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CAP Companion Meeting at 2017 USCAP

Mission Control–The Value of Cancer Protocols, Staging Manuals, and Key Revisions to Select Tumor Sites

Moderators:
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March 5, 2017

PLEASE TURN OFF YOUR CELL PHONES

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Agenda

Topic	Time
Introduction — Joseph D. Khoury & Larissa V. Furtado	8:30 AM
Why Cancer Protocols? — Thomas P. Baker	8:35 AM
Common Changes in TNM Staging — Thomas P. Baker	9:00 AM
Pathologic Staging Updates in Breast Cancer — Patrick L. Fitzgibbons	9:25 AM
Break	9:55 AM
Pathologic Staging Updates in Prostate Cancer — Ming Zhou	10:25 AM
Pathologic Staging Updates in Colorectal Cancer — Sanjay Kakar	10:55 AM
Pathologic Staging Updates in Lung Cancer — Sanja Dacic	11:25 AM
Closing Comments and Final Q&A — Moderator & Faculty	11:55 AM

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Why Cancer Protocols?

The Vision for Cancer Care and the Role of Pathology Reporting

Thomas P. Baker, MD FCAP

March 19, 2017

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Dr. Thomas P. Baker declares he has no conflict(s) of interest to disclose.

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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**

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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**

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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**

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Understanding the Landscape of Cancer Care

- **Targeted therapies increasingly become a mainstay of Cancer Care**
  - **Require tumor biomarker testing (WGS, WES, IHC, etc.)**
- **Tumor Registry is more than just Population Health**
  - **Intersection between clinical care and population health**

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Understanding the Landscape of Cancer Care

- **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**

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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**

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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**

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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**

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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***

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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**

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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**

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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**

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Understanding the Landscape of Cancer Care

From Cost to Value in Cancer Care

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

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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**

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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**

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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**

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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**

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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**

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Pathology Landscape in Cancer Care

- **Minimum data set includes:**
  - **Required or core data elements:**
    - **Required for clinical care**
    - **Required for pTNM classification**
  - **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**

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Pathology Landscape in Cancer Care

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

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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)**

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Pathology Landscape in Cancer Care

- **Challenges and gaps:**
  - **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**

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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 for clinical decision support and other technologies**
    - **Tumor Registry and population health**

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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**

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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**

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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**
  - **Provides all of the information needed for clinical management**
  - **Portable across the entire continuum of patient care including determining eligibility for Clinical Trials**

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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**

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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**

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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**

CAP

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**

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Common Changes in TNM Staging

Understanding the General Rules of Cancer Staging

Thomas P. Baker, MD FCAP

March 5, 2017

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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**

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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**

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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**

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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**

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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)**

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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**

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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**

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General Staging Rules

- **Microscopic confirmation necessary for TNM classification with rare exceptions**
- **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**

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General Staging Rules

- **Time Frame for staging cancers:**
  - **Clinical: From date of diagnosis before initiation of primary treatment or watchful waiting/supportive care *to* one of the following:**
    - **Four (4) months after diagnosis *or***
    - **Date of cancer progression *if* progression occurs within the four month window**

CAP

General Staging Rules

- **Time Frame for staging cancers:**
  - **Pathological: Information from clinical staging and data from resected specimen may be used if:**
    - **Surgical resection occurs within four months of date of diagnosis**
    - **To the date of cancer progression if progression occurs within the four month window**
    - **Can use information about extent of cancer up to the point of definitive resection if resection occurs outside of four month window *and* cancer has not clearly progressed**

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General Staging Rules

- **Time Frame for staging cancers:**
  - **Neoadjuvant Therapy (yp): Time frame should be such that surgery and staging occur within time frame appropriate for disease specific circumstances**

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General Staging Rules

- **Synchronous vs metachronous tumors:**
  - **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, ovary, lung and liver**

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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**

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Pathological Classification (pTNM)

- **Time Frame: from date of diagnosis to surgical resection in the absence of tumor progression**
- **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**

CAP

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)**

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Pathologic Nodal 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**

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Pathologic Nodal 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**

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Understanding the Rules for Reporting after Neoadjuvant Therapy

- **Represents the post-neoadjuvant therapy assessment**
  - **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)**
  - **M category is not changed in post-neoadjuvant therapy assessment**

CAP

Understanding the Rules for Reporting after Neoadjuvant Therapy

- **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’**

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Putting It All Together for the Pathologist

- **For accreditation purposes:**
  - **pTNM or ypTNM classification should be assigned on definitive resection specimens of primary tumor**
  - **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**

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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**

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Putting It All Together for the Pathologist

- **For optimal clinical care:**
  - **Understand the rules for pTNM classification!!**
    - **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**

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Putting It All Together for the Pathologist

- **For optimal clinical care:**
  - **We are part of the multidisciplinary team involved in Cancer Care**
    - **Our responsibility does not end with issuing of report**
    - **Involvement and ongoing communication**

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