College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

Direct Response To:
DIVISION OF ADVOCACY
1350 I Street, NW, Suite 590
Washington, DC 20005-3305
202-354-7100 Fax: 202-354-7155
800-392-9994 • cap.org

April 22, 2009

Patrick Conway, M.D., MSc
Executive Director
Federal Coordinating Council on Comparative Effectiveness Research
The U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Conway:

The College of American Pathologists appreciates the opportunity to forward our comments and recommendations about which areas should have the highest priority for research funding using money allotted to the Secretary of the DHHS in the American Recovery and Reinvestment Act of 2009.

The College of American Pathologists is a medical society serving more than 17,000 physician members and the laboratory community throughout the world. It is the world's largest association composed exclusively of pathologists and is widely considered the leader in laboratory quality assurance. The CAP is an advocate for high-quality and cost-effective medical care.

As medicine becomes increasingly complex, diagnostics are being used to identify complex health states, identify predisposition to disease, characterize an individual's state of health or disease, and inform clinical decision-making about personalized health care delivery. Laboratory testing already provides key health information that may influence 60 to 70 percent of medical decisions[1] and is likely to only increase in importance. Despite advances in technology and understanding, the health care system is currently operating without critical information and decision support to address the appropriateness of medical interventions, treatments, procedures, tests, and the therapeutics. Care delivery remains fragmented and providers and patients are looking for insights to help determine what treatments benefit individual patients most.

[1] Forsman R.W., Why Is the Laboratory an Afterthought for Managed Care Organizations? Clin Chem 1996; 42:813-16.

The goal of the health care system should be to provide accessible quality health care to patients. Selecting the appropriate test for a specific patient to institute optimal care is critical for achieving this goal. The CAP believes that it is necessary to support research that will give health care providers, patients and the entire health care system tools that can be used to deliver on the promise of patient-centered care and enhanced patient satisfaction. Importantly, as new assays are developed, they must be studied in the context of traditional methods.

In order to minimize barriers to achieving personalized health care, additional research is needed. The CAP urges the IOM to focus research and investigation to answer the following questions:

- How can the heath care system generate better understanding about the overuse, underuse and misuse of health care resources through provision of personalized health care?
- What metrics can be used to evaluate appropriate test selection and the role it plays in improving patient outcomes?
- By what mechanisms, processes, and practices can health care professionals and patients better use available research in support of clinical decision-making?
- What role does personalized health care play in eliminating or reducing disparities in diagnosis, treatment and patient outcomes?
- What organizational processes and practices support appropriate test selection and use?
- How can it be demonstrated that improved access and interoperability (with available data sources) support better use of laboratory tests?
- What are organizational obstacles to integrating laboratory data with other available data sources and the patient medical record?
- What tools best support clinical decision-making and help providers meet current demands for knowledge about new and emerging laboratory technologies?
- What mechanisms exist, or should exist, to ensure that providers and patients have the flexibility to tailor care and consideration of treatment options?

The following studies illustrate the important findings this type of research generates:

1. Valerie A. White MD, MHSc, FRCPC and Martin J. Trotter MD, PhD, FRCPC. 2008: **Intraoperative Consultation/Final Diagnosis Correlation: Relationship to Tissue Type and Pathologic Process.** *Archives of Pathology and Laboratory Medicine*: Vol. 132, No. 1, pp. 29–36. The correlation of the diagnosis made at intraoperative consultation (IC) with the final diagnosis is one of the cornerstones of quality assurance in the anatomic pathology laboratory.

The IC is shown to be an excellent diagnostic test. Agreement and deferral rates vary by specimen site and by type of assessment requested.

2. George J. Netto MD and Rana Domiati Saad PhD. 2006: **Diagnostic Molecular Pathology: An Increasingly Indispensable Tool for the Practicing Pathologist.** *Archives of Pathology and Laboratory Medicine*: Vol. 130, No. 9, pp. 1339–1348. Diagnostic molecular pathology is rapidly becoming an indispensable tool. Familiarity with some of the technologic principles and current, as well as upcoming, molecular diagnostic applications is greatly advantageous for diagnosis and management of disease.

3. Paul N. Valenstein MD, Molly K. Walsh PhD and Frederick Meier MD. 2004: **Heparin Monitoring and Patient Safety: A College of American Pathologists Q-Probes Study of 3431 Patients at 140 Institutions.** *Archives of Pathology and Laboratory Medicine*: Vol. 128, No. 4, pp. 397–402. Appropriate laboratory monitoring of unfractionated heparin therapy promotes effective anticoagulation while minimizing hemorrhagic complications. Prevention of heparin over-anticoagulation is an important opportunity to improve patient safety.

4. Francisco Javier Ramos, Teresa Macarulla, Jaume Capdevila, Elena Élez, Josep Tabernero 2008: **Understanding the Predictive Role of K-*ras* for Epidermal Growth Factor Receptor–Targeted Therapies in Colorectal Cancer.** *Clin Colorectal Cancer* 2008 Dec7 Suppl. 2 S52-7 New agents are now available to treat colorectal cancer patients who do not respond to more traditional treatments. Testing for genes such as K-ras help to determine which patients will benefit from these treatments.

5. Wolff Antonio et al. 2007: **American Society of Clinical Oncology/College of American Pathologists Guideline Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer.** *Arch Path Lab Med*;131:18-43 Accurate testing for Her-2/neu is essential in selecting therapy and predicting response for patients with invasive breast cancer. To promote inter-laboratory consistency, oncologists and pathologists collaborated to standardize the testing practices and interpretation of Her-2/neu test results.

6. Klee, George et al, 1999: **Analytical bias specifications based on the analysis of effects on performance of practice guidelines**. *Scand J Clin Lab Invest* 59(7):509-12. Calibration errors in cholesterol, PSA and TSH have a large impact on the proportion of tested patients who will undergo prostate biopsy, additional thyroid testing, or subsequent treatment with statins. Depending on the direction of the bias, errors of either omitted or unnecessary care may occur. This study demonstrated that specification of performance factors (precision, bias, analytical sensitivity and patient factors) leads to more effective personalized testing and patient care.

CAP recommends that the Committee prioritizes the central role that laboratory testing and diagnostics play in eliminating and minimizing the burden of disease, enhancing patient safety, and promoting patient-centered and personalized care.

Again, the CAP is supportive of the IOM efforts and suggests the following guiding principles and design strategies are taken under consideration:

- Any organizational entity that evaluates clinical effectiveness must be independent, objective, transparent and inclusive.
- Priorities should be based on consensus criteria derived from input provided by providers, specialists, patients, payers, purchasers and researchers.
- Pathologists and the pathology community should have substantial and central representation on the determining body because of their central role in medical decisions.

Thank you for your consideration of these comments and recommendations, should you have questions about this letter or other matters, please contact Fay Shamanski at (202)354-7113.

Sincerely,

John Scott
Vice President, Division of Advocacy

cc: Mary B. Barton