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Pathologist Leadership in Quality for Cancer Care and Biorepositories

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Presentation Overview

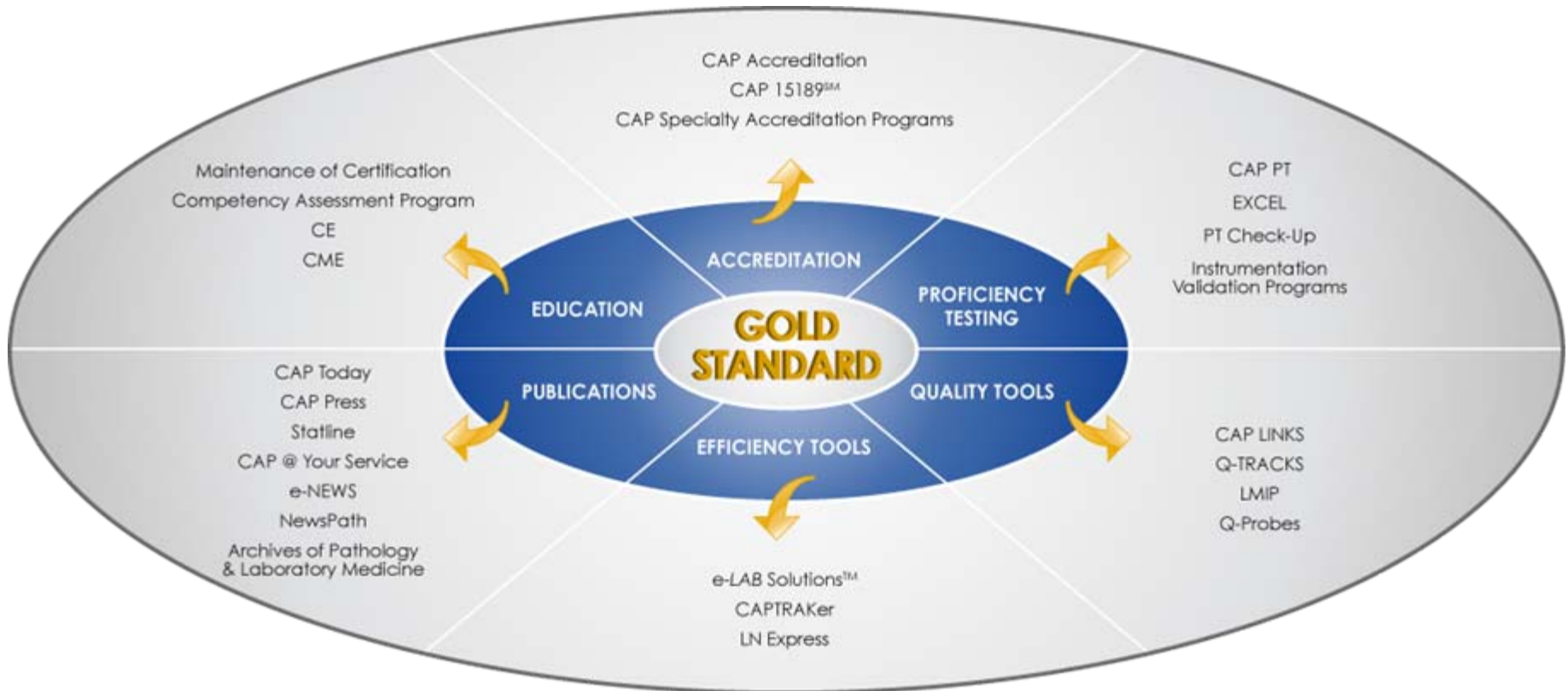
- CAP History and Background
- Pathology and Pathologist Transformation
- Leadership and Initiatives in Cancer Care
- Experience and Innovation in Accreditation
 - CAP Accreditation for Biorepositories
- Questions

CAP: Committed to Laboratory Improvement Worldwide



- Pathologists launch the CAP in 1946
- Community widely recognizes the CAP as an international leader in quality assurance and management as it:
 - Introduces first External Quality Assessment (EQA), now **proficiency testing (PT) or Surveys**, in 1947 for glucose
 - Provides PT to more than 23,000 laboratories in more than 90 countries; > 800 analytes (tests)
 - Offers robust line of **anatomic pathology** programs
 - Delivers **laboratory accreditation** for more than 50 years, since 1961
 - Accredits more than 7,000 laboratories in 45 countries; programs include: Laboratory Accreditation, Reproductive Laboratory, Forensic Drug Testing, ISO 15189, and **Biorepositories**
 - Develops **standards and guidelines** for quality laboratory and pathology practice

The CAP's Comprehensive Offering for the Laboratory



The CAP's Role and Mission: Committed to Excellence

CAP Mission: "...the leading organization of board-certified pathologists, serves patients, pathologists and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine."

We are 18,000 members; many who represent the laboratory community's interests on the CAP's accreditation and proficiency testing resource committees.



Pathologists Collaborate Worldwide to Develop and Maintain Standards in Medicine



- American Association of Clinical Chemistry
- American Association of Blood Banks
- American College of Surgeons Commission on Cancer
- American Society of Clinical Oncology
- American Society of Reproductive Medicine
- Clinical and Laboratory Standards Institute
- Commission on World Standards and Accreditation
- International Laboratory Accreditation Cooperation
- International Society for Biologic and Environmental Repositories
- ISO TC212 Working Groups
- Liaisons with specialty societies for PT
- National Quality Forum
- United Network of Organ Sharing
- World Association of Societies of Pathology and Laboratory Medicine

Collaboration Improves Patient Care

- Research showed a 50 percent response rate when HER2 positive breast cancer was treated with Herceptin
- However, HER2 was running at a 25 percent false positive and the drug is highly cardiotoxic
- CAP partnered with ASCO to write HER2 clinical practice guidelines for the improvement of HER2 accuracy



Summary of ASCO/CAP HER2 Guideline Recommendations

Optimal algorithm for HER2 testing

Recommendation:

Positive for HER2 is either IHC HER2 3+ (defined as uniform intense membrane staining of > 30% of invasive tumor cells) or FISH amplified ratio of HER2 to CEP17 of >2.2 or average HER2 gene copy number >4x signals/nucleus for those test systems without an internal control probe).

Equivocal for HER2 is defined as either IHC 2+ or FISH ratio of 1.8-2.2 or average HER2 gene copy number four to six signals/nucleus for test systems without an internal control probe.

Negative for HER2 is defined as either IHC 0-1+ or FISH ratio of <1.8 or average HER2 gene copy number of <four signals/nucleus for test systems without an internal control probe.

Comments:

These definitions depend on laboratory documentation of the following:

1. Proof of initial testing validation in which positive and negative HER2 categories are 95% concordant with alternative validated method or same validated method for HER2.
2. Ongoing internal QA procedures.
3. Participation in external proficiency testing.
4. Current accreditation by valid accrediting agency.

Optimal FISH testing requirements

Recommendation:

Fixation for fewer than 6 hours or longer than 48 hours is not recommended.

Test is rejected and repeated if:

- Controls are not as expected.
- Observer cannot find and count at least two areas of invasive tumor.
- >25% of signals are unscorable due to weak signals.
- >10% of signals occur over cytoplasm.
- Nuclear resolution is poor.
- Autofluorescence is strong.

Interpretation done by counting of least 20 cells; a pathologist must confirm that counting involved invasive tumor.

Sample is subjected to increased counting and/or repeated if equivocal report must include guideline-detailed elements.

Optimal IHC testing requirements

Recommendation:

Fixation for fewer than 6 hours or longer than 48 hours is not recommended.

Test is rejected and repeated or tested by FISH if:

- Controls are not as expected.
- Artifacts involve most of sample.
- Sample has strong membrane staining of normal breast ducts (internal controls).

Interpretation follows guideline recommendation.

- Positive HER2 result requires homogeneous, dark circumferential (chicken wire) pattern in >30% of invasive tumor.
- Interpreters have method to maintain consistency and competency.

Sample is subjected to confirmatory FISH testing if equivocal based on initial results.

Report must include guideline-detailed elements.

Wolff AC, Hammond ME, Schwartz JL, et al. American Society of Clinical Oncology/College of American Pathologists guideline recommendations for human epidermal growth factor receptor 2 testing in breast cancer. *Arch Pathol Lab Med*. 2007;131:18-43.

Pathology and Pathologists Transformation

- In response to changes in the health care system, medical science, and technology, the CAP launched a multiyear campaign to transform pathology.
- Transformation refers to the collective efforts now under way at the CAP and across the specialty to foster new and enhanced roles for the pathologist and greater recognition of the pathologist as a physician and a critical member of the patient care team.
- Transformation will have an enormous impact on:
 - The way pathologists practice
 - How their clinical colleagues, patients, and others in the medical community perceive them
 - How they are reimbursed for their services

Pathology and Pathologists Transformation

- The goal of Transformation is to strengthen and defend the value proposition i.e., unique benefits, that pathologists offer to patients and fellow clinicians.
- Transformation initiatives will define, model, and demonstrate a new set of value-added services that no other physician specialty can perform as well and that create new economic opportunities for pathologists and improve patient outcomes.

Pathology and Pathologists Transformation

- The CAP launched a Transformation Program Office, including The CAP Pathology and Laboratory Quality Center (The Center), which:
 - Helps pathologists and other clinicians make more informed decisions about diagnosis and optimal treatment, and places emphasis on transforming the pathologist's role to the center of patient care.
 - Illustrates that pathologists strive for self-regulation and continuous improvement. The development and adoption of new guidelines results in more effective use of testing, consistent, high-quality results and expert interpretations.
 - Facilitates stronger alliances with other medical specialties and patient advocacy organizations.

Pathology and Pathologists Transformation

- Genomically-informed personalized medicine is a driving impetus for the CAP's Transformation initiatives:
 - “Personalized medicine is about changing how we think about cancer and how we think about the care we deliver to patients. As pathologists, we tend to be very focused on getting the diagnosis right. We have to expand our thinking to include not only getting the right diagnosis but also taking it one or two steps further, to characterize that tumor more specifically so the treatments can be custom tailored.”
 - Sam Caughron, MD, FCAP, Vice Chair, CAP Personalized Healthcare Committee
 - Research and biorepositories offer opportunities for pathologists.
 - CAP members will publish a peer-reviewed article on roles for pathologists in the field of biospecimens and biorepositories in the *Archives of Pathology and Laboratory Medicine*, June 2012.

Leadership and Initiatives in Cancer Care

- **Cancer Protocols:**
 - The CAP provides more than 65 Cancer Protocols, one for every major tumor site or tumor type; most designed for resection specimens, some exist for biopsies, e.g. prostate, soft tissue, bone marrow.
 - CAP Cancer Committee members lead multidisciplinary teams of medical experts to facilitate development of protocols for the comprehensive pathology reporting of cancer specimens.
 - Protocols, now an integral part of routine pathology practice for many institutions, promote through standardization of pathology reporting:
 - Consistency between individuals and institutions
 - Comprehensive inclusion of all important data elements
 - Less ambiguity in terminology
 - Data to be more easily communicated, compared, and retrieved, fostering research

Leadership and Initiatives in Cancer Care

- The CAP Pathology and Laboratory Quality Center (The Center) is collaborating with International Association for the Study of Lung Cancer (IASLC) and Association for Molecular Pathology (AMP) to publish the **Molecular Testing Guidelines for Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors** in 2012 and Whole Slide Imaging Validation.
- **Q-MONITORS™: Completeness of Cancer Reporting**, a CAP quality monitor on completeness of cancer reporting, specific to cancer centers, which can be used as an ongoing quality performance measure to assess whether departments are in compliance with cancer reporting standards. Helps cancer centers fulfill the American College of Surgeons/Commission on Cancer (ACS CoC) requirements for self-auditing pathology reports.
- **CAP Learning Events:**
 - Companion Society Symposium at USCAP 2012: *Bridging the Divide between Molecular and Surgical Pathology*
 - Satellite Symposium at American Society of Breast Disease 36th Annual Symposium: *Radiologic and Pathologic Correlation of Breast Imaging Abnormalities of Breast Needle Core Biopsy*
 - Multidisciplinary Breast Pathology Advanced Practical Pathology Program (MBP AP3) and Breast Predictive Factors Testing Advanced Practical Pathology Program (BPFT AP3)

Leadership and Initiatives in Cancer Care

- **CAP Advocacy:**
 - Participates in the Cancer Leadership Council (CLC), a patient-centered forum of national advocacy organizations addressing public policy issues in cancer.
 - Supports federal legislation aimed at improving cancer care, including legislation related to cancer prevention, research, clinical trials and patient-centered care coordination.
 - Facilitates pathologists' participation in State Comprehensive Cancer Control Plans.
- **Patient-Centered Web sites:**
 - **MyBiopsy.org** provides patients and their loved ones with accurate and credible information on more than 40 of the most common cancers and cancer-related conditions. The site offers resources, tools, and features to help patients and their families better understand their diagnosis and evaluate treatment options.
 - **MyHealthTestReminder.org** gives visitors the tool to register to receive an email or text message reminder prompting them to call their physicians to schedule potentially life-saving health screening tests or make a blood donation.

Experience and Innovation in Accreditation

Considered the industry's Gold Standard, CAP Accreditation sets high standards for clinical, anatomic, and specialty laboratories that address quality, efficiency, and safety:

- Exceeds U.S. Federal Government regulatory requirements
- Provides a solid foundation for quality practices
- Leads in developing requirements for molecular oncology, cytogenetics, and reproductive medicine
- Includes field teams with mixed language capabilities in Asia, Middle East, South America, India, Europe, Mexico, etc.



Experience and Innovation in Accreditation

- In 2011-2012, we are celebrating 50 Years of CAP Accreditation
 - Since 1961, approximately 8,000 CAP member pathologists have served as accreditation team leaders or inspectors.
 - Of the more than 7,000 CAP-Accredited laboratories:
 - 250 laboratories have been enrolled for 40–50 years
 - 1,250 enrolled for 30–40 years
 - 1,000 enrolled for 20–30 years
 - CAP accreditation, in addition to core program, includes specialty programs:
 - Forensic Drug Testing (1989)
 - Reproductive Testing (1992)
 - ISO 15189 (2008)
 - Biorepositories (2011)



Experience and Innovation in Accreditation

- The CAP Biorespository Accreditation Program:
 - Represents first of its kind in the industry
 - Aims to help biorepositories:
 - Identify stages in the **biospecimen management** sequence, from patient to analysis
 - Enable continuous oversight of practices to **improve biospecimen quality**
 - Comply with **standardized criteria** to increase confidence in biospecimen quality



Experience and Innovation in Accreditation

- The CAP Biorespository Accreditation Program:
 - Integrates rigorous biorepository guidelines and best practices from:
 - International Society for Biological and Environmental Repositories
 - NCI's Office of Biorepositories and Biospecimen Research
 - Organization for Economic Co-Operation and Development
 - College of American Pathologists



CAP Accreditation for Biorepositories: Why the CAP?



- Thousands of biorepositories exist, varying in:
 - Size
 - Nature of collections
 - Specimen types
 - Purpose
 - Quality
 - Age
- Some biorepositories do not fulfill research requirements (most importantly personalized medicine); a high degree of heterogeneity exists in the methods used to collect, process, and store biospecimens: **frozen and FFPE**.
- The CAP believes excellence and quality measures in biorepositories are interrelated concerns that have direct bearing on research that can help advance health care.
- The CAP Accreditation for Biorepositories Program will help ensure consistent, industry-wide verification of biospecimen quality.

CAP Accreditation for Biorepositories: Why the CAP?

- Pathologists
 - As the custodians of specimens, pathologists work closely with clinical colleagues, e.g. surgeons, operating room nurses, etc. to:
 - Maintain specimen integrity for cancer and other clinical research
 - Preserve biospecimens quickly to protect quality and improve research, conserving:
 - RNA
 - DNA
 - Protein
 - Other macromolecules and metabolites



CAP Accreditation for Biorepositories: Why the CAP?

- As we reflect, I call upon the words of one of our past leaders, who wrote:
 - “... There has been constant surveillance, bearing in mind cost-containment and the fact the entire benefit is for the patient and the physician who treats the patient.”
 - **Maj. Gen. Joseph M. Blumberg, MC, USA Ret., FCAP, former Chair, CAP Commission on Accreditation.**
- As we look forward, the CAP:
 - Ventures into:
 - Accrediting biorepositories
 - Developing standards for genomics-informed medicine
 - Broadening accreditation internationally
 - Accreditation Programs carry on into the ages for physicians and their patients.



Questions





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