

Department of Health Research
Ministry of Health and Family Welfare, Government of India



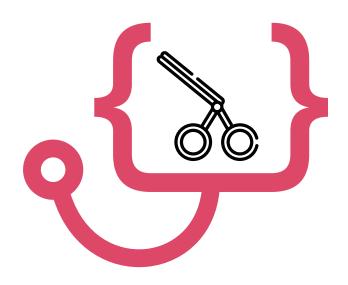




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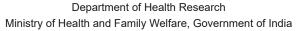






STANDARD TREATMENT WORKFLOWS of India







These STWs have been prepared by national experts of India with feasibility considerations for various levels of healthcare system in the country. These broad guidelines are advisory, and are based on expert opinions and available scientific evidence. There may be variations in the management of an individual patient based on his/her specific condition, as decided by the treating physician. There will be no indemnity for direct or indirect consequences. Kindly visit our web portal (stw.icmr.org.in) for more information.

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- SPECIALITIES COVERED IN THIS EDITION

- Oncology

Breast Cancer Lung Cancer Oral and Lip Cance





INTRODUCTION

GOAL

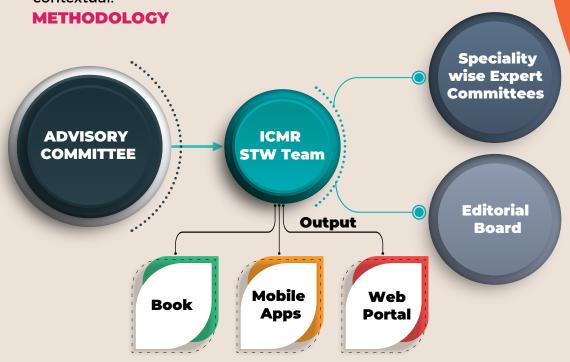
To empower the primary, secondary and tertiary health care physicians/surgeons towards achieving the overall goal of Universal Health Coverage with disease management protocols and pre-defined referral mechanisms by decoding complex guidelines.

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OBJECTIVES

To formulate treatment algorithms for common and serious medical & surgical conditions for both outdoor & indoor patient management at primary, secondary and tertiary levels of India's healthcare system that are scientific, robust and locally contextual.



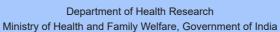
PROCESS OVERVIEW





ONCOLOGY





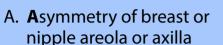


Standard Treatment Workflow (STW) for

BREAST CANCER

ICD-10-C 50

SYMPTOMS



- B. Breast lump, bulge, blood vessels prominent
- C. **C**olour change of skin or nipple areola
- D. **D**eformed breast / nipple areola (nipple retraction), dimpling of skin, Discharge from nipple, **D**irect spread-skin (satellite nodule, ulcer, skin oedema), chest wall Distant spread - headache,

jaundice, dyspnoea, bone

pains, ascites







Evaluation and management by multidisciplinary team (MDT) of oncology experts

SIGNS

A Breast changes

- · Asymmetry in shape/size of breast or nipple areola complex
- · Breast lump
- Nipple retraction/ulcer
- · Change in skin puckering, dimpling, thickening, ulcer, redness, edema & satellite nodules
- · Fixity to underlying muscles or chest wall

B Lymph node

- · lymph node(s) in axilla or supra-clavicular fossa
- C Systemic changes
- · Enlarged liver, ascites, bony tenderness, dyspnoea, pleural effusion

WORK UP OF A PATIENT WITH SUSPECTED BREAST CANCER- TRIPLE ASSESSMENT

CLINICAL BREAST EXAMINATION

IMAGING

- · Bilateral mammogram: for women >30 years
- · Ultrasound: breast and axilla
- · MRI breast in selected cases STAGING- TI, T2 No N1 Upto Stage 2A no metastatic work up Stage 2B upwards
- · Chest radiograph
- · Ultrasound whole abdomen
- · Bone scan
- · CECT chest and abdomen
- · PET-CT (optional)

PATHOLOGY

- · Core needle biopsy (preferred) for type, grade, ER, PR, HER2/neu, Ki-67
- · FISH test if HER-2/neu on IHC-2+/ equivocal

DO NOT

- · Ignore any lump or changes in breast & nipple areola complex
- Perform excision biopsy for diagnosis
- Perform FNAC or core needle biopsy before imaging.

MULTIDISCIPLINARY CARE

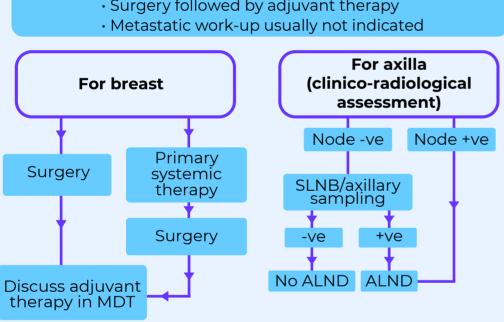
MANAGEMENT OF BREAST CANCER

Triple assessment (CBE, USG breast and axilla, mammography and core biopsy

EARLY BREAST CANCER

T1, T2, N0, N1, M0

· Surgery followed by adjuvant therapy



ADJUVANT THERAPY (AT)

Chemotherapy

· Consider for all patients with pT > 1 cm or node positive disease based on ER/PR/HER2/Ki-67

Radiotherapy

- After breast conservation surgery
- · After mastectomy with node-positive disease or pathological T3/T4

Targeted therapy

- · All HER-2/neu positive (3+) or FISH HER-2 amplified patients should receive trastuzumab for 12 months
- · Shorter schedules: 9 weeks to 6 months acceptable in some patients

Hormone therapy

- All ER and /or PR positive cases
- · For premenopausal women tamoxifen and for post menopausal women tamoxifen or aromatase inhibitors are appropriate
- · Minimum for 5 years, if high risk of recurrence like node positive, consider for up to 10 years
- · If AT is used zolendronic acid or other bisphosphonates can be added

ADVANCED BREAST CANCER

T3, T4, any N Any T, N2, N3

Metastatic work up: Chest X-ray, ultrasound abdomen, bone scan

OR CECT thorax abdomen, bone scan OR PET-CECT whole body

No metastasis

Locally Advanced Breast Cancer

Intent of treatment: curative

Neoadiuvant systemic therapy

Discuss extent of surgery MRM or Breast conservation surgery

Adjuvant systemic treatment therapy +RT surgery

Yes metastasis

Metastatic Breast Cancer

Intent of treatment: palliative care

Consider hormone therapy chemotherapy targeted therapy as clinically indicated

Treatment of metastatic breast cancer

Chemotherapy Consider - Anthracyclines taxanes, platinum, capecitabine, cyclophosphamide,

methotrexate, etc.

· Sequential single agents preferred over combinations when possible

Hormonal therapy

- · Consider tamoxifen, aromatase inhibitors, fulvestrant, megesterol acetate, CDK 4/6 inhibitors, everolimus
- · Ovarian suppression indicated in premenopausal MBC patients, which can be surgical (bilateral oophorectomy) or radiotherapeutic (ovarian radiation) or medical (GnRH analogues)

HER2 targeted therapy

· Consider - trastuzumab, lapatinib, pertuzumab, add trastuzumab-emtansine

Bone targeted therapy

· All patients with bone metastases should receive a bone modifying agent (e.g zoledronic acid) 4-12 weekly

Role of surgery

- It is indicated only for palliation of local tumour symptoms bleeding, fungation, etc
- · Insert intercostal drainage tube for malignant pleural effusion and chemical pleurodesis with talcum powder or bleomycin

Role of radiotherapy

- · Most effective method for pain relief in bone metastasis
- · Is routinely used for brain metastasis: Hemostatic RT used for bleeding ulcer

Pain control and palliative care

ABBREVIATIONS

HER2: Human epidermal growth factor receptor 2

ALND: Axillary lymph node dissection **CECT:** Contrast-enhanced computed tomography **ER/PR:** Estrogen receptor/Progesterone receptor FISH: Fluorescence in situ hybridization

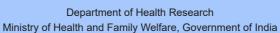
IHC: Immunohistochemistry **MBC:** Metastatic breast cancer **PET-CT:** Positron emission tomographycomputed tomography scan **RT:** Radiotherapy

SLNB: Sentinel lymph node biopsy

● ENHANCE AWARENESS AND EARLY DETECTION OF BREAST CANCER BY SCREENING AS PER NATIONAL PROGRAMME

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Standard Treatment Workflow (STW)

LUNG CANCER

ICD-10-C34.90

Evaluation and management by multidisciplinary team (MDT) of oncology experts



PRESENTATION

- · Cough
- · Chest pain
- Hemoptysis Hoarseness
- Breathlessness
- Non resolving pneumonia
- Mass lesion Symptoms persist even after treating pneumonia

IMPORTANT ASSESSMENT PARAMETERS

Pulmonary function

Age and comorbidities

Performance status

DIAGNOSTIC

CONFIRMATON

Clinical examination:

- · Palpable lymph nodes
- · Chest wall tenderness
- · Skeletal tenderness
- Pleural effusion

INITIAL EVALUATION

CXR

Sputum cytology

- Pulmonary reserve:
- Effort tolerance Walk test
- Pulmonary function tests (PFT)

ADVANCED DISEASE

- Pleural fluid cytology
- Pleural biopsy (image guidance if available)
- Cervical lymph node aspiration cytology / biopsy

All lung shadows are not tuberculosis! Obtain diagnostic investigations before starting empirical ATT!

PATHOLOGY ASSESSMENT

Biopsy/ cell block/ smear

by bronchoscopy

Histopathology

ROS-1

adenocarcinoma, squamous carcinoma, poorly differentiated carcinoma, small cell carcinoma

LIMITED DISEASE

percutaneously by image guidance or

· CECT thorax and upper abdomen

Obtain tissue for diagnosis

Immunohistochemistry

TTF 1, p40, synaptophysin/ chromogranin

analysis Molecular tests for adenocarcinoma: EGFR, ALK,

Preserve tissue for molecular

SMALL CELL LUNG CARCINOMA

Do CECT thorax and abdomen

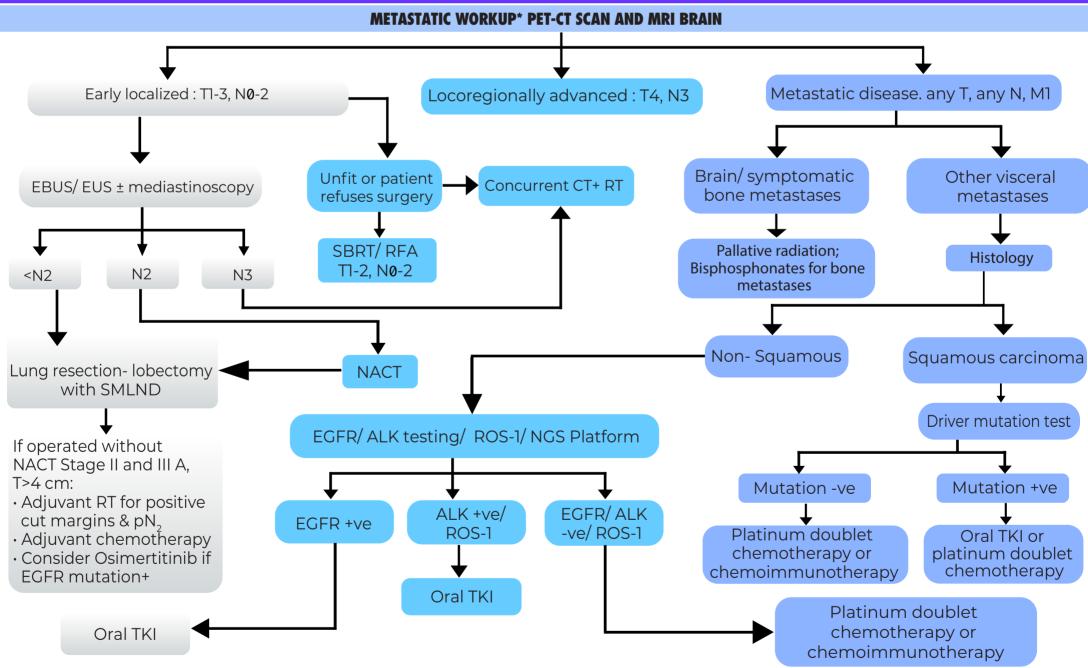
- Non metastatic disease TI-4, N0-3, M0
 - · Metastatic work up: PET CT & MRI brain
 - · Consider surgery for TI-2, No
 - · Concurrent CT + RT
- Metastatic disease Any T, any N, M1
- Prophylactic cranial irradiation
- · Symptomatic & supportive care Palliative chemotherapy carboplatin + etoposide

NON SMALL CELL LUNG CARCINOMA

Do CECT thorax and abdomen

- Non metastatic disease: □-4, №-3
- · Metastatic work up: PET CT and MRI brain
- Metastatic disease: Any T, any N, M1
 - · Symptomatic & supportive care
 - · Refer to oncology centre
- · Palliative chemotherapy (platinum doublet in fit patients, single agent chemotherapy for PS 2)
- · Oral TKI if target mutation detected
- · Immunotherapy may be an option in some patients

MANAGEMENT OF NSCLC



AVAILABLE TREATMENT OPTIONS

- · Chemotherapy doublet:
 - · Carboplatin or cisplatin with pemetrexed or paclitaxel or gemcitabine or etoposide
- · EGFR mutation positive: gefitinib, afatinib, osimertinib, erlotinib, dacomitinib
- · Immune checkpoint inhibitors: nivolumab, atezolizumab,
- pembrolizumab, ipilimumab

- Radiotherapy
- · Pain management
- · Opioids: morphine, tramadol, oxycodone
- · Paracetamol, nonsteroidal anti-inflammatory drugs Cough suppressants

PALLIATIVE CARE

- Treatment of chronic obstructive pulmonary disease
- · Treatment of anemia, anorexia, electrolyte abnormalities

TKI: Tyrosine kinase inhibitors

SMLND: Systematic lymph node dissection

T, N, M: Tumour (T), Nodes (N), and Metastases (M)

ABBREVIATIONS

ALK: Anaplastic lymphoma kinase

ATT: Anti tubercular therapy

CECT: Contrast-enhanced computed tomography

COPD: Chronic obstructive pulmonary disease

CT: Computed tomography **CXR:** Chest X Ray

- **EBUS:** Endobronchial ultrasound
- **EGFR:** Epidermal growth factor receptor **NACT:** Neoadjuvant chemotherapy
- **NGS:** Next generation sequencing
- **NSCLC:** Non-small cell lung cancer

PET CT: Positron emission tomography

- **PFT:** Pulmonary function test
 - pN2: Pathological node
 - **RFA:** Radiofrequency ablation
 - **ROS:** Ros proto-oncogene 1
 - **RT:** Radiotherapy **SBRT:** Stereotactic body radiotherapy

KEEP A HIGH THRESHOLD FOR INVASIVE PROCEDURES.

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Standard Treatment Workflow (STW)

LIP AND ORAL CANCER

ICD-10-C 06.9



Tobacco

Alcohol

Areca nut

Sharp tooth

• III-fitting dentures



Non healing ulcer/sore in the mouth especially in a tobacco chewer or smoker

Neck mass

Difficulty in opening mouth

> Difficulty in protrusion of tongue

Pain referred to ear

> Oral premalignant disorders (OPMD): leukoplakia/ erythroplakia/sub mucous fibrosis, lichen planus

Screening can detect OPMD and invasive cancer early and improve outcome. Treatment of oral cancer is ideally delivered by a multidisciplinary team(MDT)

EVALUATION

- Clinical examination, +/- examination under anaesthesia (EUA), assess pain, nutritional status, & oro-dental hygiene
- · USG neck / CT scan head & neck
- · Evaluate upper aerodigestive tract for second primary
- · Biopsy from primary site, FNAC from neck node
- · CBC, LFT, RFT, blood sugar, chest X-ray,
- · Tobacco cessation for patient and care givers
- Pure tone audiometry (PTA)
- · Speech and swallowing assessment
- · Define clinical and radiological staging, goals of treatment

TREATMENT

T1 T2, NO CANCER

OPTIONS WITH CURATIVE INTENT

Initial surgery **preferred** (wide excision with 1 cm margins & supra-omohyoid neck dissection (Level I - III) with reconstruction OR

Radical radiation therapy

T3 T4A, NO N1 N2

OPTIONS WITH CURATIVE INTENT

Initial surgery: wide excision with 1 cm margins + comprehensive neck dissection and reconstruction OR

Chemoradiation

OR

Neo-adjuvant CT followed by surgery

T4B N3 (TONGUE AND BUCCAL CANCERS WITH SKULL BASE/ INTERNAL CAROTID ARTERY INVOLVEMENT

AIM OF TREATMENT IS PALLIATION

- Palliative chemotherapy
- RT
- Immunotherapy
- Best supportive care

INDICATIONS FOR ADJUVANT RT

Close margin, positive node(s), or presence of any two of following: LVI, PNI, high grade

INDICATIONS FOR ADJUVANT CT-RT:

Metastatic nodes with extracapsular extension, involved margins

THE DRUG OF CHOICE FOR CONCURRENT CHEMOTHERAPY IS CISPLATIN

Adjuvant radiation

The minimum post-operative radiation dose is 60 Gy/ 6 weeks/ 30# or equivalent to the primary and nodal areas using conventional treatment planning, **3DCRT or IMRT**

Radical radiation

66-70 Gy is delivered using conventional planning / 3DCRT/IMRT through a telecobalt machine or a LINAC at 1.8 to 2 Gy per fraction over 7-8 weeks (or a biologically equivalent dose) with adequate margins all around the lesion and including level I, II and III nodes



Large SCC lower Lip



Intraoperative image following tumor excision





Postoperative results following reconstruction

FOLLOW UP

Follow up: 3 monthly for the first 3 years, 6 monthly for years 4 & 5 and annually thereafter with clinical examination at every visit, evaluation of symptoms as they present and endoscopy of the upper aerodigestive tract annually

To identify recurrences and second primary cancers

Treatment of common side effects - xerostomia, speech and swallowing issues, nutrition and physical rehabilitation, dental care should be looked after by the members of multidisciplinary team

Emphasize tobacco cessation for patients

- Set a quit date, tell your family
- Remove tobacco / cigarettes from your home, car, and work
- Tobacco withdrawal symptoms:
 - Trouble sleeping
 - Feeling irritable, anxious, or restless
 - Getting frustrated or angry
 - Having trouble thinking clearly
- Counsellor's help is available to deal with the cravings and triggers
- · Can combine nicotine replacement with or ± bupropion

ABBREVIATIONS

CBC: Complete blood count

CT: Chemotherapy

EUA: Examination under anaesthesia

FNAC: Fine needle aspiration cytology

IMRT: Intensity-modulated radiation therapy

LFT: Liver function tests

LVI: Lymphovascular invasion

MDT: Multidisciplinary team

OPMD: Oculopharyngeal muscular dystrophy

PNI: Perineural invasion

PTA: Pure tone audiometry **RFT:** Renal function tests

RT: Radiotherapy

USG: Ultrasound sonography test

PREVENT ORAL CANCER BY TOBACCO CONTROL

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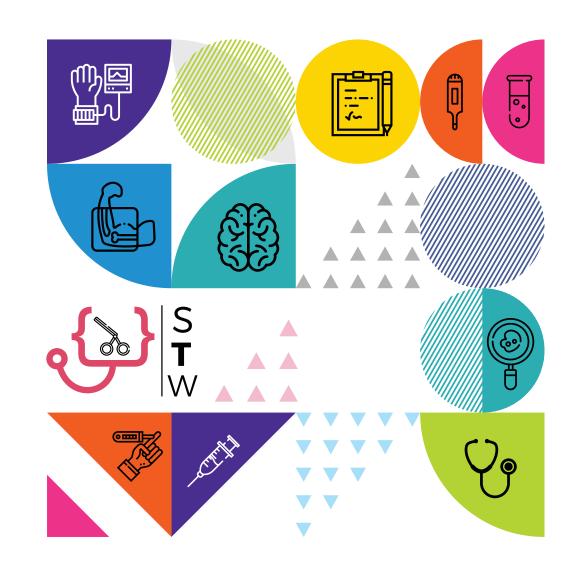


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