

Learning Objectives

- · In-depth review of select staging rules
- Dissect staging rule changes
- Influence of registry data on future staging changes
- Demonstrate use of staging rules through examples



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Difference Between Rule Frequency

- Existence of staging rule does not imply rate of usage
- Important to understand frequency of applying rule
 - Common general rules applying to all cases
 - Rules for exceptions, rare and unusual cases
 - Important for consistent handling
 - Title of rule does not always imply frequency
- Example
 - Bx of highest T and N category used for pathological staging
 - Rarely used
 - Not common in patient care



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Rules for Physicians & Registrars

- Rules written for specific scenarios
 - Doesn't imply frequency
 - Most involving incomplete information are uncommon
 - Uncertainty mostly confined to clinical staging
 - Unavailable prognostic factors for staging are unusual
 - Important for consistent handling
 - Important to mitigate effect on data analysis



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Registry AJCC Stage for Data Analysis

- Registrar not using physician stage rare exception, not rule
- Same as physician stage for patient care in most cases
 - Few situations where data must be different
 - Physician stage for personalized medicine
 - Registry stage data for large group analysis
- Registry stage needed for data analysis
 - Patient outcomes
 - Treatment
 - Revisions to staging system based on outcomes
- Plans for special webinar
 - Physician to co-present
 - Improve understanding
 - Dialogue is important





Incomplete Information & Uncertainty

- Incomplete information should not be frequent
 - Patient comorbidities precluding usual workup or treatment
 - Rules for patient care not for registry documentation
- Uncertainty definition
 - Must be unclear between two subcategories or categories
 - Not vague info, e.g. not advanced probably T1 or T2
- Missing information is different issue
 - Tests performed elsewhere, not documented in medical record
 - Physicians have info to care for patient
 - Registrars cannot use incomplete/uncertainty rules for missing info
 - Need to investigate missing info with CLP or cancer committee
 - Discussions lead to opportunity to improve



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Opportunity for Quality Improvement

- Physician stage and registry data mismatch
 - Concerns regarding registry data
 - Viewed as wrong or not reflecting physician stage
 - Frequency of incomplete info occurrence should be minimal
 - Frequency of missing info should be reviewed
- Opportunity for quality improvement
 - Identify information missing from medical record
 - Only available in physician office chart or other facility
- Physician documentation of missing info
 - Positive impact on registry data completeness
 - Patient data available to other medical team members
 - Benefits for facility, physicians, and patient care



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Assigning AJCC Stage for Patient Care

Although the pathologist and the radiologist provide important staging information, and may provide important T-, N-, and/or M-related information, stage is defined ultimately from the synthesis of an array of patient history and physical examination findings supplemented by imaging and pathology data. Only the managing physician can assign the patient's stage, because only (s)he routinely has access to all the pertinent information from physical examination, imaging studies, biopsies, diagnostic procedures, surgical findings, and pathology reports.

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Assigning AJCC Stage for Patient Care

- Assigning AJCC stage for patient care
 - Documenting in legal medical record
- Role of managing physician
 - Only managing physician may assign patient's stage in record
 - 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
 - May not assign stage



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- Managing physician pN1, not pathologist pNX
 - No nodes removed in surgical resection
 - Node biopsy during diagnostic workup
- Managing physician pN2, not pathologist pN1
 - Nodes on imaging added to pathology nodes
- Managing physician pT1, not pathologist pT0
 - No residual primary tumor on surgical resection
- Managing physician cT3, not radiologist cT2
 - Additional imaging or endoscopies provide more information



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Change in Registry Data Item for Descriptors

- Descriptor data item prior to 2018
 - Category suffix: (m)
 - Stage prefix: y
 - Stage group info for lymphoma: E, S
- Identified issues with descriptor data item
 - Confusing to mix disparate concepts in one data item
 - Poor compliance and inconsistent usage
 - Alter for 2018 by creating new items or merging into existing
- Transformation for 2018
 - Developed **new** suffix data items for T and N
 - Shifted stage prefix to new yp stage data items
 - Incorporated E into stage group, S no longer used



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Grade Issues and Solution

- New grade data items for each stage classification
 - Incorporates both AJCC and standard registry coding
 - · Prioritizes AJCC specified grade
 - · Provides standard registry grade when AJCC not applicable
 - Grade tables specific for each disease site
 - Grade system based on prognostic significance
- Grade coding rules developed with surveillance partners
 - Approved by AJCC and pathologists
 - Medically accurate
 - Follows AJCC 8th edition Chapter 1
- Rationale for new grade data items
 - Grade data unusable in many sites by AJCC experts
 - Inconsistent grading systems used
 - Data coding rules conflicted with physician guidance



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Pathology Criteria for Grading Systems

- G1 criteria identical in 3- & 4-grade systems
- G2 criteria identical in 3- & 4-grade systems
- G3 and G4
 - 4-grade system distinguishes criteria, separates
 - 3-grade system does **not** distinguish or **too subtle**, groups together
- Grading systems based on
 - Prognostic significance
 - Reproducible between pathologists
- 3-grade system coding 4-grade system coding

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- Urothelial bladder cancer uses low grade/high grade system
 - Pathologist states high grade urothelial ca, grade 3
 - Must code to high grade, HG, code H
- Invasive breast cancer uses Nottingham grade system
 - Pathologist states nuclear grade 2
 - Cannot code to 2 since that is G2 for Nottingham
 - Nuclear grade is just one of three components of Nottingham
 - Nuclear grade is the least reproducible of three components
 - Nuclear grade is used for in situ, but not for invasive
 - Must not use this for prognostic factor to assign stage group



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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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Diagnostic vs. Treatment for Staging

- Do not use old registry rules for staging
 - Anything that modified, removed, controlled, or destroyed tumor is considered treatment
- Diagnostic
 - Procedures to diagnose
 - Procedures to further define/stage in order to develop treatment plan
- Treatment
 - Treatment definition based on patient outcome/survival
 - Intent to remove all or most of cancer
 - Planned significant impact on cancer burden
 - Provides patient with greatest chance of survival



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Example

Site	Diagnostic Staging	Treatment Staging
Prostate	TURP	Prostatectomy
Bladder	TURB	Partial or complete cystectomy
Ovary	Exp Lap with no resection	Exp Lap as part of resection
Breast	Core needle biopsy (even if no residual found on treatment)	Lumpectomy, mastectomy

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Node Status Not Required

- "Node status not required in rare circumstances"
 - Direct quote from Chapter 1
 - Need to understand rationale
 - Important not to overreach and use rule to avoid unknowns
- Rare circumstances
 - Applies to disease sites where nodal involvement is rare
 - Based on biology of tumor spreading to lymph nodes
 - Not based on frequency of node dissections with surgery
- Only cN0 used
 - Any suspicion of node involvement must be investigated
 - Implications for treatment and prognosis for rare involvement
 - cN1 for pN category NOT allowed, must be microscopically proven
- AJCC document on applicable chapters available



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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)



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Node Status Not Required in pN Category

- All chapter exceptions where cN0 used for cN & pN category
 - 38 Bone
 - 40 Soft Tissue Sarcoma of Head and Neck
 - 41 Soft Tissue Sarcoma of Trunk and Extremities
 - 42 Soft Tissue Sarcoma of Abdomen and Thoracic
 - 43 Gastrointestinal Stromal Tumor
 - 44 Soft Tissue Sarcoma of Retroperitoneum
 - 53 Corpus Uteri Carcinoma and Carcinosarcoma
 - 54 Corpus Uteri Sarcoma
 - 67 Uveal Melanoma
 - 68 Retinoblastoma
- Limited exception where cN0 used for pN category
 - 47 Melanoma: pT1

Other rules also allow cT and cN in pathological staging



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Example

Bone - pelvis

- Imaging shows lesion on iliac wing, cT1a, no info on nodes
- Assign cT1a cN0 cM0 G2 stage IIA
- Surgical resection of iliac wing, no node resection
- Assign pT1a cN0 cM0 G2 stage IIA

Thyroid – differentiated, age 68

- Imaging shows small lesion It lobe thyroid, biopsy confirmed
- Assign cT1b cN0b cM0 stage I
- Surgical resection It lobe thyroid, no node resection
- Assign pT1b pNX cM0 stage I



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Sentinel Lymph Node Procedure

- 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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Example

- Gross specimen A labeled It axillary sentinel lymph nodes
 - One lymph node 2x0.6x0.4cm and
 - Other inked blue lymph node 0.5x0.5x0.5cm
 - Two lymph nodes negative for carcinoma
- Gross specimen B labeled It hottest axillary sentinel node
 - One lymph node measures 1.1x0.6x0.3cm and
 - Second inked blue lymph node 1.2x0.5x0.4cm
 - Two lymph nodes negative for carcinoma
- All 4 nodes considered sentinel node procedure
 - Two sentinel nodes inked blue
 - Two non-sentinel nodes adjacent to inked nodes
- Patient had sentinel node procedure
 - 4 nodes examined for sentinel node procedure
 - 0 nodes positive for sentinel node procedure

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pM1 for Clinical & Pathological Classifications

- 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

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Example

- Nuclear bone scan showed pelvic mets (cM1a)
- CT guided liver FNA cytology showed mets (pM1b)
- Clinical stage M category assigned pM1b
- Pathological stage M category assigned pM1b
 - If no surgical resection, assign cT cN pM1b
 - If surgical resection, assign pT pN pM1b



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New Posttherapy Stage Data Items

- New stage data items for postneoadjuvant therapy staging
- Collect clinical, pathological, posttherapy staging separately
- Emphasizes differences between p and yp stage
 - Timing and criteria
 - Staging rules
- Cannot easily determine whether p or yp in pre-2018 data
 - Descriptor y not always coded
 - Cannot depend on systemic therapy codes
 - All coded therapy is NOT neoadjuvant
- Pathological stage ONLY in Path T, N, M, stage group
- Posttherapy stage ONLY in NEW Post Therapy items



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Classification Depends on Rx Sequence

- Pathological or posttherapy classification
 - Patient **never** eligible for both p and yp classifications
 - Depends on treatment sequence
 - Sometimes say "first" treatment, not meaning first vs. subsequent
 - Refers to order of treatment modalities

Pathological Rx Sequence	Posttherapy Rx Sequence
Surgical resection	1. Neoadjuvant systemic/radiation therapy
Assign p stage	Assign yc stage
2. Adjuvant systemic/radiation therapy	2. Surgical resection
	Assign yp stage
	£



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Posttherapy Classification Assignment

- Posttherapy classification assigned regardless of response
- Always assign ypT ypN cM
 - Does NOT depend on response to treatment
 - Even if pt responds completely, no evidence of tumor
 - Even if pt has partial response, tumor or nodes shrink
 - Even if pt did not respond, tumor/nodes stayed the same
 - Even if pt did not respond, tumor/nodes grew while on treatment
 - · Not considered progression that stops staging
 - Not considered progression that makes surgery subsequent treatment

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Posttherapy Classification Stage Group

- Posttherapy staging
 - CRITICAL to assign ypT ypN to assess response
 - No stage group for complete response in all chapters
 - Stage group for partial/no response in all chapters except breast
- New thoughts on stage group
 - Currently: mainly use stage group table designed for c and/or p
 - May not have same prognostic meaning for yc and/or yp
- AJCC will be looking at data for future direction

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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
 - Most important information
 - Whether or not stage group assigned is not as critical
- 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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Example

- Rectal ca clinical stage cT3 cN1b cM0 stage IIIB
- Neoadjuvant chemoradiation
- · Low anterior resection showing increased involvement
- Pathologist noted tumor regression score 3
- Clinical stage: cT3 cN1b cM0 stage IIIB
- Posttherapy stage: ypT4a ypN2a cM0 stage IIIC



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In Situ Change Rationale

- Separate designations, cTis and pTis, indicate
 - Timeframe and
 - Type of specimen
- Importance of this differentiation
 - Especially when resection specimen shows invasive tumor
 - Mitigates potential confusion regarding T category specimen
 - In past editions
 - pTis based on diagnostic biopsy or on resection specimen
 - Depending on whether clinical stage T or pathological stage T
 - Especially confusing if
 - Diagnostic biopsy showed carcinoma in situ, pTis, and
 - Resection specimen showed invasive carcinoma, pT1a





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Example

- Needle core biopsy breast showed DCIS
- Pt underwent lumpectomy with no residual
- Clinical T category assigned cTis(DCIS)
- Pathological T category assigned pTis(DCIS)

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Registry Cautions with Incomplete Stage

- Incomplete staging information
 - Critical for physician to use to plan patient care
 - Essential for patient to understand their prognosis
 - Skews data analysis
- Registry use of incomplete staging information
 - Must only record complete and accurate aspects of T, N, M
 - Do not record T, N, or M category when it breaks staging rules
 - Do **not** record stage group since some categories are missing
- Always record accurate information
 - Use blanks and unknown stage groups when accurate
 - Do **not** skew data to lessen "unknown" data percentage
 - Future patient care could be harmed by falsified data



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Registry Cautions with Incomplete Stage

In patient care, it may be appropriate for the managing physician to combine clinical and pathological T and N categories if only partial information is available in the pathological classification. Although this strategy may be used to plan treatment and to provide the patient with a stage group and prognosis, it does not represent the actual TNM stage and therefore is not used to assign a stage group.



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- · Elderly patient with core needle bx proven breast ca
- Lumpectomy, no nodes removed

Physician

- cT2 cN0 cM0 Gr 2 HER2 neg ER pos PR pos stage IB
- pT2 cN0 cM0 Gr2 HER2 neg ER pos PR pos stage IA

Registrar

- cT2 cN0 cM0 Gr 2 HER2 neg ER pos PR pos stage IB
- pT2 pNX cM0 Gr2 HER2 neg ER pos PR pos stage 99
- Remember clinical staging cN0 available for data analysis



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Uncertainty: Cancer Registry Data

- Cancer registry data uncertainty rules do NOT apply
 - Subcategory info not available to registrar
 - Assign main category (available in all AJCC tables)
 - 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

Uncertainty rules do not apply to cancer registry

If information is not available to the cancer registrar for documentation of a subcategory, the main (umbrella) category should be assigned (e.g., T1 for a breast cancer described as <2 cm in place of T1a, T1b, or T1c). If the specific information to assign the stage group is not available to the cancer registrar (including subcategories or missing prognostic factor categories), the stage group should not be assigned but should be documented as unknown.



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- Imaging shows stomach tumor invading serosa (T4a)
- Radiologist states cannot determine if invading transverse colon (T4b)
- Physician assigns cT4a
- Registrar assigns cT4

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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
 - Registry may NOT assign stage group if factor needed
 - Allows for accurate data analysis

In contrast, cancer registry data collection should record *X* or *unknown* if the prognostic factor is not available, and should not use the lowest category. This allows for accurate analysis of the data.

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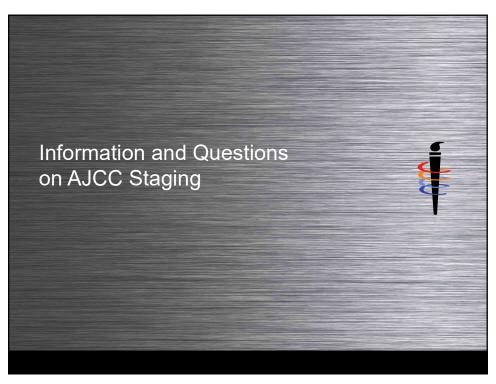


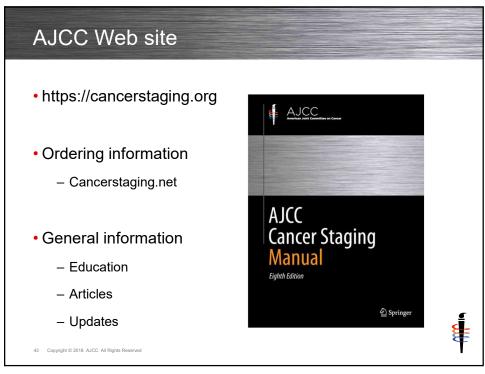
- Breast core biopsy for 2cm tumor not assigned Nottingham grade by pathologist
- Physician assigns G1 or appropriate G for clinical stage
- Registrar assigns GX

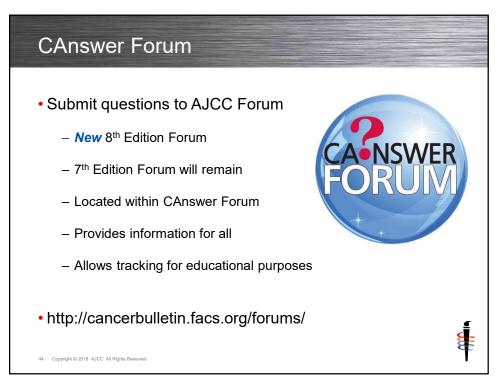


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Summary

- In-depth review to understand intention of rules
- Dissect rule changes in order to implement
- Realize influence of registry data on future staging changes
- Enhanced understanding through staging rule examples

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