



COLLEGE of AMERICAN
PATHOLOGISTS

The Cancer Protocols and Changes to Tumor Staging

*The Evolving Role of Pathology in Cancer
Reporting and General Rules for Cancer
Staging*

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- Advisory Board for American Joint Committee on Cancer
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Understanding the Landscape of Cancer Care

- **Cancer Care is complex**
 - **Episode(s) of care likely extend across numerous years**
 - Diagnosis
 - Primary treatment of cancer: surgical and medical
 - Watchful waiting and surveillance
 - Survivorship care

Understanding the Landscape of Cancer Care

- **Cancer Care is complex**
 - **Involve multiple providers**
 - Medical oncologists
 - Surgical oncologists
 - Radiation oncologists
 - Primary care team
 - Ancillary support: Radiology, Pathology, Clinical Laboratory
 - Others

Understanding the Landscape of Cancer Care

- **Geography: Patients move through different levels of care**
 - Community Hospitals
 - Cancer Centers or regional/referral centers
- **Clinical Trials are a standard part of Cancer Care for numerous malignancies**
 - NCCN Clinical Management Guidelines recommend consideration/enrollment as a routine part of clinical care
- **Target therapies increasingly become a mainstay of Cancer Care**
 - Require tumor biomarker testing (WGS, WES, IHC, etc.)

Understanding the Landscape of Cancer Care

- **Tumor Registry is more than just Population Health**
 - Intersection between clinical care and population health
- **Gap between clinical care, population health and research is rapidly closing**
- **Clinical Decision Support (CDS) and patient-facing technologies increasingly integrated and important part of Cancer Care**
- **The Cancer Moonshot: transforming Cancer Care**

Understanding the Landscape of Cancer Care

- **Standards for Cancer Care**
 - **Accreditation by Commission on Cancer (CoC)**
 - Drive quality and improved care and outcomes
 - Define the ‘standard of care’ irrespective of facility size and accreditation status
 - **Anatomic Staging: TNM Classification**
 - American Joint Committee on Cancer (AJCC) and Union for International Cancer Control (UICC)
 - Mainstay of determining prognosis and treatment

Understanding the Landscape of Cancer Care

- **Standards for Cancer Care**
 - **Evidence-based Clinical Practice Guidelines (CPG)**
 - National Comprehensive Cancer Network (NCCN)
 - American Society of Clinical Oncology (ASCO)
 - College of American Pathologists (CAP) Cancer Protocols
 - **Oncology Medical Home concept**

Understanding the Landscape of Cancer Care

- **Challenges and Gaps in Cancer Care**
 - Complexity of care
 - Barriers to access
 - Portability of patient information
 - Role of observational data in improving care and outcomes
 - Molecular testing laboratory infrastructure and data storage/management
 - Threats to bench-to-bedside research

Understanding the Landscape of Cancer Care

ASCO Vision: '*Cancer Care in 2030*'

- ✓ *Big Data-The Transformation of Cancer Care through Health Information Technology*
- ✓ *Panomics: Precision Medicine Realized*
- ✓ *From Cost to Value in Cancer Care*

Understanding the Landscape of Cancer Care

Big Data-The Transformation of Cancer Care through Health Information Technology

- Analyze and share data on every patient with care
- Draw immediate practice-changing conclusions from an immense body of data
- Transform clinical guidelines into living ‘crowd sourced’ documents
- The oncologist’s role transformed: robust and truly informative decision support at the point of care
- Patients as full partners: the power of patient-facing technologies

Understanding the Landscape of Cancer Care

Panomics: Precision Medicine Realized

- **Smarter better care**
 - Panomic tools simple, ubiquitous and affordable
 - Tumors will be molecularly well-understood and highly treatable
 - Combination targeted therapy will be the standard of care for most tumors
 - Cancer prevention and detection through precision medicine will come of age

Understanding the Landscape of Cancer Care

Panomics: Precision Medicine Realized

- **Biospecimens as a common good**
 - Will become standard practice
 - Collective responsibility through public dialogue
- **Clinical Cancer Research in the panomic era aided by powerful observational data**

Understanding the Landscape of Cancer Care

From Cost to Value in Cancer Care

- Value as the driver of oncology practice
- Keeping treatments affordable

The Role of Pathology in Cancer Care

- **High quality diagnostic, prognostic and treatment information to follow patient through entire course of Cancer Care**
 - Evidence-based and standardized reporting
 - Ensure that ALL the relevant information is present
 - Support patient care through entire continuum of care
 - Support downstream uses including Tumor Registry, clinical decision support, patient-facing technologies and survivorship care
 - Reduce fragmentation of reporting

The Role of Pathology in Cancer Care

- **High quality laboratory testing driven by accreditation requirements**
- **Biobanking as a standard part of clinical practice**
- **Precision Medicine: reducing the quality gap between routine collection of specimens for clinical care and biospecimen collection**

Pathology Landscape in Cancer Care

- **CAP Cancer Protocols**
 - **66 protocols and 13 biomarker templates**
 - **Focus on *content and clarity***
 - Identify minimum data set needed for cancer care
 - Provide format to ensure easy readability and reduce errors
 - **Biomarker templates parallel the Cancer Protocols for biomarker studies**

Pathology Landscape in Cancer Care

- **CAP Cancer Protocols**
 - **Paper version and electronic version available**
 - **Electronic version utilizes structured data and structured reporting**
 - Available as stand-alone product or as APLIS product
 - Approximately 2/3 of practices still use paper format

Pathology Landscape in Cancer Care

- **CAP Cancer Protocols**
 - **For accreditation purposes, Cancer Protocols required for use in:**
 - Definitive surgical resection of primary tumor of invasive malignancy and DCIS
 - Definitive surgical resection after neoadjuvant therapy when tumor is present

Pathology Landscape in Cancer Care

- **Minimum data set includes:**
 - **Required elements (core and conditional data elements)**
 - Required for clinical care
 - Required for staging
 - **Optional or recommended elements**
 - Generally do not meet stringent levels of evidence
 - Used for elements not necessary for immediate clinical management
 - Based on the opinion of the protocol authors

Pathology Landscape in Cancer Care

- **Format: The ‘synoptic report’**
 - Format based on general principles for reporting clarity
 - Ensures completeness and reduces risk of error

Pathology Landscape in Cancer Care

- **Accreditation Requirements:**
 - CAP Requirements for both completeness and clarity as well as audit process
 - Joint Commission Laboratory Accreditation Program requirements
 - Commission on Cancer (CoC) requirements (Standard 2.1)

Pathology Landscape in Cancer Care

- **Challenges and gaps:**
 - Information ecosystem for clinical care is broadening based on expanded and new uses for information
 - Cancer Care is becoming increasingly complex and so will our reporting requirements
 - Gap between clinical care, research and population health is rapidly closing
 - Requirements for Cancer Care changing rapidly

Pathology Landscape in Cancer Care

- **Challenges and gaps:**
 - Need for structured data becoming increasingly important
 - Electronic Health Records
 - ‘Big data’ uses for information
 - Portability of information to follow patient and for Clinical Decision Support/patient facing technologies
 - Tumor Registry and population health

Pathology Landscape in Cancer Care

- **Challenges and gaps:**
 - Cancer Protocols required ONLY for definitive surgical resection of primary tumor
 - Does not address the content requirements for Cancer Care that does not involve definitive surgical resection
 - Does not fully address the data needs of the cancer registry community

Pathology Landscape in Cancer Care

- **Challenges and gaps:**

- Two-thirds of practices use the paper protocols modified for their LIS
 - Data not in a structured format for integration into EHR and for downstream users
- Fragmented reporting due to biomarker testing done at a later date

Pathology Landscape in Cancer Care

- **Challenges in a nutshell: How do we report cancers in such a way that it is:**
 - Complete, clear and high quality **and**
 - *Provides all of the information necessary to allow a patient to navigate the entire continuum of care*

Pathology Landscape in Cancer Care

- **Challenges in a nutshell: How do we report cancers in such a way that it is**
 - Able to be used by our downstream users for clinical decision support, patient facing technologies, cancer registries among others
 - Information fully supports the information required for clinical management as defined in clinical practice guidelines **and**
 - Is manageable by the pathologist

The Way Forward for Cancer Reporting

- ***Fully supports the entire patient care episode throughout the entire Cancer Care continuum***
 - Expanding and promoting use for biopsies, other non-definitive surgical resections, cytologies, etc.
 - Able to support entire continuum of care including clinical trial enrollment

The Way Forward for Cancer Reporting

- ***Standardized terminology and content***
 - Fully aligning with terminology in AJCC Staging Manual
 - Utilizing WHO and ICDO-3 terminology
 - Content to support other downstream uses

The Way Forward for Cancer Reporting

- ***True structured reporting using structured data to support full utilization by EHR and downstream uses***
 - Moving from a primarily paper-based format to true electronic reporting
 - Supporting portability of data across entire continuum of Cancer Care
 - Reducing fragmentation of reporting
 - Fully supporting the ‘big data’ uses of pathology information
 - Reduces information burden for pathologists

General Rules for Cancer Staging: Overview

- **The extent or stage of tumor at the time of diagnosis is critical for:**
 - Defining prognosis
 - Determining treatment
 - Inclusion and stratification for randomized clinical trials (RCT)
 - Evaluating the results of treatment and clinical trials
 - Facilitating comparison of care across cancer treatment centers
 - Population health and surveillance
 - Basis for translational research

General Rules for Cancer Staging: Overview

- **Anatomic staging is still mainstay of cancer staging**
- **Evolving role of non-anatomic factors**
 - Provide critical information for stage grouping
 - Predict benefit of target-specific therapies
 - Enhancing clinical decision making
- **Assigning stage is the role of the managing physician**

General Rules for Cancer Staging: Overview

- **Several different staging systems based on anatomic factors**
 - TNM staging classification system most widely used
 - American Joint Committee on Cancer (AJCC) and Union for International Cancer Control (UICC)
 - Other staging systems

Understanding Terminology

- **Stage vs. stage group vs category vs classification**
- **‘Stage’ should be reserved for aggregate information from TNM categorization**
- **Stage groups or prognostic stage groups:**
 - Aggregate information from T, N and M and
 - Specified nonanatomic factor (“Prognostic Factors for Stage Grouping”) for specific cancer

Understanding Terminology

- **Classification: lower case prefix used to describe point in time of Cancer Care continuum:**
 - Clinical (c)
 - Pathologic (p)
 - Post-neoadjuvant therapy (yc or yp)
 - Recurrent or Retreatment (rc or rp)
 - Autopsy (a)

Understanding Terminology

- **Categorization: T, N, M and Prognostic Factors**
 - T, N, or M data used to assign site-specific T, N, and/or M for a patient at a given point in time
 - E.g. T1 or N1c
 - Prognostic Factors for Stage Grouping
 - Non-anatomic factors that have strong correlation with prognosis
 - Site and tumor-specific
 - Used to determine stage group

Understanding Terminology

- **Subcategorization:**
 - Specific cancers have subcategories to facilitate reporting of more detailed information
 - E.g. Breast: T1mi, T1a, T1b, T1c
- **Unknown designation X:**
 - Used if information on T or N is unknown
 - Usually not able to assign stage group
 - TX or NX should only be used if absolutely necessary
 - There is no MX category

General Staging Rules

- **Uncertainty regarding T, N, M categories or stage groups:**
 - Assign the lower of the two categories or stage groups
 - Does not apply to unknown or missing information
 - Does not apply to cancer registry
- **Grade:**
 - Recommended grading system for each cancer type
 - Specified in cancer-specific chapters of Staging Manual

General Staging Rules

- **Synchronous vs metachronous tumors:**
 - **Synchronous: multiple tumors of the same histology in an organ:**
 - Tumor of the highest T category is classified and staged
 - Use the (*m*) designation: e.g. pT3(*m*)N0
 - If number of tumors is important, then replace *m* with number e.g. pT3(4)N0
 - **Synchronous primaries in paired organs:**
 - Classify and stage as separate tumors
 - Site specific exceptions: thyroid and ovary

General Staging Rules

- **Synchronous vs metachronous tumors:**
 - **Metachronous tumors**
 - Defined as second or subsequent primary cancers occurring in same organ or in different organs outside the staging window
 - Stage independently
 - Do not use the y prefix

Pathological Classification (pTNM)

- **Time Frame:** from date of diagnosis to surgical resection in the absence of tumor progression (generally a four month window)
- **Criteria:** surgery is first therapy
- **Based on:**
 - **Pathologic evaluation of resected specimen and**
 - **Clinical stage information prior to definitive surgery including:**
 - Imaging studies
 - Clinical exam
 - Any biopsy or cytology information

Pathologic T Categorization (pT)

- **Optimally based on resection of single specimen**
- **If fragmented or resected at several different procedures:**
 - Reasonable estimate of tumor size should be made through pathologic assessment with the aid of imaging studies, if necessary
- **Direct extension of tumor into a node is classified as nodal involvement (pN)**
- **Direct extension into an adjacent organ is not considered metastatic involvement (pM)**

Pathologic N Categorization (pN)

- pN only applied to regional lymph nodes
- Distant nodal involvement categorized as a metastasis (M)
- Only one node needs to be documented in resection specimen to assign pN
 - Chapters often have minimum number of nodes defined for optimal resection
 - Fine needle aspiration is sufficient to assign pN
- **Direct extension of tumor into a regional lymph node:**
 - Assigned as pN and not as part of pT categorization

Pathologic N Categorization (pN)

- **Evolving Concepts:**
 - Isolated Tumor Cells and the use of the (*i+*) designator
 - Micrometases and use of the (mi) designator
 - Molecular techniques for identifying isolated tumor cells (mol+)

Pathologic M Categorization (pM)

- **pM0 and pMX are not valid categories**
- **pM1 with subcategorization, as appropriate, is only valid category**
- **If biopsy of clinically suspicious lesion is negative for tumor, then no pM should be assigned**
- **Fine needle aspiration is sufficient for pM categorization**

Understanding the Rules for Reporting after Neoadjuvant Therapy

- **Represents the post-therapy assessment**
 - **Time Frame:** surgery and staging occur within time frame appropriate for disease-specific circumstances
 - Use the 'yp' designator for definitive resection specimen
 - ypT and ypN represent pathologic response to neoadjuvant therapy
 - Complete pathologic response: ypT0N0
 - Partial pathologic response: assigned irrespective of original clinical categorization (e.g. cT3N1 may end up as ypT1N0 on resection)

Understanding the Rules for Reporting after Neoadjuvant Therapy

- **Represents the post-therapy assessment (continued)**
 - M category is not changed in post-neoadjuvant therapy assessment
- **Histologic confirmation of residual cancer requires presence of non-necrotic tumor cells**
 - Pools of acellular mucin or necrosis is not residual cancer
- **Not all treatment prior to definitive resection is considered 'neoadjuvant'**

Putting It All Together for the Pathologist

- **For accreditation purposes:**
 - pTNM or ypTNM classification should be assigned on definitive resection specimens of primary tumor
 - Recommend:
 - ✓ For most accurate classification, should include information from prior biopsies, imaging, etc., as appropriate
 - ✓ Note any assumptions or equivocal findings in comment
 - ✓ Pathologist should not provide stage grouping

Putting It All Together for the Pathologist

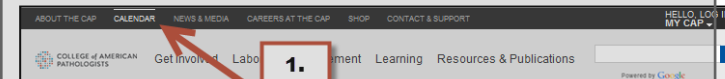
- **For optimal clinical care:**
 - **Biopsies:**
 - In general, shouldn't provide pTNM classification on biopsy specimens
 - Provide information necessary for appropriate clinical or pathologic classification in report, when possible
 - **Resection of recurrent tumors**
 - There is an rp designator, so pathologist should provide adequate information for staging, when possible

Putting It All Together for the Pathologist

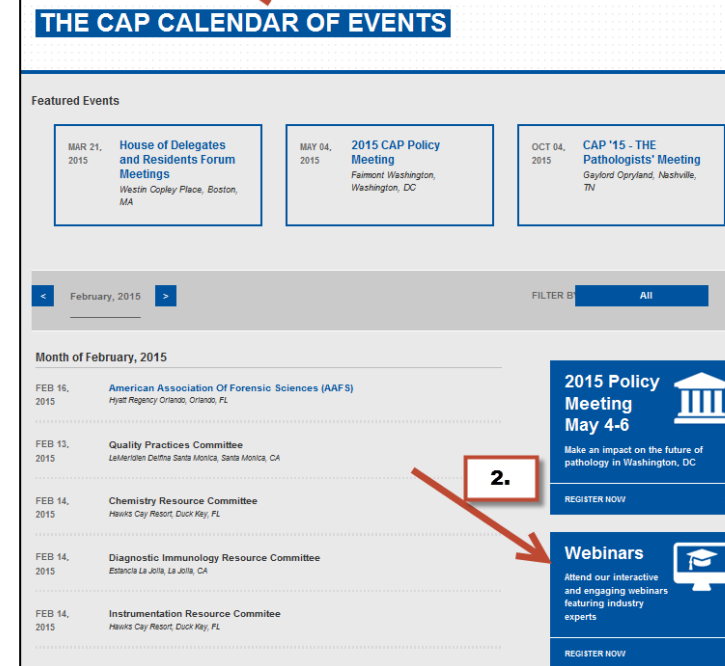
- **For optimal clinical care:**
 - **Understand the general rules for pTNM categorization!!**
 - Site-specific pTNM categorization much easier if you understand general rules
 - A wealth of information in Chapter 1 of the AJCC Staging Manual
 - Understand the general rules for determining pT, N or M categories
 - There are differences between tumor sites so use the Staging Manual for clarification

Save the Date for Upcoming Complimentary CAP PHC Webinars

DATE	TOPIC	SPEAKERS
June 14 11 AM CT	Emerging Concepts on Liquid Biopsy Testing	Abhijit A. Patel, MD, PhD Pranil Chandra, DO, FCAP

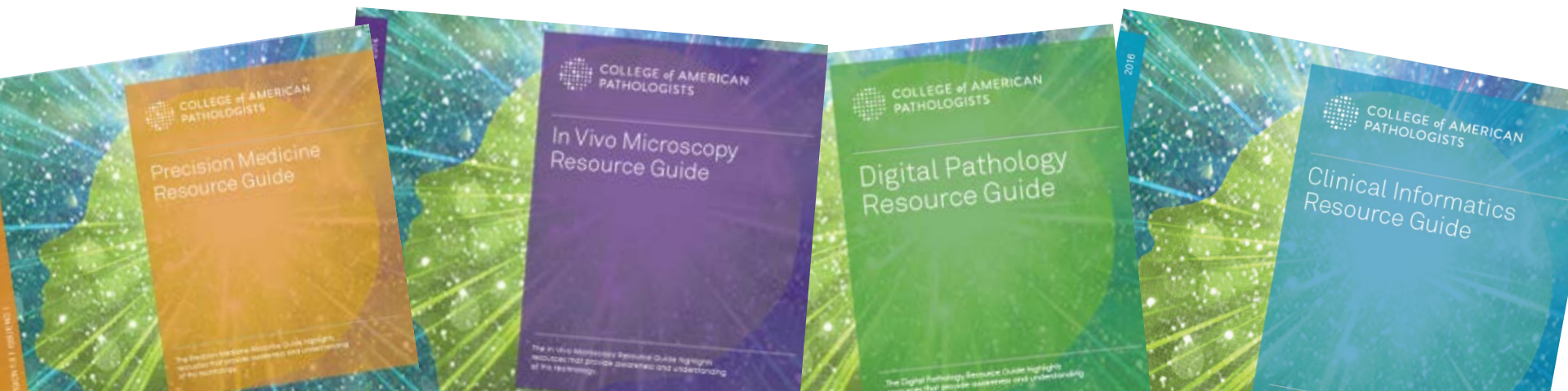


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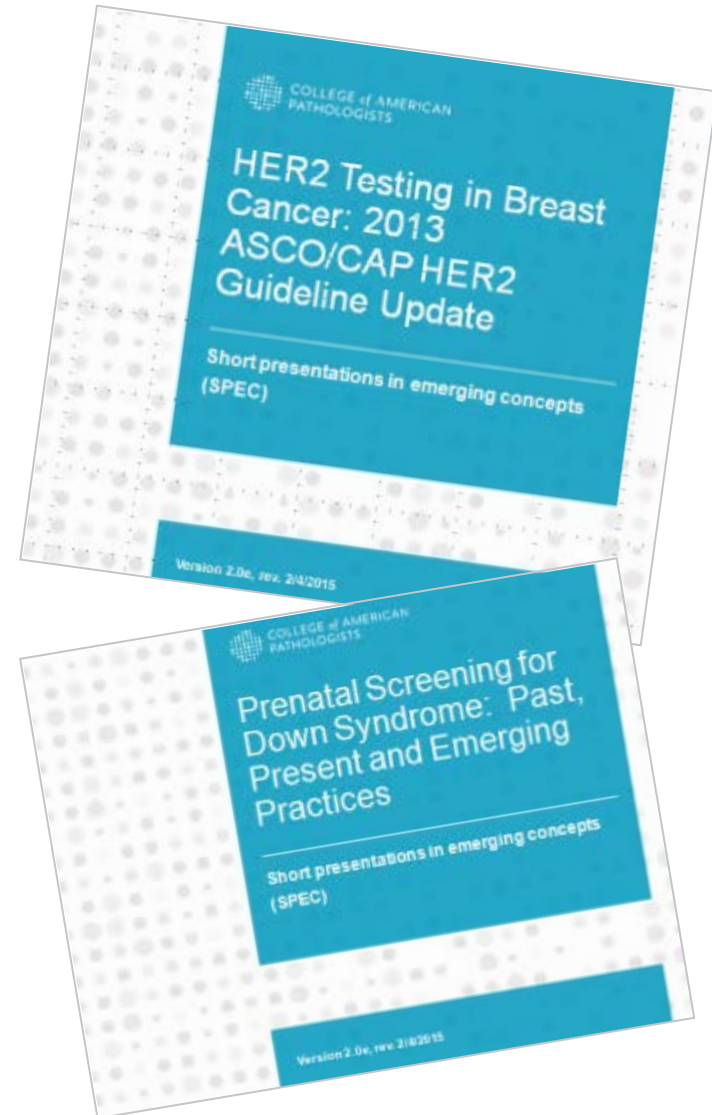
CAP's Pathology Resource Guide: Precision Medicine – **see handout**

- The CAP has created the Pathology Resource Guides to assist pathologists in understanding key emerging technologies.
 - Printed guides are now available for members (\$39) and non-members (\$69)
 - The digital copy of the Resource Guides are a complimentary member benefit
 - Access them www.cap.org > Resources and Publications



Short Presentations on Emerging Concepts (SPECS) – see handout

- Pathology SPECS are:
 - short PowerPoints, created for pathologists
 - Focused on diseases where molecular tests play a key role in patient management
- **New topics** are Renal Tumors, cell free DNA (cfDNA), and PD-L1 as well as other emerging topics
- Access them www.cap.org > Resources and Publications





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