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

Moderators:
Joseph D. Khoury, MD, FCAP
Larissa V. Furtado, MD, FCAP
March 5, 2017

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

PLEASE TURN OFF YOUR CELL PHONES

Agenda

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

Disclosure of Relevant Financial Relationships

USCAP requires that all planners (Education Committees) in a position to influence or control the content of CME disclose any relevant financial relationship WITH COMMERCIAL INTERESTS which they or their spouse/partner have, or have had, within the past 12 months, which relates to the content of this educational activity and creates a conflict of interest.

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

Disclaimer

The identification of specific products or scientific instrumentation is considered an integral part of the scientific endeavor and does not constitute endorsement or implied endorsement on the part of the author, DoD, or any component agency. The views expressed in this presentation are those of the author and do not reflect the official policy or position of the United States Army, United States Air Force, United States Navy, the Department of Defense, or the U.S. Government.
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

- 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

- 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

- 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

- 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

- 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

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

- 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

- 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
  - 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 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

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:
  - 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

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

Pathology Landscape in Cancer Care

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

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 ICD-O-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