

Protocol for the Examination of Specimens from Patients with Cancers of the Nasal Cavity and Paranasal Sinuses

Protocol applies to carcinoma of the nasal cavity and paranasal sinuses, including squamous cell carcinoma, neuroendocrine carcinoma, minor salivary gland carcinoma, and mucosal melanoma. This protocol does not apply to olfactory neuroblastoma, lymphoma, or sarcoma.

Based on:

AJCC/UICC TNM, 8th edition
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This protocol is revised to the 8th edition of the AJCC Cancer Staging Manual and the current version of the CAP Cancer Protocol NasalCavityParanasalSinus 4.0.0.1.

Procedures Covered in this Protocol:

- Excision
- Partial maxillectomy
- Radical maxillectomy
- Neck (lymph node) dissection

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**AAPA Macroscopic Examination Guidelines:
Utilization of the CAP Cancer Protocols at the Surgical Gross Bench**

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The purpose of the Protocols is to support Laboratory Personnel engaged in the macroscopic examination of cancer resection specimens. The Protocols are based on specified relevant source documents, drafted by pathologists' assistant experts, and supported by information provided by the College of American Pathologists (CAP) and the American Joint Committee on Cancer (AJCC). These Protocols are intended to serve patients by ensuring that the macroscopic examination of cancer resection specimens is compliant with CAP Cancer Protocols, the AJCC Cancer Staging Manual, and provide optimization of the pre-analytic steps necessary to promote appropriate molecular studies.

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Molecular Considerations:

There is increasing evidence that human papillomavirus (HPV), particularly the high-risk type 16 (HPV-16), plays a pathogenic role in a subset of head and neck cancers, termed HPV-associated head and neck squamous cell carcinoma (HPV-HNSCC). Present in most oropharyngeal carcinomas, positivity for high risk HPV16 is detected in 93% of cases. These carcinomas arise predominantly from the palatine and lingual tonsils of the oropharynx (i.e., tonsil or base of tongue) and are non-keratinizing carcinomas characterized by a basaloid cell type. Initial presentation may include metastatic cancer to a cervical neck lymph node from an unknown primary site. Among the methods of detecting HPV16, polymerase chain reaction (PCR), in-situ hybridization (ISH) and a p16 immunohistochemical stain may all be utilized, however these techniques are considered investigative at this time and not required.

Immunohistochemistry Considerations:

For mucosal melanoma biopsies, immunohistochemical stains to isolate its categorization may include HMB-45, S-100 and Melan-A.

These tests can be performed on formalin fixed paraffin embedded tissue sections. The macroscopic description should provide the fixative used. 10% neutral buffered formalin is the preferred fixative. It is recommended that the duration of fixation be provided as well.

PROCEDURES AND GENERAL ANATOMIC CONSIDERATIONS:

■ **Procedures Covered by this Protocol:**

- Excision
- Partial maxillectomy
- Radical maxillectomy
- Neck (lymph node) dissection
- Other (specify)

■ **Specimen Size and Extent of Resection:**

- Provide three dimensions; (when oriented, specimen dimensions should be specified e.g., anterior to posterior, medial to lateral, superior to inferior).
 - Maxilla (partial or total)
 - Nasal cavity
 - Nasal septum
 - Floor
 - Lateral wall
 - Vestibule
 - Paranasal sinuses (maxillary, ethmoid, frontal, sphenoid)
- List any adjacent structures and provide sizes of each.

■ **Specimen Integrity and Adequacy:**

Provide an assessment of the specimen integrity. Identify and describe any defects or disruptions. *

**Statements should include the location of any defects in relation to surrounding anatomical structures and the tumor. Disruptions of margins must also be noted. Surgical disruptions should be differentiated from tumor breach by consultation with the surgeon and pathologist. The defect may need to be specifically identified and applied with ink. It may be critical to determine the breach of a particular margin, especially if such a margin constitutes an increase in staging. For example, destruction or erosion into the hard palate would constitute a pT2 lesion for maxillary sinus tumors.*

TUMOR ("T" of TNM)

■ Tumor Size:

- Three dimensions measured; (when oriented, anatomic dimensions should be specified, e.g., anterior to posterior, medial to lateral, superior to inferior).
- If multiple tumors are present, provide dimensions of each or a range of sizes.

■ Tumor Description:

- Polypoid
- Exophytic
- Endophytic
- Ulcerated
- Sessile

Note: These descriptors are not all encompassing, and any and all appropriate macroscopic descriptive terms should be used (i.e., solid/cystic, verrucoid).

■ Tumor Site(s):

- Nasal septum (specify laterality)
 - Septum
 - Floor
 - Lateral wall
 - Vestibule
- Paranasal sinuses (specify laterality)
 - Maxillary, divided diagonally by Ohngren's line
 - Suprastructure (posterosuperior)
 - Infrastructure (anteroinferior)
 - Ethmoid
 - Frontal
 - Sphenoid
- Other (specify):

■ Tumor Laterality:

- Right
- Left
- Midline

■ Tumor Focality:

- Specify if tumor is unifocal or multifocal.

■ **Tumor Depth of Invasion and Relationship to Attached Organs / Structures:** * (Figure 1)

Definition of Primary Tumor (pT)

Maxillary Sinus

pT Category	pT Criteria
pTX	Primary tumor cannot be assessed
pTis	Carcinoma <i>in situ</i>
pT1	Tumor limited to maxillary sinus mucosa with no erosion or destruction of bone
pT2	Tumor causing bone erosion or destruction including extension into the hard palate and/or middle nasal meatus, except extension to posterior wall of maxillary sinus and pterygoid plates
pT3	Tumor invades any of the following: bone of the posterior wall of maxillary sinus, subcutaneous tissues, floor or medial wall of orbit, pterygoid fossa, ethmoid sinuses
pT4	Moderately advanced or very advanced local disease
pT4a	Moderately advanced local disease. Tumor invades anterior orbital contents, skin of cheek, pterygoid plates, infratemporal fossa, cribriform plate, sphenoid or frontal sinuses
pT4b	Very advanced local disease. Tumor invades any of the following: orbital apex, dura, brain, middle cranial fossa, cranial nerves other than maxillary division of trigeminal nerve (V2), nasopharynx, or clivus

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Nasal Cavity and Ethmoid Sinus

pT Category	pT Criteria
pTX	Primary tumor cannot be assessed
pTis	Carcinoma <i>in situ</i>
pT1	Tumor restricted to any one subsite, with or without bony invasion
pT2	Tumor invading two subsites in a single region or extending to involve an adjacent region within the nasoethmoidal complex, with or without bony invasion
pT3	Tumor extends to invade the medial wall or floor of the orbit, maxillary sinus, palate, or cribriform plate
pT4	Moderately advanced or very advanced local disease
pT4a	Moderately advanced local disease. Tumor invades any of the following: anterior orbital contents, skin of nose or cheek, minimal extension to anterior cranial fossa, pterygoid plates, sphenoid or frontal sinuses
pT4b	Very advanced local disease. Tumor invades any of the following: orbital apex, dura, brain, middle cranial fossa, cranial nerves other than maxillary division of trigeminal nerve (V2), nasopharynx, or clivus

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*The most significant prognostic factor is the status of cervical lymph nodes and to a lesser but nonetheless important extent, perineural invasion, which, independent of nerve diameter, is a reliable predictor of local recurrence.

TNM Classification for Mucosal Melanoma:

Mucosal melanoma is an aggressive neoplasm that calls for separate consideration. Approximately two-thirds of these lesions arise in the nasal cavity and paranasal sinuses; one quarter are found in the oral cavity and the remainder occur only sporadically in other mucosal sites of the head and neck. Even small melanomas behave aggressively with advanced initial presentation, high rates of recurrence and high mortality rates. To reflect this aggressive behavior, primary melanomas limited to the mucosa are considered T3 lesions.

Definition of Primary Tumor (pT)

pT Category	pT Criteria
pT3	Tumor limited to the mucosa and immediately underlying soft tissue, regardless of thickness or greatest dimension; for example, polypoid nasal disease, pigmented or nonpigmented lesions of the oral cavity, pharynx, or larynx
pT4	Moderately advanced or very advanced disease
pT4a	Moderately advanced disease. Tumor involving deep soft tissue, cartilage, bone, or overlying skin
pT4b	Very advanced disease. Tumor involving brain, dura, skull base, lower cranial nerves (IX, X, XI, XII), masticator space, carotid artery, prevertebral space, or mediastinal structures

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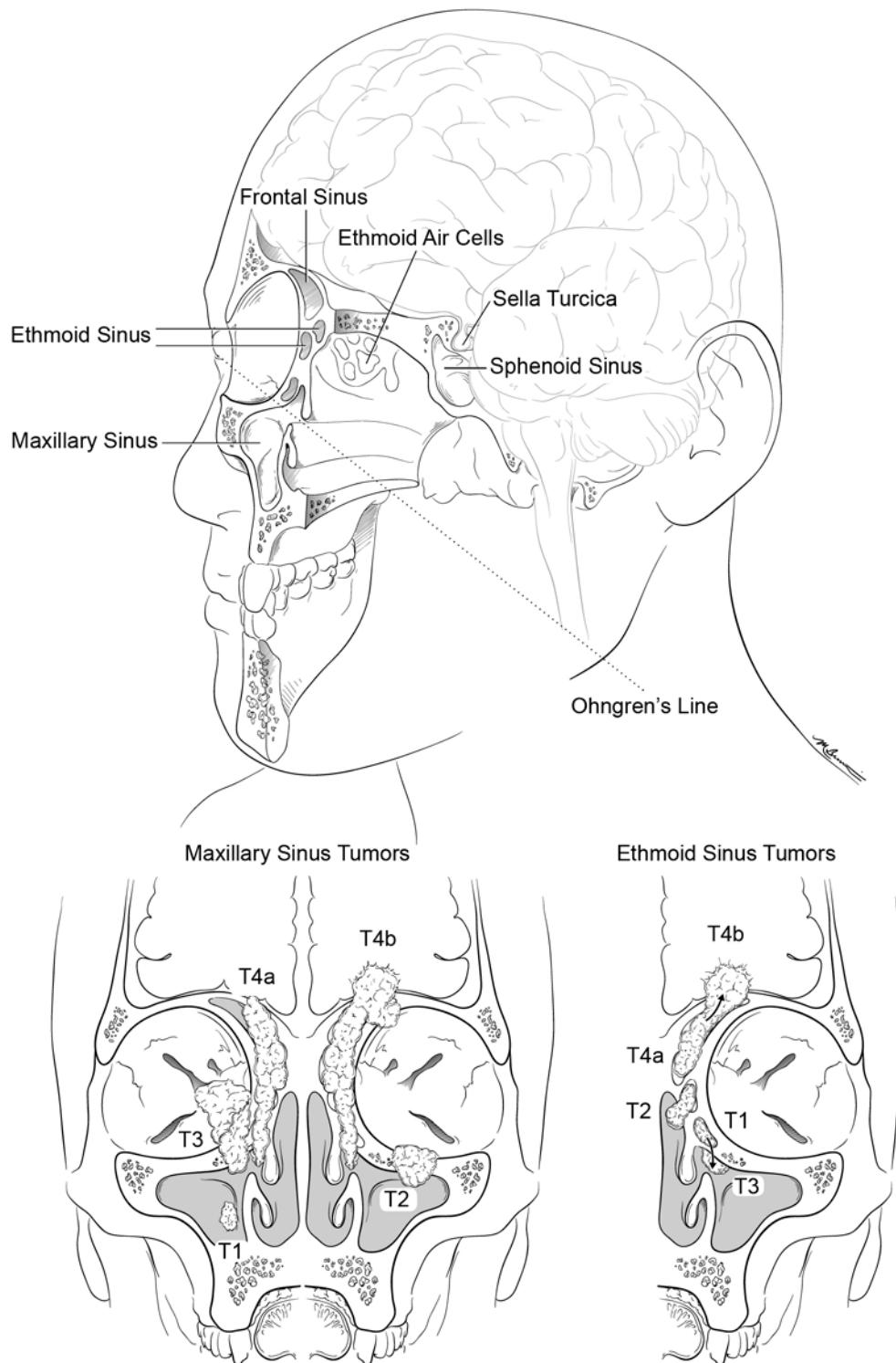


Figure 1: Nasal Cavity Paranasal Sinuses - T1-T4 Criteria

TNM Descriptors:

For identification of special cases of TNM or pTNM classifications, the “m” suffix and “y” and “r” prefixes are used. Although they do not affect the stage grouping, they indicate cases needing separate analysis.

The “m” suffix indicates the presence of multiple primary tumors in a single site and is recorded in parentheses: pT(m)NM.

The “y” prefix indicates those cases in which classification is performed during or following initial multimodality therapy (i.e., neoadjuvant chemotherapy, radiation therapy, or both chemotherapy and radiation therapy). The cTNM or pTNM category is identified by a “y” prefix. The ycTNM or ypTNM categorizes the extent of tumor actually present at the time of that examination. The “y” categorization is not an estimate of tumor prior to multimodality therapy (i.e., before initiation of neoadjuvant therapy).

The “r” prefix indicates a recurrent tumor when staged after a documented disease-free interval and is identified by the “r” prefix: rTNM.

Residual Tumor (R) Category

The absence or presence of residual tumor at the primary tumor site after treatment is denoted by the symbol R. The R categories for the primary tumor site are as follows:

R	R Definition
RX	Presence of residual tumor cannot be assessed
R0	No residual tumor
R1	Microscopic residual tumor
R2	Macroscopic residual tumor at the primary cancer site or regional nodal sites

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■ **Margins:**

- Specify if margins are involved or uninvolved by tumor.
 - If margins are involved by tumor, specify the margin, per orientation.*
 - If margins are uninvolved by tumor, specify the location of the closest margin, per orientation.
 - Specify the distance from the closest margin in mm.
- Margins are in large part guided by frozen section. (These margins are often separately submitted by the surgeon; see * below regarding piecemeal resection.)
- Apply ink to the soft tissue margins and take mucosal and soft tissue margin sections.
- Margins should be evaluated by either shave or radial (perpendicular) sections, depending on the nature of the specimen.
 - If the tumor is relatively distant from a margin, 1 to 2 mm shave sections may be taken, however, radial (perpendicular) sections are preferred.*
 - If the tumor approximates a margin to < 1 to 2 mm, radial (perpendicular) sections are taken.

**It is recommended to take radial (perpendicular) margins whenever possible, even when margins are distant from the tumor. With this technique, the distance to occult tumor or dysplasia, if present, can still be measured. Bone margins may be taken en face, and if applicable, the gingival margin close to bone/tooth must be scraped or shaved off and then can only be submitted en face.*

Reporting of surgical margins should include information regarding the distance of invasive carcinoma, carcinoma in situ, or high-grade dysplasia (moderate to severe) from the surgical margin. Microscopic closeness of less than 5 mm from the surgical border should be noted in the report, as tumor presence within 5 mm of the surgical border carries a significant risk for subsequent local recurrence and constitutes a positive margin.

*Complex intact specimens should be examined and oriented with the assistance of the attending surgeon(s). Direct communication between the surgeon and pathologist is a critical component in specimen orientation and proper sectioning. For multipart, piecemeal endoscopic resections, specimens should be clearly and accurately labeled and specifically designated as margin, if they are indeed true margins. Parts that are margins should be designated explicitly as such. Whenever possible, the surgical pathology requisition should include a drawing or photograph of the resected specimen showing the extent of the tumor and its relation to the anatomic structures of the region.

■ **Explanatory note:**

Assessment of surgical margins within head and neck continues to be controversial with inconsistency in terms of what is considered a “close” margin. While the oral cavity allows a clearance of just 1 mm, the maxilla requires 5 mm. Difficulty in predicting local recurrence lies in surgical margin adequacy, both in terms of resection and tissue submission. Consequently, the grosser should accurately and precisely measure and report the distance to margins since there is no agreed upon definition of a close margin.

For mucosal melanoma, its highly aggressive nature and advanced progression at the time of diagnosis is reflected in its high T score for mucosal disease without immediately identified invasion.

LYMPH NODES ("N" of TNM)

- **Lymph Nodes:** (if applicable)

Definition of Regional Lymph Node (pN)

Pathological N (pN)

pN Category	pN Criteria
pNX	Regional lymph nodes cannot be assessed
pN0	No regional lymph node metastasis
pN1	Metastasis in a single ipsilateral lymph node, 3 cm or smaller in greatest dimension and ENE(-)
pN2	Metastasis in a single ipsilateral lymph node, 3 cm or smaller in greatest dimension and ENE(+); or larger than 3 cm but not larger than 6 cm in greatest dimension and ENE(-); or metastases in multiple ipsilateral lymph nodes, none larger than 6 cm in greatest dimension and ENE(-); or in bilateral or contralateral lymph node(s), none larger than 6 cm in greatest dimension and ENE(-)
pN2a	Metastasis in a single ipsilateral lymph node 3 cm or less in greatest dimension and ENE(+); or a single ipsilateral node larger than 3 cm but not larger than 6 cm in greatest dimension and ENE(-)
pN2b	Metastases in multiple ipsilateral lymph nodes, none larger than 6 cm in greatest dimension and ENE(-)
pN2c	Metastases in bilateral or contralateral lymph nodes, none larger than 6 cm in greatest dimension and ENE(-)
pN3	Metastasis in a lymph node larger than 6 cm in greatest dimension and ENE(-); or metastasis in a single ipsilateral node larger than 3 cm in greatest dimension and ENE(+); or multiple ipsilateral, contralateral or bilateral nodes, any with ENE(+); or a single contralateral node of any size and ENE(+)
pN3a	Metastasis in a lymph node larger than 6 cm in greatest dimension and ENE(-)
pN3b	Metastasis in a single ipsilateral node larger than 3 cm in greatest dimension and ENE(+); or multiple ipsilateral, contralateral or bilateral nodes, any with ENE(+); or a single contralateral node of any size ENE(+)

Note: A designation of "U" or "L" may be used for any N category to indicate metastasis above the lower border of the cricoid (U) or below the lower border of the cricoid (L).

Similarly, clinical and pathological ENE should be recorded as ENE(-) or ENE(+).

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Note: Metastases at level VII are considered regional lymph node metastases. Midline nodes are considered ipsilateral nodes.

Definition of Regional Lymph Node for Mucosal Melanoma (pN)

pN Category	pN Criteria
pNX	Regional lymph nodes cannot be assessed
pN0	No regional lymph node metastases
pN1	Regional lymph node metastases present

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Regional lymph nodes:

Involvement of buccinator, prevascular facial, submandibular, upper jugular, and (occasionally) retropharyngeal nodes may occur with advanced maxillary sinus cancer, particularly those extending beyond the sinus walls to involve adjacent structures including soft tissues of the cheek, upper alveolus, palate, and buccal mucosa or overlying skin.

Lymph node examination:

A selective neck dissection will ordinarily include 15 or more lymph nodes, and a comprehensive neck dissection (radical or modified radical neck dissection) will ordinarily include 22 or more lymph nodes.

Macroscopically negative lymph nodes:

- Count the number of macroscopically negative lymph nodes identified.
- Measure the lymph nodes in three dimensions; if multiple, provide a range in size.
- Describe the cut surface of the identified lymph nodes.
- Submit all lymph nodes for microscopic examination.
 - Submit smaller nodes in toto.
 - Section and entirely submit larger macroscopically negative lymph nodes.
- If possible, submit lymph node sections so that the long axis of the lymph node is demonstrated.
- Take steps to ensure that an accurate lymph node count can be rendered.

Macroscopically positive lymph nodes:

- Count the number of macroscopically positive lymph nodes identified.
- Specify the site and laterality of macroscopically positive nodes.
- Measure the lymph nodes in three dimensions; if multiple provide a range in size.
- Describe the cut surface of the macroscopically positive node.
 - Provide a measurement for the lymph node metastasis in cm.
 - If multiple lymph nodes are positive, provide the measurement of the largest lymph node metastasis. *
- If extranodal extension is seen, submit one representative section from each macroscopically positive lymph node to include the area of extranodal extension.
- If extranodal extension is not seen, either entirely submit the lymph node, or, submit the sections that show the tumor deposit in the node to include the entire lymph node capsule with surrounding extranodal tissue (to rule out the possibility of extranodal extension).

- If possible, submit lymph node sections so that the long axis of the lymph node is demonstrated.
- Take steps to ensure that an accurate lymph node count can be rendered.

*The cross-sectional diameter of the largest metastatic tumor deposit within the lymph node is measured in the gross specimen at the time of macroscopic examination, or, if necessary, on the histological slide at the time of microscopic examination. Measurement of the metastatic focus in the lymph node is based on the largest metastatic deposit size, which may include matted or fused lymph nodes.

Non-regional lymph nodes:

Delineation as to what constitutes non-regional is still unspecified. The above procedure may be employed for more distant level lymph nodes.

Classification of Neck Dissection: (*Figure 2*)

- Radical neck dissection
- Modified radical neck dissection, internal jugular vein and/or sternocleidomastoid muscle spared
- Selective neck dissection (SND), as specified by surgeon
 - Supraomohyoid neck dissection: above the hyoid bone, which includes lymph nodes of levels IA, IB, IIA and IIB
 - Posteriorlateral neck dissection: bordered anteriorly by the stylohyoid muscle and posteriorly by the sternocleidomastoid, it includes level III lymph nodes above the hyoid and level IV below the hyoid
 - Lateral neck dissection: anteriorly bordered by the sternocleidomastoid muscle, it includes level VA, VB and supraclavicular lymph nodes
 - Central compartment neck dissection: includes the pre- and paratracheal, Delphian and perithyroid lymph nodes of level VI
- Superselective neck dissection (SSND), as specified by the surgeon – “SSND” with levels and sublevels designated
 - Fibrofatty soft tissue contents of two contiguous neck levels are removed both electively for patients with no nodal metastasis (N0) or persistent lymph node disease following chemoradiotherapy (N+).
- Extended radical neck dissection, as specified by surgeon

■ **Explanatory notes:**

Lymph nodes greater than 3 cm (N2) likely represent multiple matted lymph nodes, an indication of extranodal extension (EE), which is a poor prognostic indicator. The number of lymph nodes involved can be estimated. While Level VII lymph nodes are still considered “regional”, metastasis to lower level lymph nodes below level IV involves a more extensive radiographic protocol to identify the primary tumor location and carries a more unfavorable prognosis.

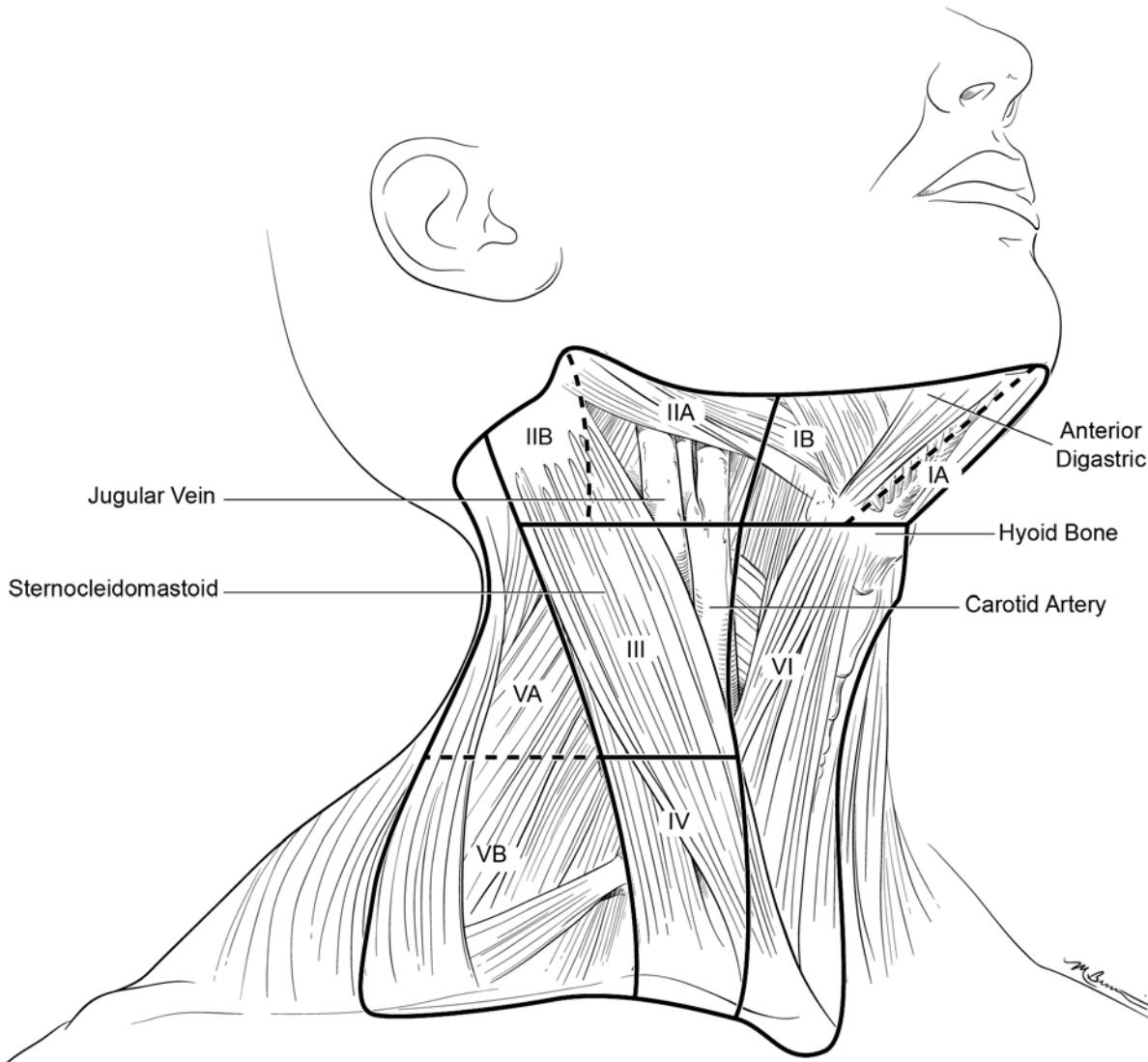


Figure 2: The Six Levels of the Neck with Sublevels

- Level IA: Submental group
- Level IB: Submandibular group
- Level IIA: Upper jugular nodes along the carotid sheath, including the subdigastric group
- Level IIB: Upper jugular nodes in the submuscular recess
- Level III: Middle jugular group
- Level IV: Lower jugular group
- Level VA: Spinal accessory nodes
- Level VB: Supraclavicular and transverse cervical nodes
- Level VI: Anterior (central) compartment

METASTASIS ("M" of TNM)

- **Metastasis:**

TNM classification for all carcinomas including mucosal melanoma:

Definition of Distant Metastasis (pM) (required only if confirmed pathologically)

pM Category	pM Criteria
M0	No distant metastases (no pathologic M0; use clinical M to complete stage group)
pM1	Distant metastases

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The most common sites of distant metastasis are the lungs and bone.

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