancer of the Lip

Early N0 LC	*T1-2, N0 clinically negative neck*	Figure 7.1
Operable advanced LC	*T3, T4a, N0 or Any T, N1-3*	Figures 7.2 & 7.3
Inoperable primary LC	*T4b, any N or un-resectable nodal disease: (Inoperable primary lip cancer due to advanced local disease, unresectable nodal disease or unfit for surgery)*	Figures 7.6 & 7.7
Recurrent or residual LC	*Recurrent or persistent disease*	Figures 7.8 & 7.9

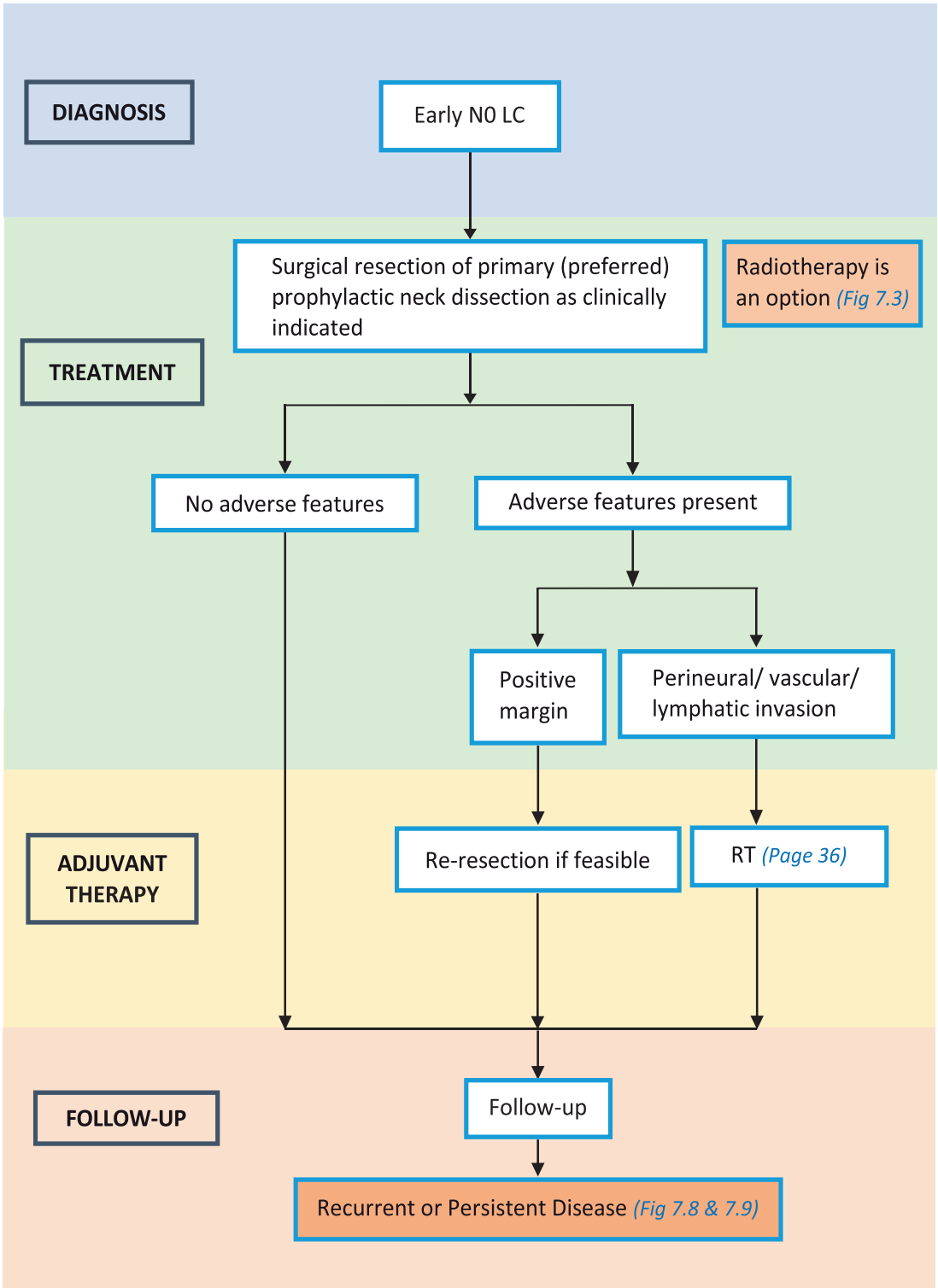


Figure 7.1: Treatment pathway of Early N0 LC: clinically negative neck

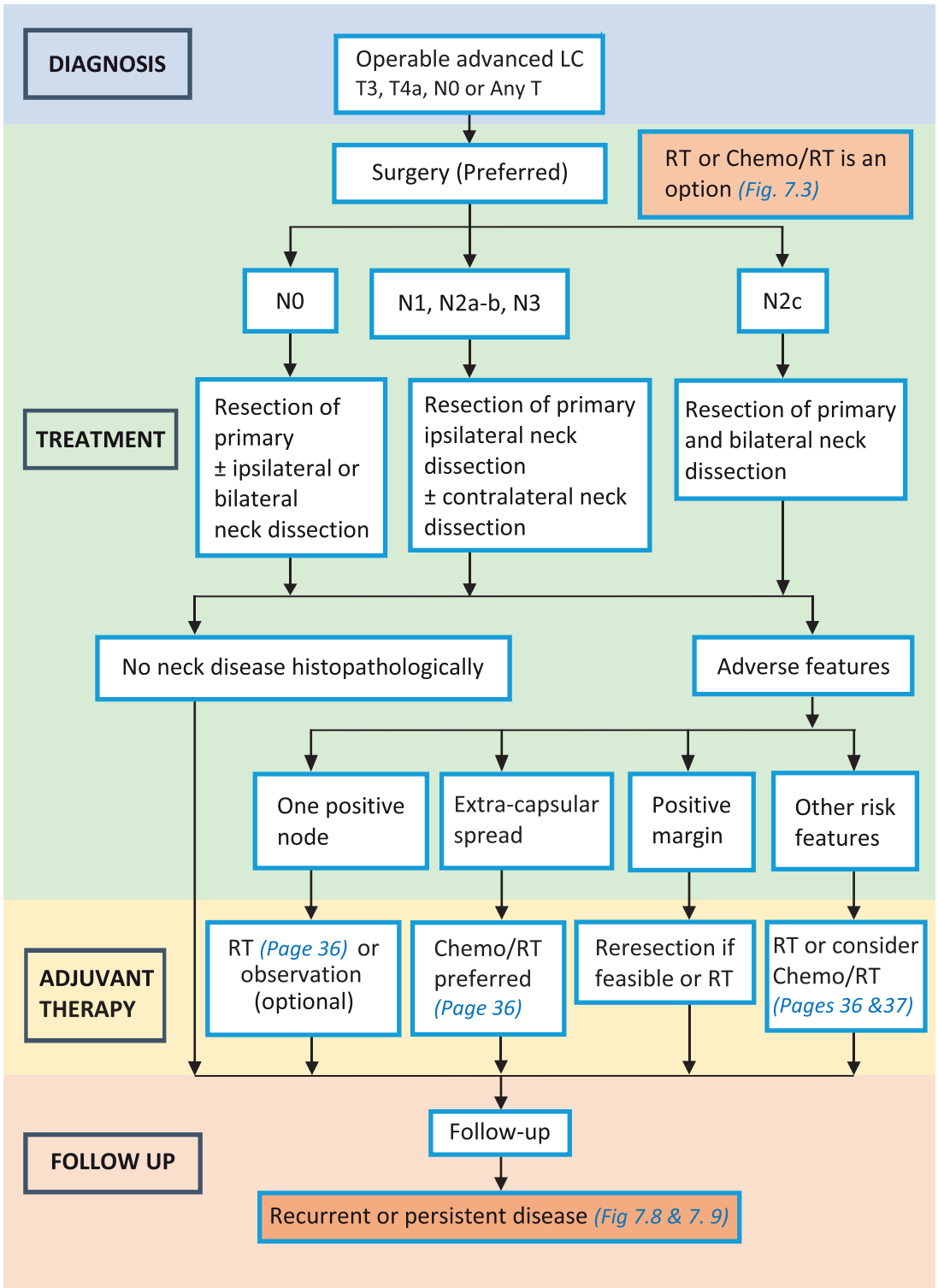


Figure 7.2: Treatment pathway of operable advanced LC

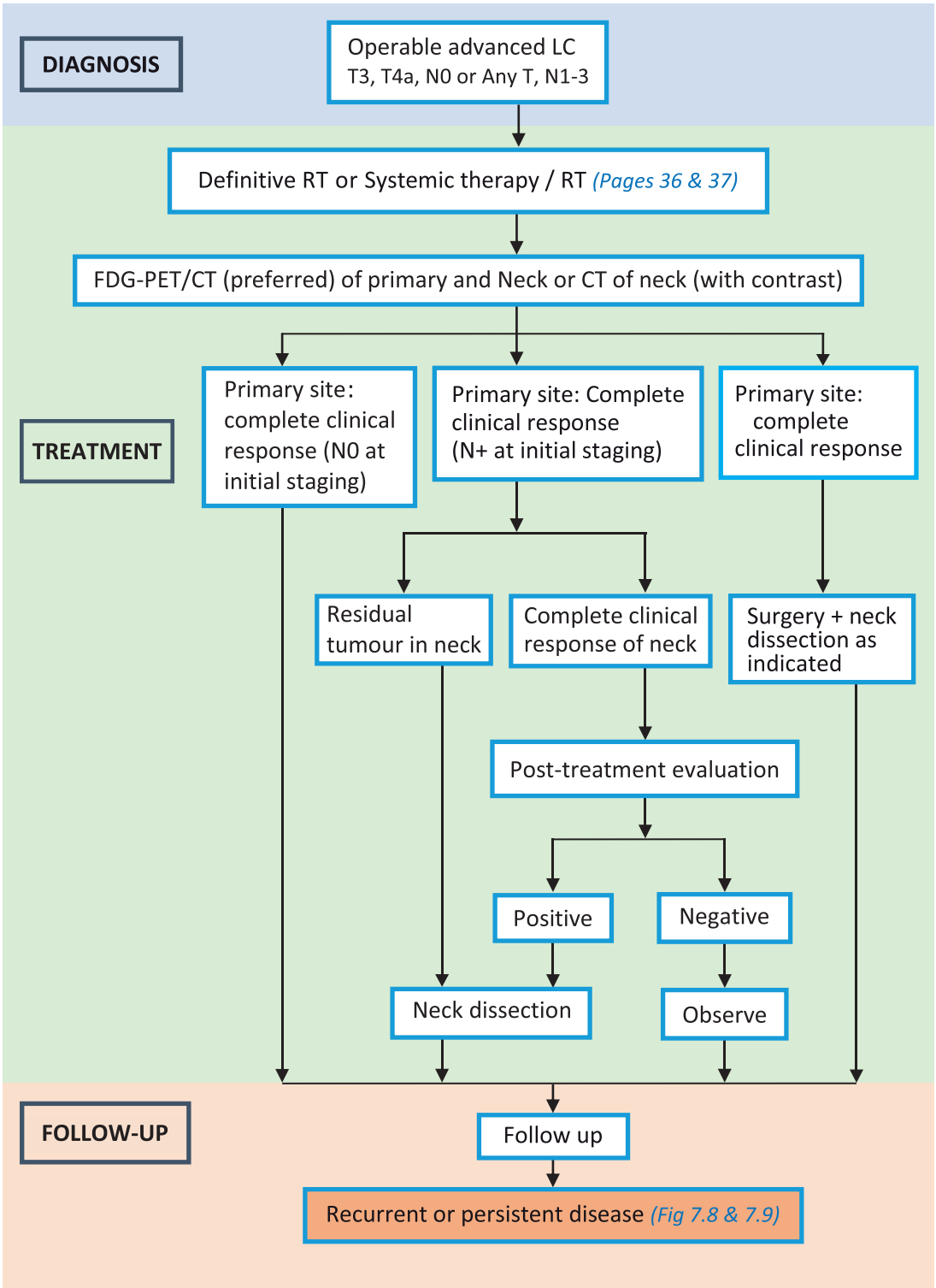


Figure 7.3: Treatment pathway of operable advanced LC (Radiotherapy pathway)

Principles of radiation therapy for cancer of the lip

DEFINITIVE:

RT ALONE - External Beam Therapy

For early stages T1/ T2 N0

Most superficial tumours can be treated with electrons or superficial X – rays

- PTV should be covered by 90% isodose of the electron beam.

For Small tumour (<2cm diameter)

- Target volume (Gross Tumour Volume) GTV - includes the primary site only or with first echelon nodes if clinically indicated.
- 3-5mm margin can be added to the GTV to produce clinical target volume CTV and further 5mm to get Planning target volume PTV.
- *Radiotherapy fractionation*; 55Gy in 20 daily fractions (2.75Gy/fraction)

For Larger tumour needs (>2cm)

- 5-10 mm GTV - CTV margin to primary lesion to include possible local subclinical infiltration at the primary site and involved lymph nodes and high-risk level of lymph node(s) - PTV1
- Also need to irradiate the bilateral neck nodes depending on the site and grade of the tumour - PTV2
- *Radiotherapy fractionation ;*
  - High risk: PTV1: 66 Gy (2.0 Gy/fraction) to 70 Gy (2.0 Gy/fraction); daily Monday - Friday in 6-7 weeks
  - Low to intermediate risk: PTV2 dose of 44-54 Gy over 6-7 weeks
  - Either direct EBRT depending on the size of the tumour or 3-D conformal/ IMRT can be used.

Brachytherapy - When expertise available with facilities

- Interstitial brachytherapy is considered for selected cases as it can give excellent local control rates with cosmesis and maintain functions.
- Consider LDR or HDR boost if combined with 50 Gy EBRT or 60 - 70 Gy or LDR /HDR as sole therapy.

CONCURRENT CHEMORADIATION (For high risk patients as indicated)

- Cisplatin 75 - 100/m^2 every 3weekly 3 doses or 40mg/m^2 weekly 5 doses during RT
- *Radiotherapy fractionation*
  - High risk volume: PTV 1: 66 - 70 Gy (2.0 Gy/fraction)
  - Low to intermediate risk: PTV2: 44 - 54 Gy (2.0 Gy/fraction)

POSTOPERATIVE RADIOTHERAPY (For adverse features such as close/positive margins)

Preferred interval between resection and postoperative RT is equal or less than 6 weeks

- PTV1 High risk: 60 - 66 Gy (2.0 Gy/fraction) daily Monday-Friday in 6 - 6.5 weeks or 65Gy (2.1Gy/fraction) in 6 weeks
- PTV2 Low to intermediate risk: Sites of suspected subclinical spread 44 - 50 Gy (2.0 Gy/fraction) to 54 - 63 Gy (1.6 - 1.8 Gy/fraction)
- 3-D conformal/ IMRT can be used.

Cancer of the oral cavity

(Cancers of buccal mucosa, floor of mouth, anterior tongue, alveolar ridge, retromolar trigone, hard palate)

Workup for cancer of the oral cavity

- History and Physical Examination including a complete head and neck examination; Mirror and fiber-optic examination as clinically indicated
- Biopsy
- Chest imaging as clinically indicated
- CT with contrast and/or MRI with contrast of primary and neck as indicated
- Examination under anesthesia (EUA) with endoscopy, if indicated
- Preanesthesia studies as clinically indicated
- Dental/prosthodontic evaluation, including jaw imaging as clinically indicated
- Nutrition, speech and swallowing evaluation/therapy as indicated
- Multidisciplinary consultation as indicated

Treatment pathways for the cancer of the oral cavity

Early N0 OCC	*T1-2, N0 (Early OCC with clinically negative neck)*	Figure 7.4
Moderate N0 OCC	*T3, N0 (Moderate oral cavity cancer with clinically negative neck)*	Figure 7.5
Early to moderate N+ OCC	*T1-3, N1-3 (Early to moderate oral cavity cancer with clinically positive neck)*	Figure 7.5
Operable advanced OCC	*T4a, any N (Operable advanced oral cavity cancer)*	Figure 7.5
Inoperable primary OCC	*T4b, any N or unresectable nodal disease or unfit for surgery (Inoperable primary oral cavity cancer due to advanced local disease, unresectable nodal disease or patient unfit for surgery)*	Figures 7.6 & 7.7
Recurrent or residual OCC	*Recurrent or persistent disease*	Figures 7.8 & 7.9

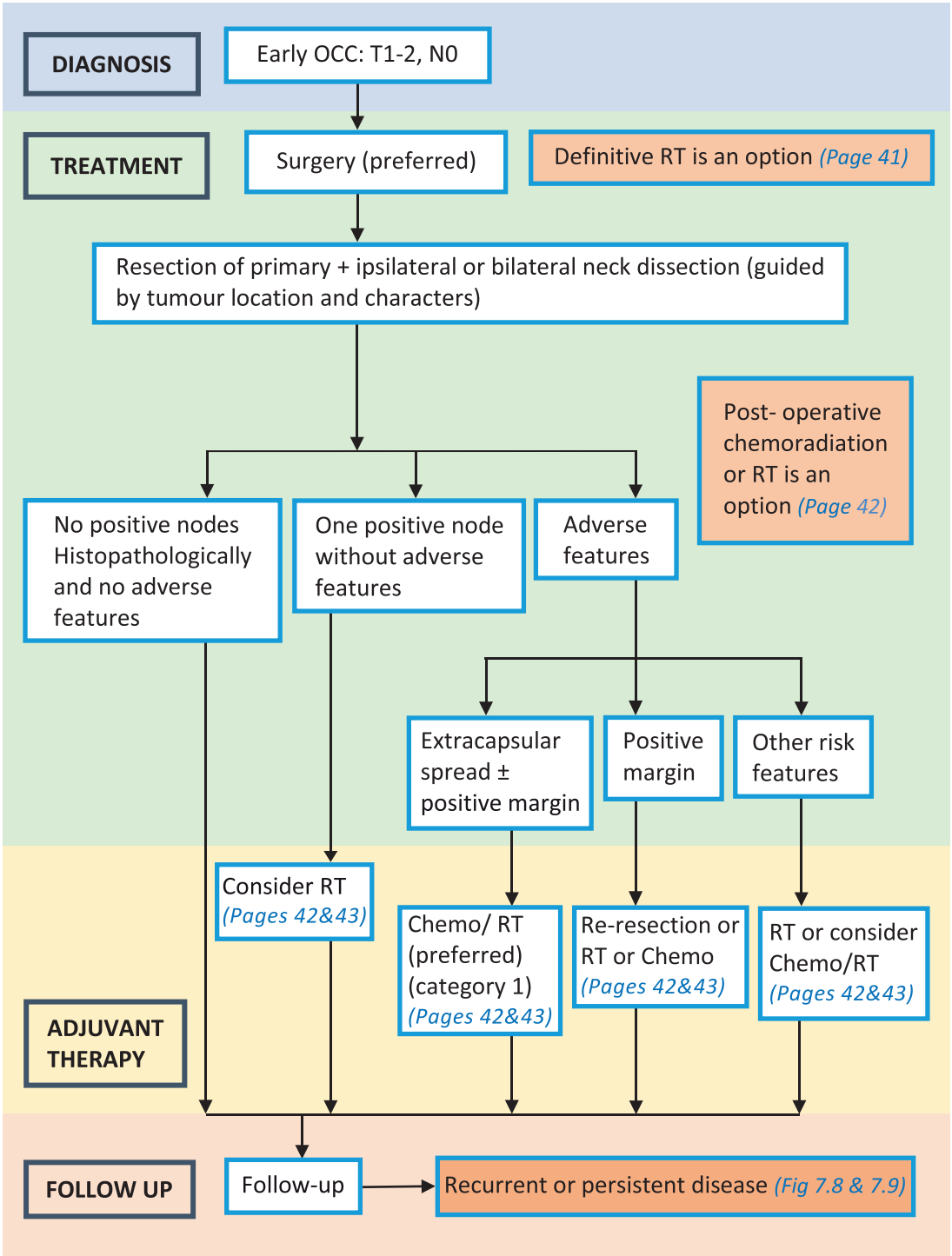


Figure 7.4: Treatment pathway of early OCC

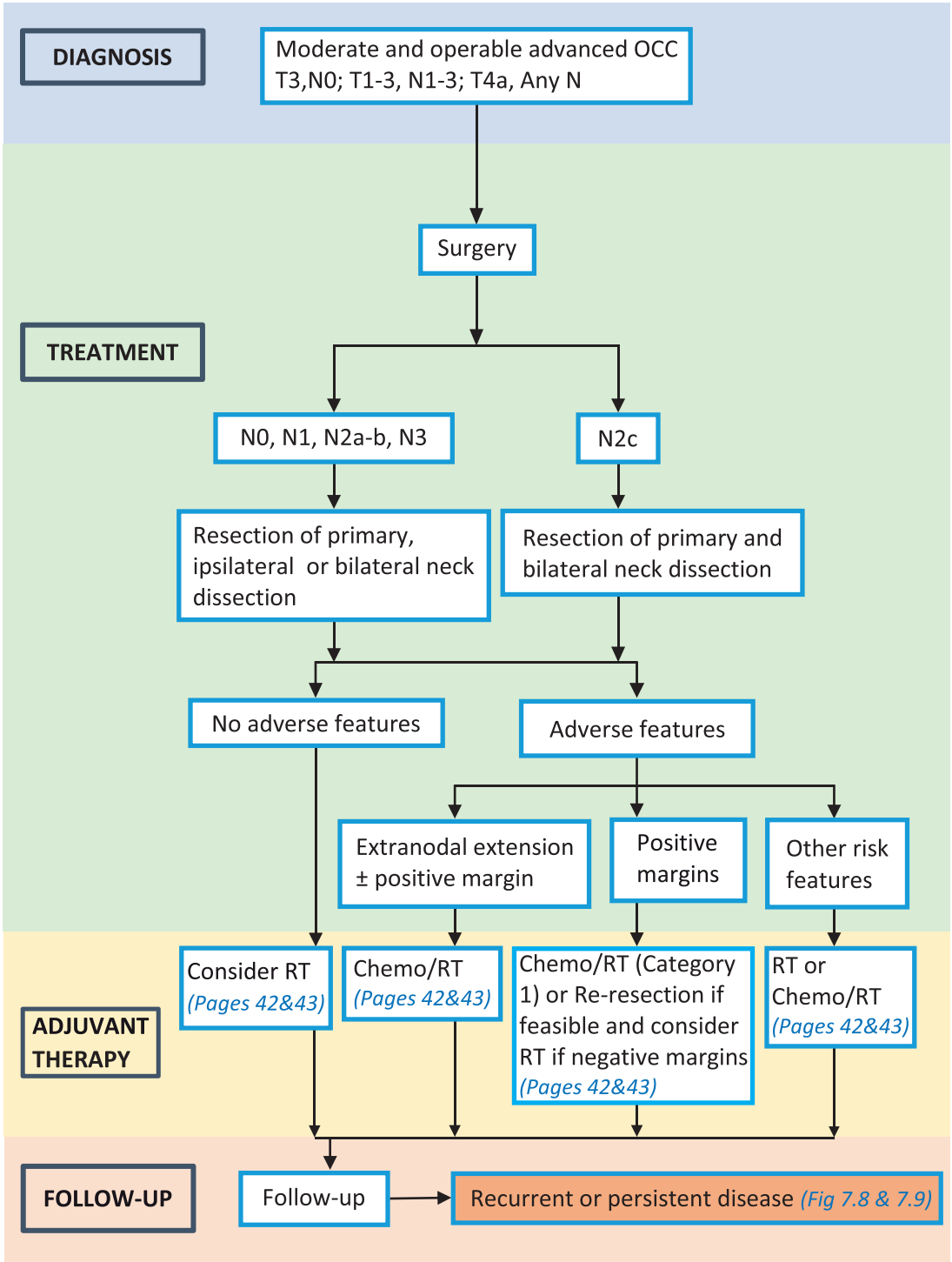


Figure 7.5: Treatment pathway of moderate to operable advanced OCC

Principles of radiation therapy for OCC - definitive

RT ALONE FOR CURATIVE TREATMENT

- *PTV 66 /70* - Primary tumour and involved lymph nodes (this includes possible local subclinical infiltration at the primary site and at the high - risk level lymph node(s). *10mm margin from macroscopic tumour edge will be taken for clinical target volume CTV and PTV can obtain by adding 5mm margin.*
- *PTV 44/50 - Prophylactic lymh nodes /sub clinical nodes*
- Fractionation:
    - 66Gy to 70 Gy (2.0 Gy/fraction); daily Monday - Friday in 6 - 7 weeks
    - 44 - 50 Gy (2.0 Gy/fraction) to 54-63 Gy (1.6 -1.8 Gy/fraction)

  Altered fractionation schedules

    - 66 - 70 Gy (2.0 Gy/fraction; 6 fractions/week accelerated)
    - Concomitant boost accelerated RT: 72 Gy/6 weeks (1.8 Gy/fraction, large field; 1.5 Gy boost as second daily fraction during last 12 treatment days)
    - Hyper fractionation: 81.6 Gy/7 weeks (1.2 Gy/fraction, twice daily)

  Either IMRT or 3-D conformal RT is recommended to spare some of the mucosa of the oral cavity and pharynx and parotid gland.

Brachytherapy - When expertise available with facilities

- Interstitial brachytherapy is considered for selected cases as it can give excellent local control rates with cosmesis and maintain functions.
- Consider LDR or HDR boost if combined with 50 Gy EBRT or 60-70 Gy OR LDR /HDR as sole therapy.

Principles of radiation therapy for OCC: post-operative – adjuvant therapy

RT ONLY

Preferred interval between resection and postoperative RT is 6 weeks.

PTV - For High risk: Adverse features such as positive margins and extracapsular spread of lymph nodes

66 y (2.0 Gy/fraction); daily Monday-Friday in 6 - 6.5 weeks

- For close resection margins and high risk adjacent lymph nodes

60Gy (2.0Gy/fraction);daily Monday – Friday in 6 weeks

- Low to intermediate risk volume/prophylactic lymph nodes

44-50 Gy (2.0 Gy/fraction) to 54-63 Gy (1.6-1.8 Gy/fraction)

Either IMRT or 3 - D conformal RT is recommended to spare mucosa of oral cavity and pharynx and parotid gland.

POSTOPERATIVE CHEMO-RADIATION

- Concurrent single - agent cisplatin at 100 mg/m^2every 3 weeks is recommended.
- Cisplatin 40mg /m^2 weekly 5 doses can also be given.
- Recommend to have conventional fractionation with concurrent chemotherapy.

PALLIATIVE RADIOTHERAPY

For advanced oral cavity cancers curative intent management is not appropriate, to relief or to prevent loco regional symptoms palliative radiotherapy should be considered. But should avoid severe toxicities and recommend to have short hypofractionated course of radiotherapy.

Recommended RT regimens;

50Gy in 20 fraction

37.5Gy in 15 fractions

30Gy in 10 fractions

30Gy in 5 fractions

44.4Gy in 12 fractions (3.7 Gy twice per day 2day cycles repeat in 3 weekly 3 cycles)

REIRRADIATION

For recurrences - if previously irradiated volume overlaps with new volume it should be at least 6 months from the last treatment.

To achieve better outcome with reirradiation;

- performance status of patient ECOG 0 - 1
- gap between previous RT is more than 2 years
- surgery has been done for gross disease and
- free of organ dysfunction (free of tracheostomy, laryngectomy, feeding tube)

Planning target volume should be only known disease to reduce toxicities.

Post - operative - 56 - 60Gy (2GY/fraction)

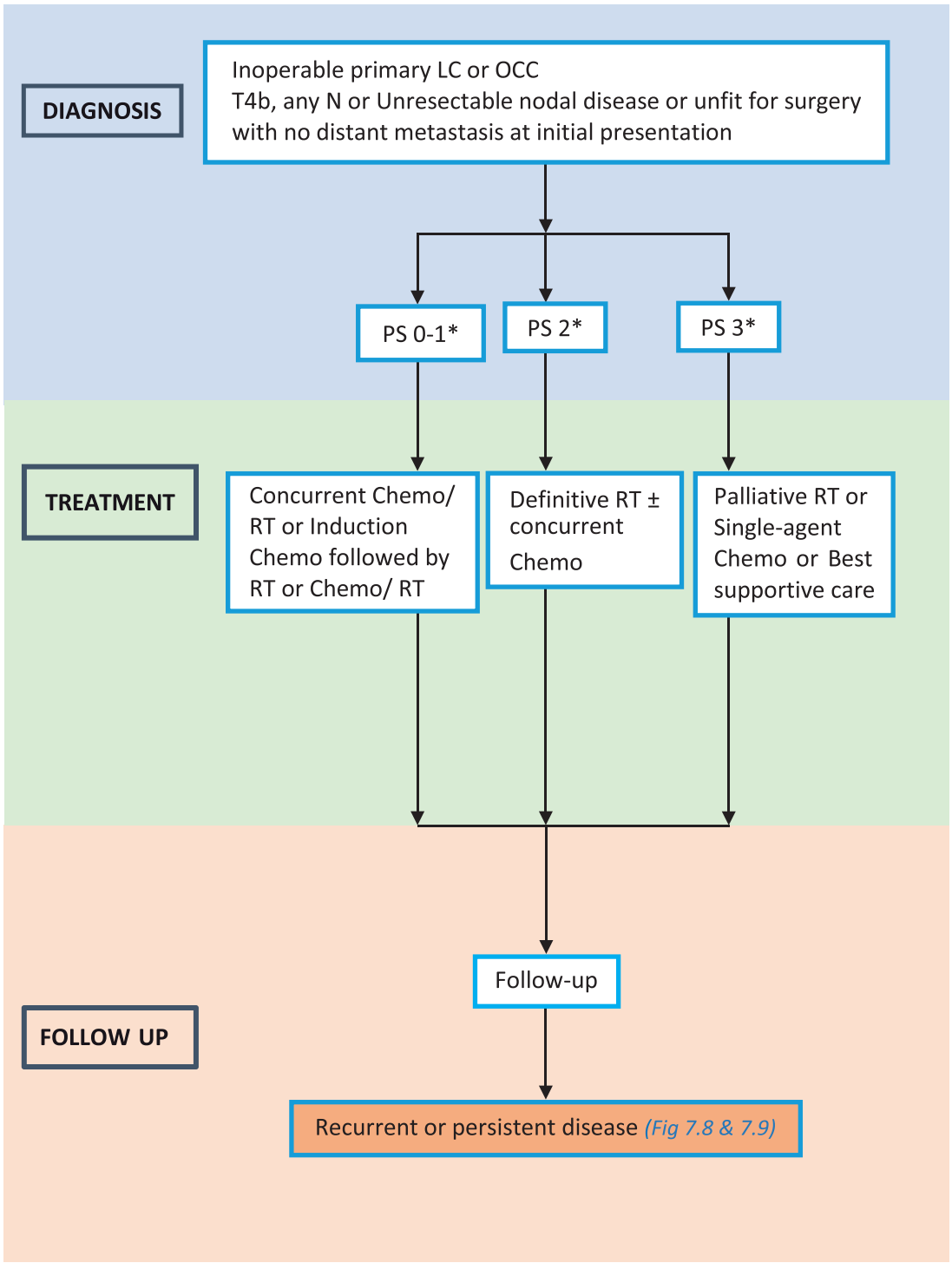
Hypofractionation /SBRT - 35 - 44Gy with 5 fractions

SYSTEMIC THERAPY

Choice of chemotherapy depends on goals of therapy and performance status of the patient.

For primary systemic therapy and concurrent radiotherapy /post-operative /induction;

- Preferred systemic therapy approach is concurrent chemoradiotherapy and most recommended regimen is high dose cisplatin with radiotherapy.
- Post-operative chemoradiotherapy is given for tumours with high risk features
- Cisplatin based induction chemotherapy can be used and should be followed by radiation based loco regional RT (sequential therapy).



Note: *PS*: Performance status (Eastern Cooperative Oncology Group (ECOG))*

Figure 7.6: Treatment pathway of inoperable primary LC or OCC without distant metastasis

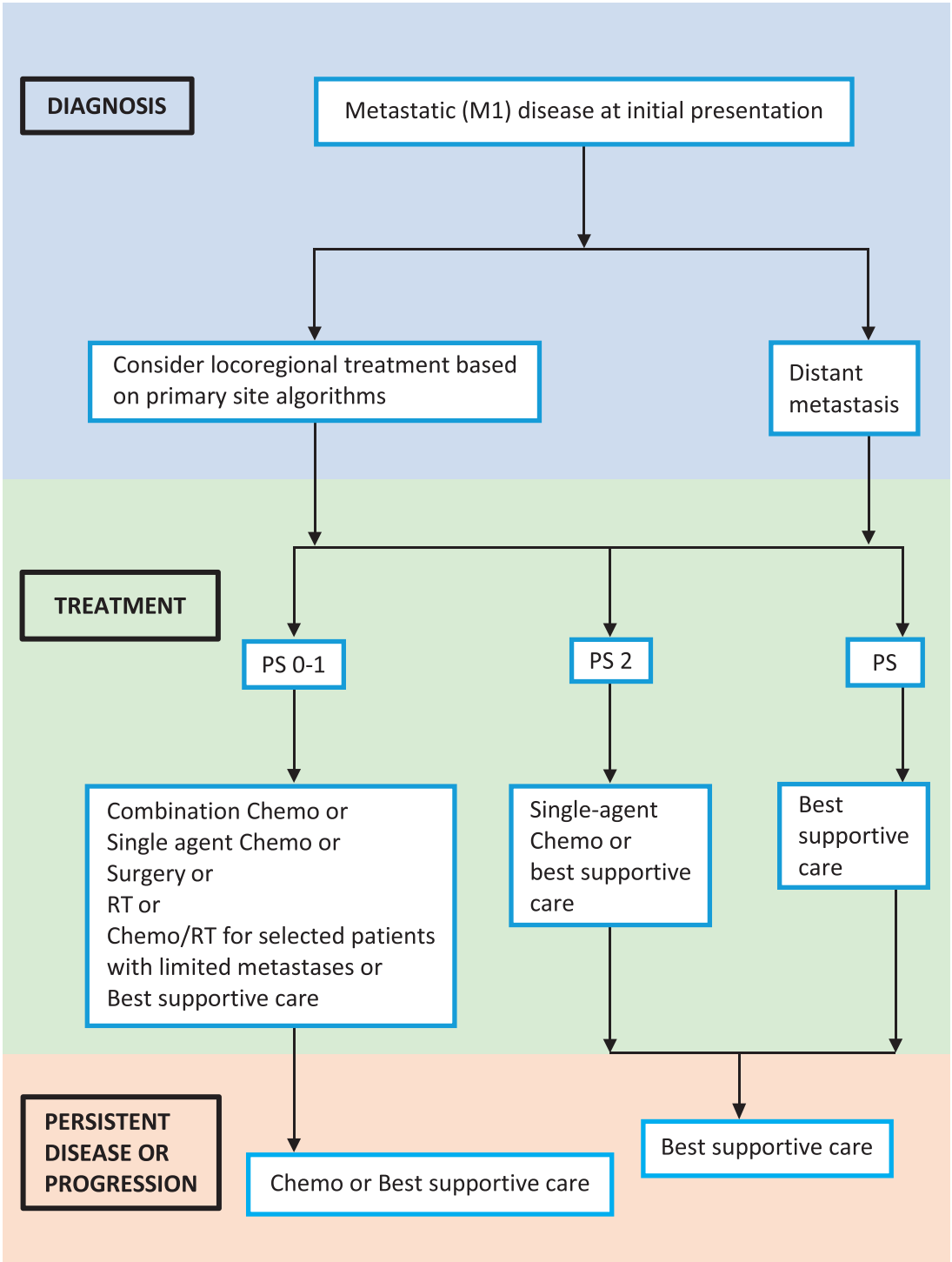


Figure 7.7: Treatment pathway of inoperable primary LC or OCC with distant metastasis (M1)

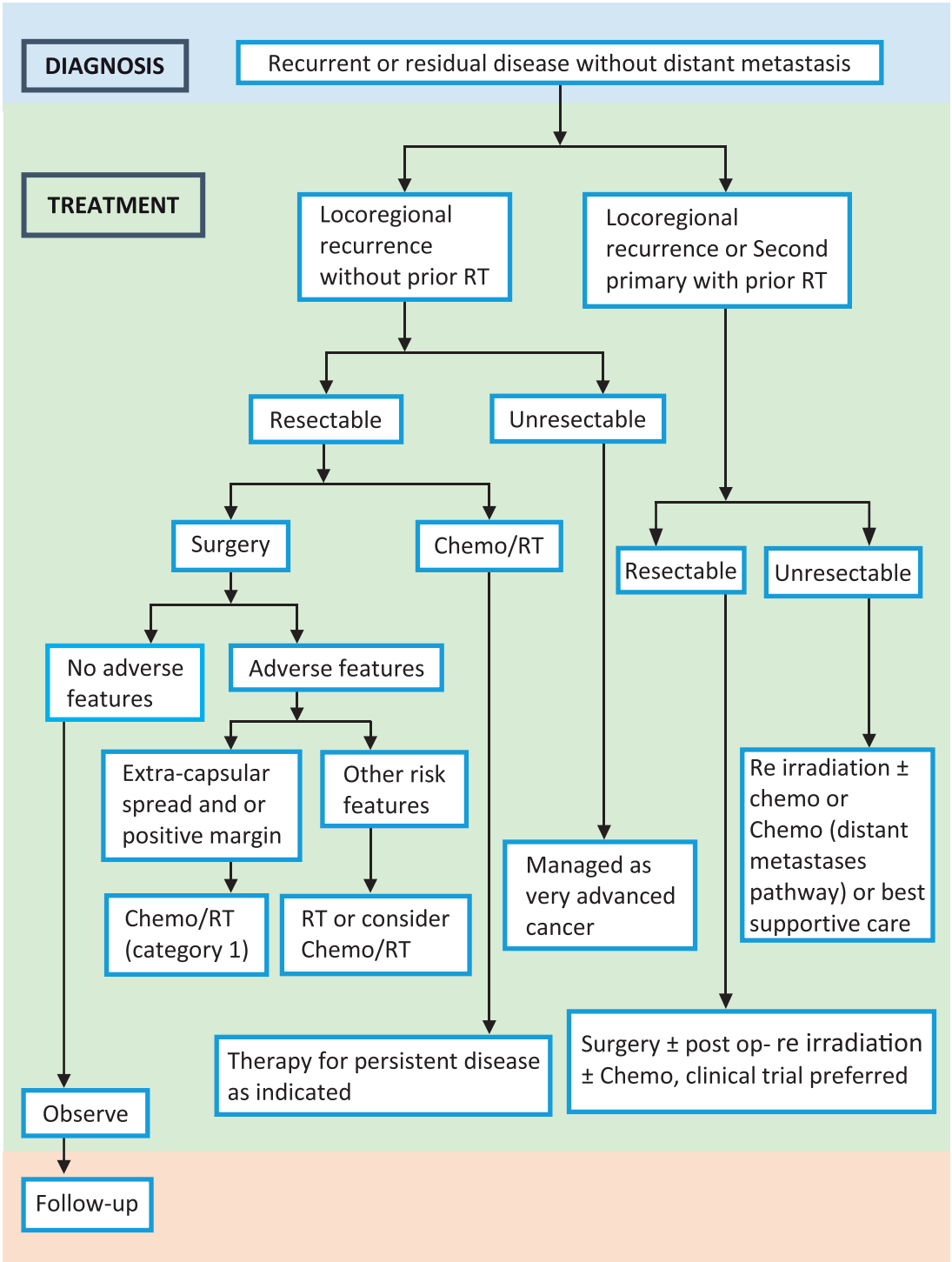


Figure 7.8: Treatment pathway of recurrent or residual LC or OCC without distant metastasis

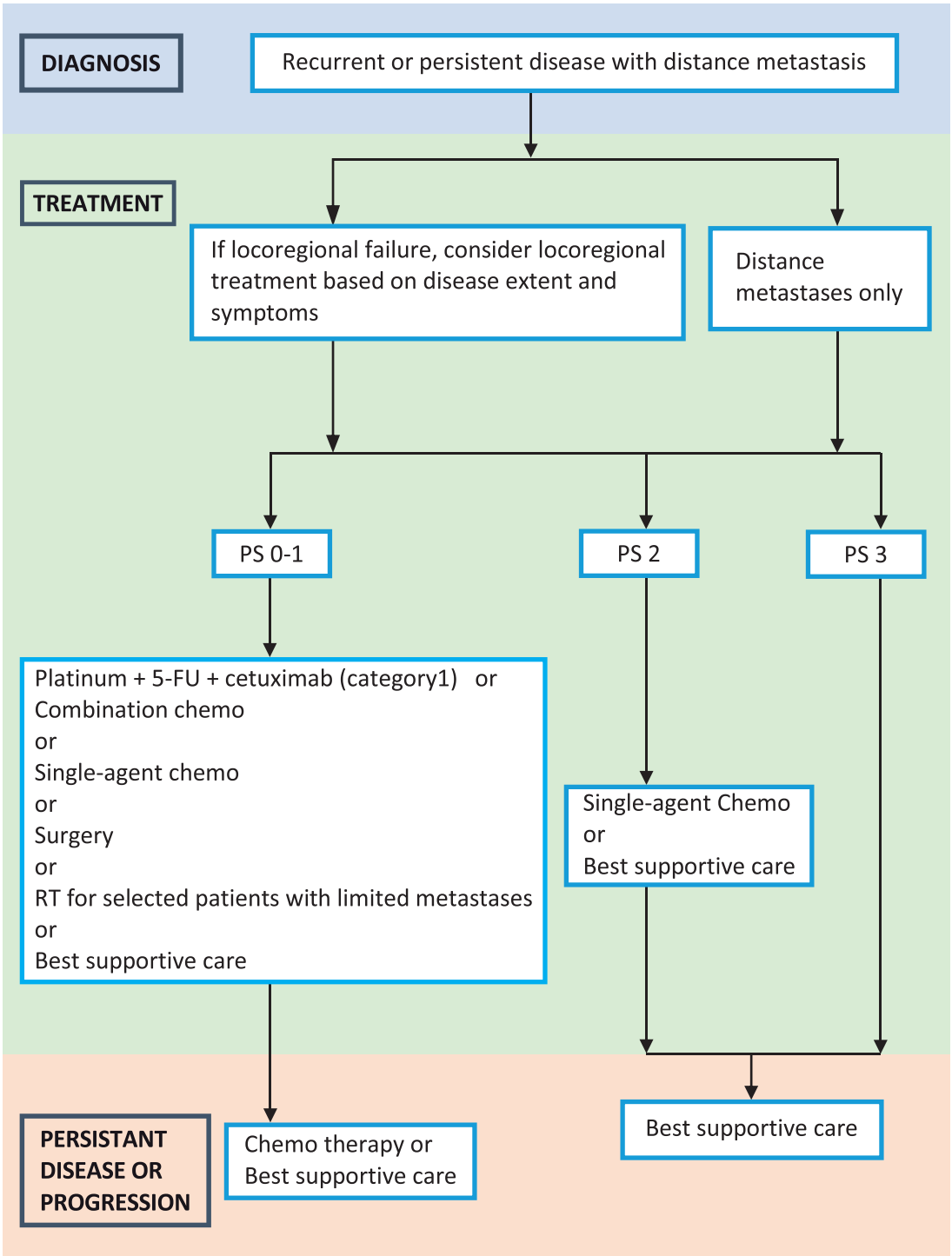


Figure 7.9: Treatment pathway of recurrent or residual LC or OCC with distant metastasis

Follow-up recommendations

Follow-up recommendations (based on risk of relapse. second primaries. treatment squelae and toxicities)

- H & P exam
    - Year 1, every 1-3 months
    - Year 2, every 2-6 months
    - Years 3-5, every 4-8 months
    - 5 years, every 12 months
- Post-treatment baseline imaging of primary (and neck, if treated) recommended within 6 months of treatment as clinically indicated.
    - Further reimaging as indicated based on signs/symptoms; not routinely recommended for asymptomatic patients
    - Chest imaging as clinically indicated
    - Thyroid-stimulating hormone (TSH) every 6-12 months if neck irradiated
    - Speech / hearing and swallowing evaluation and rehabilitation as clinically indicated
    - Smoking cessation and alcohol counselling as clinically indicated
    - Dental evaluation

References

1. NCCN Clinical Practice Guidelines in Oncology Head and Neck Cancers. Version 2.2019 National Comprehensive Cancer Network (NCCN), 2019

Chapter 8

Surveillance of oral cancers

Introduction

Surveillance of OC is a process of systematic, continuous collection, analysis, interpretation and dissemination of epidemiological information related to oral cancer for action on cases occurring in a particular geographic area. It provides information about the occurrence (incidence), locations (site / topography) and types (morphology / histology), extent of OC at the time of diagnosis (disease stage) and the kinds of treatment that patients receive.

Oral cancer surveillance system in Sri Lanka

The National Cancer Control Programme (NCCP) of Ministry of Health, conducts surveillance for OC and Oral Potentially Malignant Disorders (OPMD). The surveillance system for OC and OPMD starts at primary contact level.

In Sri Lanka, suspected OC and OPMD is detected at dental clinics. Dental clinics get cases from three mechanisms.

1. Referrals from Primary Health Care (PHC) staff or from others
2. Self-referral: People with suspected lesions come directly to the dental clinic
3. Opportunistic detection from patients who have come for other dental treatment

According to the General Circular No. 01- 54/2018, PHC staff are advised to identify high-risk individuals for OC and OPMD during their clinics/field visits and are advised to refer them to the nearest dental clinic[1,2]. Dental surgeons (DS) then detect and refer suspected OC and OPMD cases to the nearest Oral and Maxillofacial (OMF) centres for further management. In addition, some patients are managed in the private sector. Details of management and referral instructions of OPMDs are given in the *'National guidelines for management of Oral Potentially Malignant Disorders for Dental and Medical practitioners',* published by the NCCP[2]. Referral forms with feed-backs are available to refer high-risk individuals from PHC staff to the DSs and to refer suspected patients from Dental Surgeons to OMF units[1,2].

NCCP collects OPMD data from two settings; Hospital dental clinics and OMF clinics.
Hospital dental clinics record all suspected OC and OPMD cases in a separate register called *'Register for new patients with oral cancer and Oral Potentially Malignant Disorders'.* The total count of OC and OPMD are reported to the Regional Dental Surgeon (RDS) and to the Research and Surveillance Unit at Institute of Oral Health (IOH) Maharagama through the *'Monthly Report of Hospital Dental Clinics' (format H 1201).* Compiling all returns, the Research and Surveillance Unit of IOH, submit an annual summary of OPMD data to the Ministry of Health and this data is published in the Annual Health Bulletin.

To strengthen the monitoring system, NCCP has introduced a separate reporting system for OPMDs in 2019. Accordingly, dental clinics have to submit a detailed monthly report of suspected OC and OPMDs to the RDS. Based on monthly returns, RDS has to compile a quarterly return of OC and OPMD in the district and send to the NCCP. Moreover, it is expected to get a quarterly OPMD return from OMF clinics. Compiling all returns, NCCP plans to publish OPMD data in the proposed *'Annual report of National Cancer Control Programme'.*

The surveillance mechanism and data flow of OPMD is given in figure 8.1

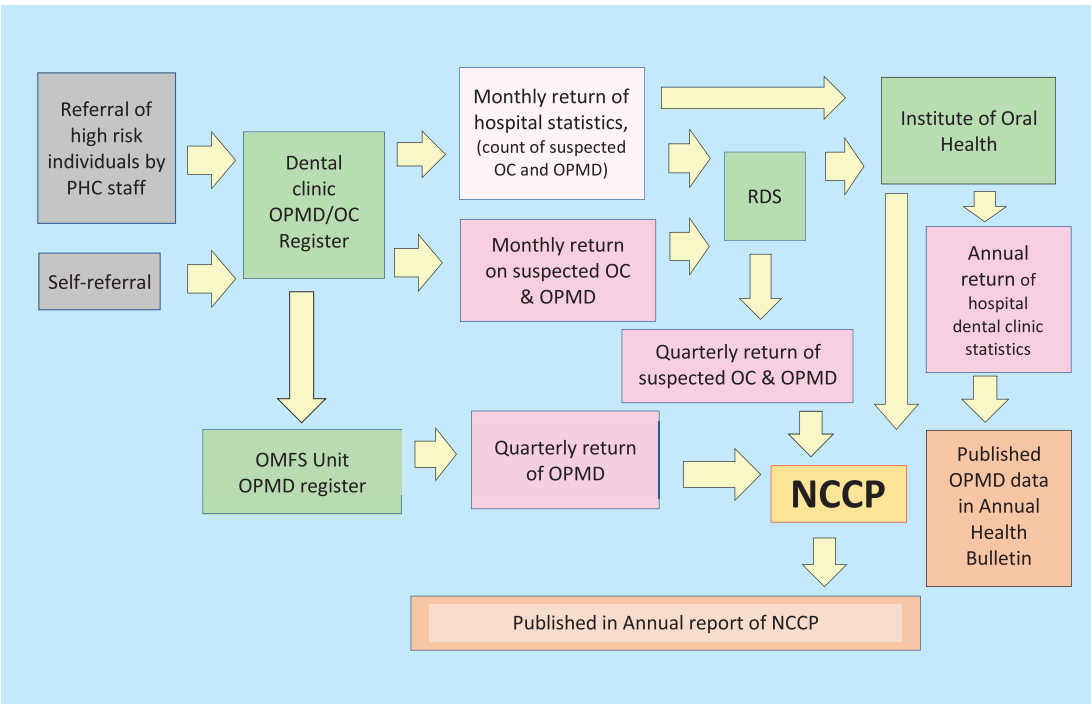


Figure 8.1: Flow chart for the surveillance system of OPMD

Oral Cancer surveillance data

The NCCP collects OC incidence data from three settings. Details of setting, relevant data forms, mode of abstraction and frequency of collection are given in the table 8.1.

Table 8.1 Points of data collection for surveillance of oral cancers

Setting	Data abstraction form	Mode of data abstraction	Frequency of receiving data to NCCP
Histopathology /Oral Pathology laboratory *(Point of diagnosis)*	Cancer Return Form 1 (H-1290)	By an identified officer; Medical Officer (MO), DS, Medical Laboratory Technician (MLT) or Development Officer (DO) of the laboratory under the supervision of the Consultant	Monthly
OMF Units of Secondary and Tertiary care hospitals *(Point of treatment)*	Annual Notification Form of Oral Cancer (H-1294)	By an identified officer: DS, Nursing Officer (NO) or DO under the supervision of the Consultant	Annually
Oncology clinics at the cancer treatment centers *(Point of treatment)*	National Cancer Surveillance Form (H-1256)	By a MO, NO or DO	At least 6 months after the registration at the oncology clinic

Instructions of completing the relevant data dorms are given in the booklet on *"Standard operating procedures for cancer registration"*, published by the NCCP[3]. Table 8.2 describes the key elements of information required for OC surveillance.

Table 8.2: Basic data items of the oral cancer incidence form in oral cancer surveillance

Variable	Remark
Reg. No/BHT No.	Patient registration No./Bed head ticket (BHT) No.
Patient details	
Name	Full name
Address	Patients' usual residential address (compulsory for the completion of data)
Sex	Male/ Female
Age	In years
NIC No.	National Identity Card number
Tumour details	
Incidence date	The most appropriate date can be mentioned as the incidence date • Date of first diagnosis of the cancer by a Surgeon. • Date of the first pathology report (the date of biopsy done). • If cancer is diagnosed during treatment for another illness, the appropriate incidence date is the date of diagnosis of cancer. If the above information is not available, other dates may be used. Date of first consultation or admission to a hospital/clinic/institution for the cancer in question
Site of Cancer (Topography)	Anatomical site with sub-sites. Example: left side of the Mandible. Primary site should be mentioned. Carefully review all clinical records and reports to identify the primary site
Primary or secondary	Record whether site of cancer is primary, secondary (metastatic) or unknown. In the case of multiple primaries, two separate rows should be filled for each cancer of the same patient
TNM Staging	Based on TNM classification At the time of diagnosis. Based on clinical examination and before any treatment
Histology (Morphology)	Exact histology type with behavior & differentiation

Deaths due to OC are collected through hospital Indoor Morbidity and Mortality Registers (IMMR) and vital registration system (compulsory registration of deaths). In addition, in Colombo district where first population-based cancer registry (PBCR) is commenced, cancer related death data are collected directly from divisional death registrars monthly. The data flow of oral cancer incidence and deaths is given in figure 8.2.

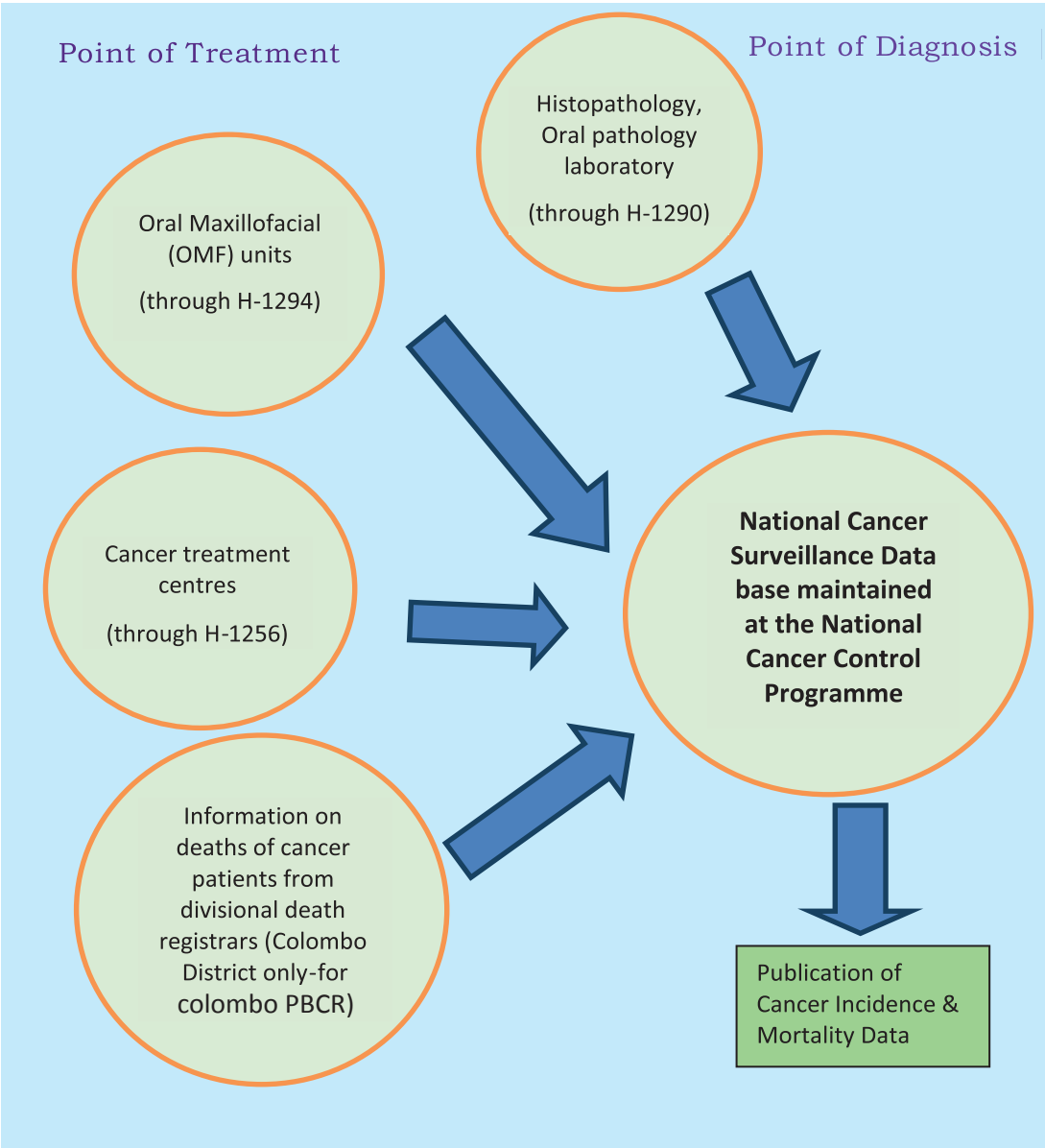


Figure 8.2: Data flow of oral cancer incidence and deaths to National Cancer Control Programme

Coding of oral cancers

ICD coding

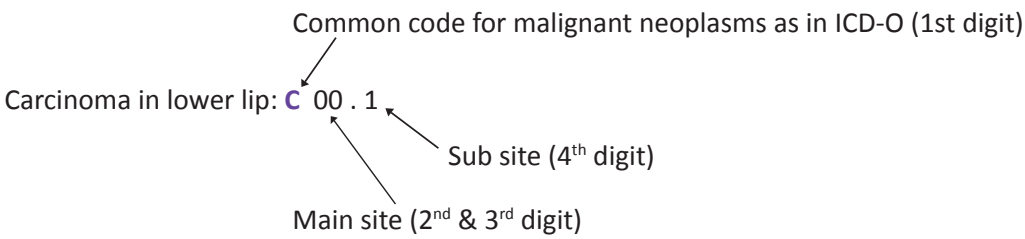
The International Classification of Diseases for Oncology (ICD-O) 3rd edition is used for coding the site (topography) and the histology (morphology) of cancers[4].

Coding will enable uniform classification of cancers necessary for clinical, epidemiological and research purposes.

The ICD-O coding system is a multi-axial classification of the site, morphology, behavior and grading of neoplasms.

Topography axis

Topography axis consists of four digit codes. This code indicates the point of origin of the tumour. This is the most important data item to be collected and it provides the main basis of tabulation of cancer incidence data. Example is given below.



Common ICD codes used for oral cancers are given in the table 8.3

Morphology axis

The morphology axis consists of 5 digit codes ranging from M-8000/0 to M-9989/3. The first four digits indicate the specific histological term (Tumour/cell type).

The fifth digit is after a slash is a behaviour code which indicate whether the tumuor is malignant, benign in-situ or uncertain.

Example: M-**8070** (Tumour/cell type) / **3** (Behaviour)

Common codes used for morphology are given in tables 8.4 to 8.5.

Table 8.3: ICD codes of main sites: Lip, oral cavity and pharynx (C00-C14)

Code	Main Site	Code	Main Site
C00	**Lip**		
C00.0	External upper lip, vermillion border of upper lip, upper lip, NOS (excludes skin)	C00.1	External lower lip, vermillion border of lower lip, lower lip, NOS (excludes skin)
C00.2	Vermillion border of lip, NOS	C00.3	Mucosa of upper lip (inner aspect & frenulum)
C00.4	Mucosa of lower lip (inner aspect & frenulum)	C00.5	Mucosa of lip, NOS (inner aspect & frenulum)
C00.6	Commissure of lip	C00.8	Overlapping lesion of lip
C00.9	Lip, NOS *(excludes skin of lip C44.0)*		
C01	**Base of the tongue**		
C01.9	Base of tongue NOS: Dorsal surface of base of tongue, posterior third of tongue, posterior tongue NOS, root of tongue		
C02.0	**Other and unspecified parts of tongue**		
C03	**Gum**		
C03.0	Upper gum: Maxillary gingiva, upper alveolar mucosa including ridge	C03.1	Lower gum: Maxillary gingiva, lower alveolar mucosa including ridge
C03.9	Gum NOS		
C04	**Floor of the mouth**		
C04.1	Anterior floor of mouth	C04.8	Overlapping lesions of floor of the mouth
C04.2	Lateral floor of the mouth	C04.9	Floor of the mouth, NOS
C05	**Palate**		
C05.0	Hard palate	C05.1	Soft palate, NOS (excludes nasopharyngeal surface of soft palate C11.3)
C05.2	Uvula	C05.8	Overlapping lesion of palate
C05.9	Palate, NOS		
C06	**Other and unspecified parts of mouth**		
C06.0	Cheek mucosa: buccal mucosa, internal cheek	C06.1	Vestibule of mouth: alveolar sulcus, buccal sulcus, labial sulcus
C06.2	Retromolar area: retromolar triangle, retromolar trigone	C06.8	Overlapping lesions of other and unspecified parts of the mouth
C06.9	Mouth, NOS: buccal cavity, oral cavity, oral mucosa, minor salivary glands, NOS.		
C07	**Parotid gland**		
C08	**Other and unspecified major salivary glands**		
C08.0	Submandibluar gland	C08.1	Sublingual gland
C08.8	Overlapping lesions of major salivary glands	C08.9	Major salivary glands, NOS
C09	**Tonsil**	**C10**	**Oropharynx**
C11	**Nasopharynx**	**C12**	**Pyriform sinus**
C13	**Hypopharynx**	**C14**	**Other and ill-defined sites in lip, oral cavity and pharynx**

Note: *NOS = Not otherwise specified*

Table 8.4: Codes of main histology types

Code	Main histological type
8000 -8005	Neoplasms NOS
8010 – 8046	Epithelial neoplasms NOS
8050 -8084	Squamous cell neoplasms
8090 - 8110	Basal cell neoplasms
8120 - 8131	Transitional cell papillomas and carcinomas
8140 - 8384	Adenomas & adenocarcinomas
8390 - 8420	Adenexal and skin appendage neoplasms
8430	Mucoepidermoid neoplasms
8440 - 8490	Cystic, mucinous and serous neoplasms
8500 – 8543	Ductal & lobular neoplasms
8550 - 8551	Acinar cell neoplasm
8560- 8576	Complex epithelial neoplasms
8580 - 8589	Thymic epithelial neoplasms
8590– 8671	Specialized gonadal neoplasms
8680- 8713	Paragangliomas and glomus tumours
8720 - 8790	Naevi and melanomas
8800 - 8806	Soft tissue tumours and sarcomas NOS
8810-8836	Fibromatous neoplasms
8840 - 8842	Myxomatous neoplasms
8850 -8881	Lipomatous neoplasms
8890-8921	Myomatous neoplasms
8930-8991	Complex mixed and stromal neoplasms
9000 - 9030	Fibroepithelial neoplasms
9040 - 9044	Synovial like neoplasms
9050 - 9055	Mesothelial neoplasms

Code	Main histological type
9060 -9091	Germ cell neoplasms
9100 - 9105	Trophoblastic neoplasms
9110	Mesonephormas
9120 - 9161	Blood vessel tumors
9170 - 9175	Lymphatic vessel tumours
9180 -9243	Oseous and chrondrmatous neoplasms
9250 -9252	Giant cell tumours
9260 -9262	Miscellaneous bone tumours
9270 - 9342	Odontogenic tumours
9350 -9373	Miscellaneous tumours
9380-9480	Gliomas
9490 - 9523	Neuroepitheliomatous neoplasms
9530 -9539	Menigiomas
9540 -9571	Nerve sheath tumours
9580 -9582	Granular cell tumours & alveolar soft part sarcomas
9590-9729	Hodgkin & Non Hodgkin Lymphomas
9731 - 9734	Plasma cell tumours
9740 - 9742	Mast cell tumours
9750 - 9758	Neoplasms of histiocytes and accessory lymphoid cells
9760 - 9769	Immunoproliferative diseases
9800 - 9948	Leukaemias
9950 - 9964	Chronic myeloproliferative disorders
9970 - 9975	Other haematologic disorders
9980 – 9989	Myelodysplastic syndrome

Behaviour type

Codes used for assessment of behavior are given in table 8.5

Table 8.5: Behaviour codes of tumours

Code	Behaviour type
0	Benign
1	Uncertain whether benign or malignant
2	Carcinoma in situ
3	Malignant
6	Metastatic site
9	Uncertain whether primary or metastatic site

A separate one-digit code (6th digit) is also provided for histological grading of tumour (differentiation) as shown in table 8.5

Table 8.6: Codes for differentiation of tumour

Code	Differentiation
1	Grade I – Well differentiated / differentiated not otherwise specified
2	Grade II – Moderately differentiated / moderately well differentiated / intermediate differentiation
3	Grade III – Poorly differentiated
4	Grade IV – Undifferentiated / anaplastic
9	Grade or differentiation not determined, not stated or not applicable

e.g. Poorly differentiated malignant Squamous cell carcinoma is coded as 8070/33

M-**8070** (Tumour/cell type) / **3** (Behaviour) **3** (differentiation)

Data entering, verification and duplicate checking

At the NCCP, the cancer incidence data obtained from pathology returns/reports, cancer patient clinic files and OMF units. Those dara are entered into the software for cancer registration named *'CanReg 5'*. This is an open-source software which is used to enter, store,

check and analyze cancer incidence data. This software also contains different modules for data entry, quality control, consistency checks and basic analysis of the data.

Analysis of cancer incidence data

OC incidence data are analyzed using *'CanReg 5'* and *SPSS* software. The main objective of data analysis is to provide a descriptive overview of the incidence including crude incidence rates (CR) and age standardized incidence rates (ASR). ASR are calculated using International Agency for Research on Cancer (IARC) standard population.

Dissemination of information

Oral cancer data is available in the report of *'National Cancer Incidence data'* published by the National Cancer Control Programme. These reports are available in printed format as well as available at: **http://www.nccp.health.gov.lk**

Confidentiality of cancer incidence data

Cancer is not a notifiable disease in Sri Lanka at the moment. Therefore, currently case reporting is based primarily on an administrative order issued by the Secretary of the Ministry of Health.

Confidentiality of all records is guaranteed. Information related to patient's identity is secured and not released or published. Although personal details of cancer patients are collected, it is known only to designated surveillance staff of the National Cancer Control Programme. Analysis of data is carried out by using a serial number given to each case during data entry. Access to the main data base is restricted to authorized officials only.

Patient's identification information is not allowed to use for any research, public presentation or publication without the permission of respective patients.

Data containing files both in printed format and electronic format are kept securely at the NCCP for 5 years after the publication of cancer incidence data and then disposed under strict supervision.

Limitations of existing oral cancer surveillance in Sri Lanka

It is estimated that current cancer surveillance in Sri Lanka provides more than 90% of oral cancers in Sri Lanka.

Even though pathology-based cancer surveillance has been initiated, still some pathological laboratories in the government sector and most of the pathology laboratories in the private sector are not sending monthly returns.

Generally, cancer patients who seek treatment from the private and Ayurveda sectors or from overseas are also not included.

Since cancer patients tend to use multiple treatment centers for the same cancer, duplicate entries is a common issue in cancer reporting data. Clearing duplicates by case-by case verification makes a delay in publishing cancer incidence data.

Since the existing cancer surveillance system is based on paper-based hospital records, there is no detailed information available on mode of treatment, medications given, follow-up visits, occurrence of complications etc. Therefore the available information is not adequate for planning treatment and allocation of resources. To overcome this, it is planned to introduce an electronic-based patient management information system (MIS) with Hospital Based cancer registries (HBCR).

Since HBCR do not provide generalizable survival status data, initiative has been made to develop population-based cancer registries (PBCR) in selected geographic areas to obtain best estimates of incidence, mortality and survival data.

References

1. Ministry of Health. General Circular 1-54/2018 Screening programme for Oral Potentially Malignant Disorders and early detection of oral cancer 2018. Available at: http://www.nccp.health.gov.lk

2. National Cancer Control Programme. National guidelines for management of Oral Potentially Malignant Disorders for Dental and Medical practitioners. 2019 National Cancer Control Programme. Available at: http://www.nccp.health.gov.lk

3. National Cancer Control Programme, Standard Operating Procedures for Cancer Registration in Sri Lanka 2019 Available at: http://www.nccp.health.gov.lk

4. World Health Organization, International classification of diseases for Oncology ICD-O, Editors April Fristz et.al. Third edition, World Health Organization Geneva 2000

Chapter 9

Annexures

Annexure I
Minimum data set – Histopathology

Habits:

Betel Chewing: ☐

Alcohol: ☐

Smoking: Beedi: ☐

Cigarette: ☐

Cigar: ☐

Treatment:

Clinical TNM stage: _____

Radiotherapy: ☐

Chemotherapy: ☐

Surgery: ☐

Multimodality: ☐

Adjuvant: ☐

Neoadjuvant: ☐

Incision ☐ Excision ☐

Location:.....

.....

Subsites:

Left ☐ Right ☐ Midline ☐

Upper ☐ Lower ☐

Type of resection:

Single ☐ Multiple ☐

Histological Type:.....

.....

.....

Depth of invasion:.....mm

Tumor invades into:

Corium ☐ Muscles ☐ Skin ☐

Subcutaneous tissue ☐ Bone ☐

Differentiation:

Early ☐ Moderate ☐

Well ☐ Poorly ☐

Invasive front:

Type I ☐ Type II ☐

Type III ☐ Type IV ☐

Host Response:

Minimal ☐ Moderate ☐

Light ☐ Dense ☐

Distance form tumor to mucosal margin:

Margin	Distance (in mm)
Anterior	
Posterior	
Medial	
Lateral	
Deep	
Superior	
Inferior	

Vascular Invasion ☐

Neural Invasion ☐

Bone Invasion ☐

Tumor induced stroma ☐

Abnormal mitosis ☐

Dysplasia at surgical margins:

Anterior ☐

Posterior ☐

Medial ☐

Lateral ☐

Deep ☐

Superior ☐

Inferior ☐

Right neck dissection:

Radical ☐

Modified ☐

Type I ☐

Type II ☐

Type III ☐

Selective ☐

Levels removed ☐

Number of nodes	Number of nodes positive	Capsular invasion	Extra capsular spread
Level I	Level I	Level I	Level I
Level II	Level II	Level II	Level II
Level III	Level III	Level III	Level III
Level IV	Level IV	Level IV	Level IV
Level V	Level V	Level V	Level V
Level VI	Level VI	Level VI	Level VI

Total number of nodes: ☐

Number of positive nodes: ☐

Pathological TNM: ☐

Left neck dissection:

Radical ☐

Modified ☐

Type I ☐

Type II ☐

Type III ☐

Selective ☐

Levels removed ☐

Number of nodes	Number of nodes positive	Capsular invasion	Extra capsular spread
Level I	Level I	Level I	Level I
Level II	Level II	Level II	Level II
Level III	Level III	Level III	Level III
Level IV	Level IV	Level IV	Level IV
Level V	Level V	Level V	Level V
Level VI	Level VI	Level VI	Level VI

Total number of nodes: ☐

Number of positive nodes: ☐

Pathological TNM: ☐

Annexure II
Biopsy request form

Centre for Head and Neck Pathology Telephone: 081-2397432/3	Path No: ..... PR No: ..... (Office use only)

Patient's name: ..... Date of surgery: .....

Age: ..... Gender: M F Referring clinician: .....

BHT / Case: ..... Race: S T M O Clinic: .....

Patient's Address: ..... Name of hospital: .....

....

Habits: Betel chewing Duration: .....

Smoking Duration: ..... Signature: .....

Alcohol Duration: ..... Present biopsy: Excision: ..... Incision: .....

Previous biopsy: Y N Diagnosis: ..... Path No: .....
(Incision/Excision)

Is this a recurrence: Yes ☐ No ☐ If yes, date of the 1st excision: .....

Site: ..... (Please mark the biopsy site on the diagram) Size: .....cm x .....cm

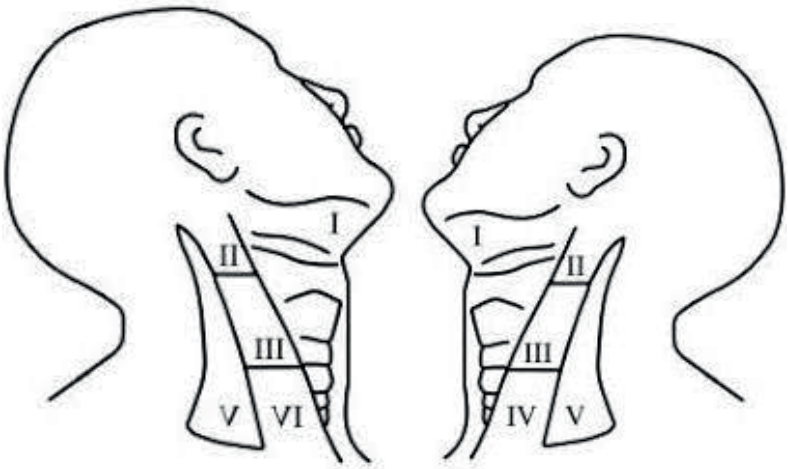
TNM stage: .....

Pretreatment: Radiotherapy ☐ Chemotherapy ☐

History and Clinical features: .....

.....

Right Left Type of neck dissection
(Please mark on the diagram)



1. Radical ☐
2. Modified
   a. Type I ☐
   b. Type II ☐
   c. Type III ☐
3. Selective: ……

Method of reconstruction: ……

Annexure III
Register for Oral cancer Incidence data

Name of the OMF surgeon:…… Year/ month:……

BHT/ Reg.no	Patient's details					Tumour details						Treatment done
	Name	Age/sex	NIC. NO	Address	Referred by / Ref. No.	Date of Incidence	Site	Primary/ Secondary/ Unknown	Details of Diagnosis / Histology / Morphology	TNM	Stage	

Notes

Notes

Notes

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