

## Learning Objectives

- Examine format and expansion of Chapter 1
- Explain key rules with their rationale
- Identify changes between 7<sup>th</sup> and 8<sup>th</sup> editions
  - Minor to keep pace with changing medicine, clarifications
  - Major based on data showing inconsistency or inaccuracy



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## Purpose of AJCC Stage

- Stage is for patient care
  - Defines prognosis
  - Critical for appropriate treatment
- Stage serves as basis for
  - Clinical trial inclusion, exclusion, and stratification
  - Evaluate results of treatment
  - Facilitate exchange and comparison of info between registries
  - Clinical and translational cancer research
- Cohesive approach to staging provides method for
  - Clearly conveying clinical experience to others
  - Without ambiguity
  - At national and international levels



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#### Format and Expansion

- Chapter 1 "Principles of Cancer Staging"
  - New user-friendly format
  - Rules repeated so each staging classification has complete info
  - Provide examples and exceptions
- Comprehensive analysis of staging rules and nomenclature
  - AJCC-UICC Lexicon Project January 2012
  - Content Harmonization Core August 2014
    - Team of fifteen physicians
    - · Line by line review over span of two years
  - Harmonization Summit September 2015
    - 60 physicians voted on rules, along with registrars
  - Resulted in expansion of chapter
  - Precise standardized definitions and rules for staging
  - Final chapter reviewed/edited by 7 physicians



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#### Assigning AJCC Stage

- · Role of managing physician
  - Only managing physician may assign patient's stage
  - Only person with access to all pertinent information
  - Only person who can synthesize array of physical exam & findings
- Role of pathologist and radiologist
  - Provide important T-, N-, and/or M-related information
- Cancer registry documentation and data
  - Specific registry guidelines throughout chapter 1
  - Document what is found
  - Do not adjust, interpret, change
  - Critical for researchers to have this unaltered data
  - Registry data affects future patient care
  - Altered data could negatively impact patient care



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## Terminology

- Stage used only for aggregate information resulting from T, N, and M, never individual categories
- Classifications time point in patient's care continuum
  - Time frame (staging window)
  - Criteria
- Categories T, N, M, and prognostic factors required for stage group
- AJCC Prognostic Stage Groups stage groups, stage, aggregate information



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## Stage Classifications: Time Frame & Criteria

- All stage classifications have time frame & criteria
- Time frame or staging window
  - Defines point in time of patient's care
  - Starting and stopping time points

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## Stage Classifications: Time Frame & Criteria

- All stage classifications have time frame & criteria
- Criteria defined by
  - Diagnostic workup
  - Definitive treatment
- Diagnostic procedures are sample
  - No intent to remove entire tumor
  - Do not know entire tumor removed until after treatment performed
  - Surgical diagnostic procedures ≠ surgical treatment
- Definitive treatment
  - Surgical treatment meets resection requirement in chapter
  - Neoadjuvant therapy must satisfy NCCN/ASCO/other guidelines

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## Any T, Any N

- Any T defined
  - Includes all T categories except Tis
  - Includes TX and T0
- Any N defined
  - Includes all N categories
  - Includes NX and N0



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#### Stage Classification Criteria

- Clinical staging criteria: known or suspected tumor
  - Must be known or suspected
  - Have diagnostic workup including at least history & physical exam
  - NOT incidental finding at time of surgical treatment
  - No retrospective assignment during/after treatment
- Pathological staging criteria: primary tumor surgical resection
  - Must meet surgical resection criteria
  - Surgical resections ranges from
    - · Resection of tumor, up to
    - · Complete resection of organ, and
    - · Usually includes resection of some regional lymph nodes
  - Depends on site-specific info necessary to determine
    - Adjuvant therapy
    - Patient's prognosis

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## Unknown Primary or No Evidence of Primary

- T0
  - No evidence of primary tumor
  - Primary site of tumor is unknown
  - Staging based on clinical suspicion of primary organ site
  - T0 not available in all sites, cannot suspect primary from nodes/mets
- Example
  - Axillary node involvement, suspected clinically to be from breast
- Example of exception
  - T0 not used for head & neck squamous ca sites
  - Use Cervical Nodes & Unknown Primary Tumor chapter
  - Exception to exception: T0 is valid for
    - · HPV-related oropharynx and
    - EBV-related nasopharynx

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#### Rarely Node Status Not Required

- Node status not required in rare circumstances
- Clinical and pathological staging N category
  - Cancer sites where node involvement is rare
  - NX may not be category option
  - Node status not determined as involved assigned as cN0
  - cN0 for pathological staging ensures no confusion with nodes microscopically proven to not contain tumor (pN0)
- Nonexhaustive examples
  - Soft tissue does not have NX
  - Bone note states NX may not be appropriate, may be cN0
  - Melanoma allows cN0 for pathologic stage group with pT1
  - Corpus uteri at times permits cT and cN in pathological staging
    - Surgeon's nodal assessment specifically noted in operative report



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### Microscopic Assessment cN & pN

- Microscopic assessment for cN and pN
  - Fine needle aspiration (FNA)
  - Core (needle) biopsy
  - Incisional biopsy
  - Excisional biopsy
  - Sentinel node biopsy/procedure
  - pN ONLY: regional lymph node dissection
- Specifies cytology just as valid as tissue
- cN microscopic info also included in pathological staging
- Requirements for assigning pN category
  - Pathological documentation of presence/absence of ca in 1 node
  - Pathological assessment primary tumor, except in T0
  - FNA and core needle biopsy of node both satisfy requirement



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#### Sentinel Lymph Node Clearly Defined

- Sentinel lymph node (SLN)
  - Receives direct afferent lymphatic drainage from primary tumor
  - Represents nodes most likely to contain disease
  - More than 1 node may be present in nodal basin
  - Some tumors drain to more than 1 regional nodal basin
- SLN procedure lymphatic mapping
  - Injection of colloidal material into primary tumor or organ
    - Isosulfan blue stain and/or radiotracer technetium-99 sulfur colloid
  - Identification and removal of nodes
    - Sentinel nodes: those containing colloidal material
    - · Nonsentinel nodes: palpably abnormal nodes without colloidal material
- SLN procedure includes sentinel & nonsentinel nodes
  - Nonsentinel nodes **not** separate nodal procedure
  - Nonsentinel nodes not lymph node dissection





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## pM1 for Clinical & Pathological Classifications

- Microscopic evidence of distant mets, pM1, includes
  - Cytology from FNA
  - Core (needle) biopsy
  - Incisional or excisional biopsy
  - Resection
- Use of pM1 for multiple distant mets
  - If M subcategories distinguish between one or more sites
  - Microscopic evidence of one site needed for higher subcategory
  - Microscopic evidence of all sites is not necessary
  - Note: both sides of paired organ considered one site
- Direct extension into organ not M category
  - Example: colon ca extends into liver, pT4 and cM0





#### Criteria for Neoadjuvant Therapy

- Not all medication meets criteria for neoadjuvant therapy
  - Examples include short course endocrine Rx for breast & prostate
  - Provided for variable and often unconventional reasons
  - Not categorized as neoadjuvant therapy for AJCC staging
  - Do not assign yp, surgical resection staging is p (pathological)
- Treatments that satisfy definition of neoadjuvant therapy
  - NCCN Guidelines
  - ASCO Guidelines
  - Other treatment guidelines
- Not in 7<sup>th</sup> edition because it is recent trend
  - Physician experts provided clarification
  - Valid for 7<sup>th</sup> edition AJCC staging and 8<sup>th</sup> edition AJCC staging



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#### Response to Neoadjuvant Rx

- Systems for pathologist to document response
  - Consult disease site chapter
  - Complete, partial, no response
  - Regression score
- Critical to assign ypT and ypN for analysis of response
- Mucin pools, necrosis, and reactive changes
  - Without viable-appearing tumor cells
  - Insufficient for diagnosis of residual cancer
  - Not included in assessment of residual cancer



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## Critical Exceptions: Size and Rounding

- Melanoma exception T category
  - Primary tumor thickness measured to nearest 0.1 mm
  - Was 0.01 mm in 7<sup>th</sup> edition
  - Other sites size measured in whole mm
- Breast exception T category
  - >1.0 mm to 1.4 mm rounded to 2 mm
  - Avoid assigning "microinvasion" category to cancer >1.0 mm
  - Other sizes rounded for T category assignment
    - Round down between 1 and 4
    - Round up between 5 and 9

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### In Situ and Noninvasive T Category

- In situ neoplasia and noninvasive papillary ca
  - Identified during diagnostic workup on core or incisional biopsy
  - Assigned cTis or cTa
  - Refer to "In Situ Neoplasia AJCC Cancer Staging Manual 8th Edition" posted 11/2/2016 on AJCC website
- In situ neoplasia and noninvasive papillary ca
  - Identified from surgical resection specified in disease site pathological criteria
  - Identified microscopically in diagnostic workup with no residual in surgical resection
  - Assigned pTis or pTa



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### In Situ and Noninvasive Stage Group 0

- Insitu neoplasia, stage 0 or stage 0is
  - cTis cN0 cM0 clinical stage 0 or 0is
    - Must have microscopic confirmation
  - pTis cN0 cM0 pathological stage 0 or 0is
    - · Must meet primary tumor surgical resection pathological criteria
    - Exception: lymph node microscopic assessment **not** required
- Noninvasive papillary ca stage 0a rules now documented
  - cTa cN0 cM0 clinical stage 0a
    - Must have microscopic confirmation
  - pTa cN0 cM0 pathological stage 0a
    - Must meet primary tumor surgical resection pathological criteria
    - Exception: lymph node microscopic assessment not required
- Reminder: disease sites with two stage 0 groups denoted
  - 0is
  - 0a

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#### Extranodal Extension - ENE

- Extranodal extension (ENE) defined as
  - Extension through lymph node capsule into adjacent tissue
  - Preferred terminology
- Regional node extending into distant structure or organ
  - Categorized as ENE
  - Not considered distant metastatic disease



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## Assigning Stage with Incomplete Information

- Assigning stage with incomplete information
  - Presumptive stage may be used
  - Not a formal stage classification type
  - Only for physician use to facilitate patient care
  - Never documented by cancer registries
- Clinical stage
  - Preliminary clinical stage assigned during diagnostic workup
  - Continually update stage as workup progresses
  - Once final stage determined
    - Preliminary stages no longer used
    - Replaced by clinical stage
  - Stage(s) provisionally assigned referred to as presumptive stage(s)
  - Registry only records clinical stage



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### Assigning Stage with Incomplete Information

- Pathological stage
  - If only partial info available in pathological classification
  - Managing physician may combine clinical and pathological T and N categories
  - This strategy may be used to
    - · Plan patient's treatment
    - · Provide patient with stage group and prognosis
  - Does **NOT** represent actual TNM stage
  - Therefore NOT used to assign a stage group
  - Registry does NOT record combined clinical and pathological T and N categories
  - Registry does **NOT** record stage group



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## Uncertainty: Physician & Cancer Registry Data

- Physicians
  - May assign lower of two possible categories or stage groups
- Cancer registry data uncertainty rules do NOT apply
  - Subcategory info not available to registrar
    - · Assign main category
    - Do NOT assign lower subcategory
  - Stage group info not available to registrar
    - e.g., missing subcategory or prognostic factor category
    - Do NOT assign stage group
    - Document stage group as unknown



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#### Required Prognostic Factor Unavailable

- Prognostic factor required for staging is unavailable
  - X category provided for use by managing physician
- If factor is absent and X not provided as option
  - Physician's determination or lowest category used to assign stage
- · Cancer registry data collection
  - Registry must record X or unknown if factor not available
  - Registry must **NOT** use lowest category
  - Allows for accurate data analysis



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### Registry Documents Facts

- Tis N1-3
  - Pathology shows Tis only with nodal involvement
  - Stage group assigned by managing physician based on N category
- Examples of rare situations of Tis N1-3
  - Melanoma: may be associated with a regressed tumor
  - Breast: may be unidentified occult invasive cancer
- Cancer registry
  - Assign factual Tis, appropriate N category
  - Do NOT adjust according to registry rules, don't change to T1
  - Do NOT assign stage group in registry database
  - Allows study of these patient in future



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## N Suffixes: (sn) and (f) Method of Assessment

- (sn) sentinel node procedure indication
  - Diagnostic workup & before definitive surgical treatment, cN1–3(sn)
  - Part of initial surgical management, pN1–3(sn)
  - Note: suffix NOT used if completion lymph node dissection performed as component of initial surgical management
- (f) FNA or core needle biopsy of node indication
  - Diagnostic workup before treatment, cN1-3(f)
  - Part of primary site surgical resection, pN1-3(f)
  - Note: suffix NOT used if subsequent completion lymph node dissection as component of initial surgical management



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## **Unknown Primary Site**

- No primary tumor evidence, BUT anatomic site suspected
- cT0
  - Primary tumor not identified on
    - Physical exam
    - Imaging
    - Endoscopy
    - · Other diagnostic procedures
- pT0
  - No evidence of primary tumor identified
    - · After surgical resection of suspected primary tumor, and
    - · Never identified on biopsy



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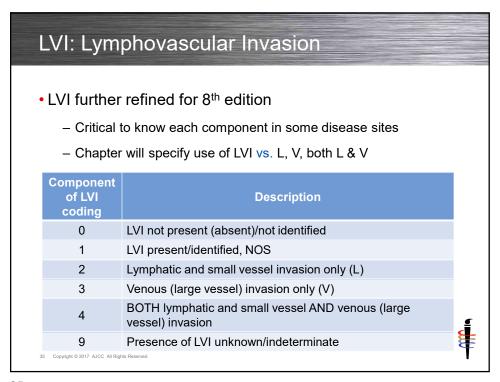
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#### Grade

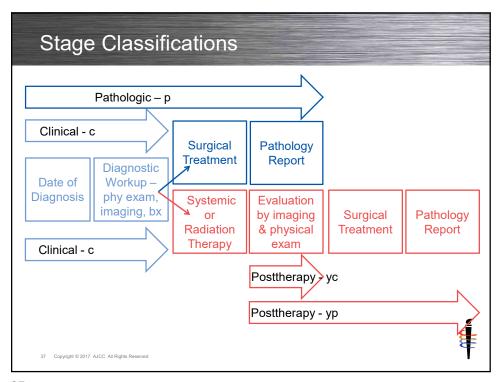
- Recommended grading system specified in each chapter
  - Grading system to be used by pathologist and
  - Documented in cancer registry
- Cancer registry
  - Must record grade as specified in disease site chapter
  - According to rules only in chapter 1 and disease site chapter
  - Do NOT use registry rules for AJCC grade data item

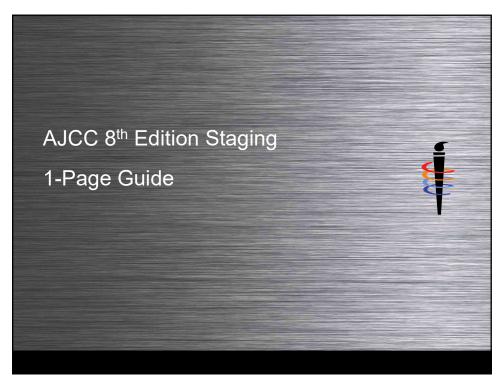


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## AJCC 8th Edition Staging: 1-Page Guide

#### AJCC 8th Edition Staging

- The following rules and associated rationale are for the Eighth Edition AJCC Cancer Staging Manual.
- Note that these are general rules described in Chapter
   1 of the AJCC Cancer Staging Manual.
- Please refer to relevant disease site chapters to learn more about specific allowable disease site differences to correctly stage such patients and that are necessary for appropriate medical care of the patient.



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## AJCC 8th Edition Staging: 1-Page Guide

#### **KEY TERMINOLOGY**

- Classifications: Describes the points in time of the care of the cancer patient. Criteria include:
  - Timeframe
  - Specific medical assessments and practices
- Categories: T, N, M, and any non-anatomic factors needed to assign the stage group
- Stage group: Easily communicated summary of categories, groups patients with similar prognosis
- Assigning stage: AJCC stage is assigned by the managing physician based on data from all relevant sources including history, examination, laboratory studies, imaging, and surgical and pathology findings

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#### AJCC 8th Edition Staging: 1-Page Guide

#### **CLINICAL STAGING CLASSIFICATION RULES**

- General: Clinical classification includes information from the date of cancer diagnosis until the start of definitive treatment, or within four months, whichever is shorter
- **T category** includes information from clinical history, symptoms, physical exam, labs, imaging, endoscopy, biopsy, surgical exploration without resection
- N category physical exam, imaging, FNA or core needle biopsy, excisional biopsy, sentinel node biopsy
  M category clinical history, physical exam, imaging, FNA or biopsy

#### Rationale

- · Diagnostic biopsies of the primary site, regional nodes, and distant metastatic sites are included in clinical classification
  • Pathological exam of resected tissue (pathology report) does not

- ratiological exam of resected tissue (patriology report) does not necessarily make this pathologic staging
  Clinical N category is cN even if based on lymph node biopsy
  Clinical M category is cM if based on history, physical exam and imaging, pM1 if based on biopsy proven involvement

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### AJCC 8th Edition Staging: 1-Page Guide

#### PATHOLOGICAL STAGING CLASSIFICATION RULES

- General: includes all information from the date of cancer diagnosis (clinical stage), surgeon's operative findings, and pathology report from resected specimen – must use all 3
  • T category – must meet definitive surgical treatment specified in
- chapter
- N category microscopic assessment of at least one node required, include imaging and diagnostic biopsy
- M category history, physical exam, imaging, FNA or biopsy, resection

#### Rationale

- Include all findings even if not microscopically proven, i.e., physical exam, imaging, operative findings
- Pathological staging is based on synthesis of all information and not solely on resected specimen pathology report – pathologist cannot assign final stage
- Pathological M category is cM if based on physical exam and imaging, pM1 if based on biopsy proven involvement, "pM0" is NOT a valid category

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### AJCC 8th Edition Staging: 1-Page Guide

# POST NEOADJUVANT THERAPY STAGING CLASSIFICATION RULES

- yc Clinical: includes physical exam and imaging assessment after neoadjuvant systemic/radiation therapy
- yp Pathological: includes all information from yc staging, surgeon's operative findings and pathology report from resected specimen

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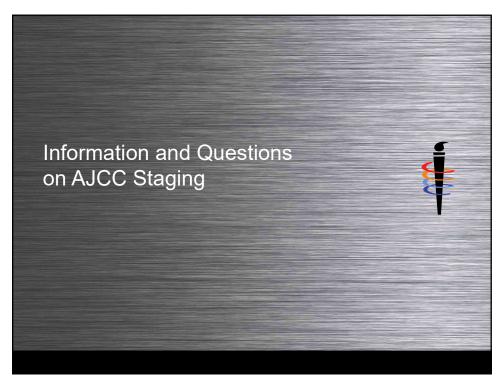
### Cohesive Approach to AJCC TNM

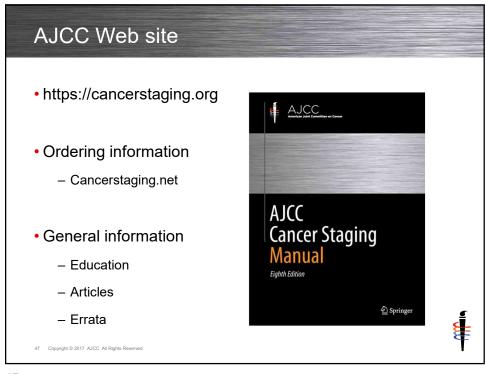
- Aligning registry data items with AJCC TNM system
  - Plans are moving forward
  - Need cohesive approach to break down barriers
  - Allow registrar to document AJCC TNM without alteration
- Existing differences hinder ability to communicate, affects
  - Registrar and physician communication
  - Researchers utilizing national databases
  - Electronic exchange between systems



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### Summary

- Navigate new format and expansion of Chapter 1
- Comprehend key rules and rationale behind development
- Identify changes between 7<sup>th</sup> and 8<sup>th</sup> editions
  - Minor to keep pace with changing medicine, clarifications
  - Major based on data showing inconsistency or inaccuracy

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