



Association for Molecular Pathology

Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology

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Association for Molecular Pathology Urges Comprehensive Measures to Incorporate Molecular Diagnostic Tests Into Comparative Effectiveness Research

AMP Outlines Priority Concerns and Identifies Key Areas of Opportunity in Letter to Federal Coordinating Council

Washington, DC – June 12, 2009 -- The Association for Molecular Pathology (AMP) today released the text of a comment letter it has provided to the Federal Coordinating Council for Comparative Effectiveness Research (CER) in which AMP sets forth its recommendations for priority areas on which to focus CER activities.

“CER is garnering substantial attention in Congress and among other policy makers who see it as a method to examine the comparative effectiveness of treatments, including how they relate to coverage and reimbursement decisions” wrote AMP President Jan A. Nowak, MD, Ph.D. “Diagnostic tests will most definitely be included in this paradigm, especially when the effectiveness of treatments will vary among different population subgroups. Unfortunately, the value of diagnostics in improving clinical outcomes has not been appreciated adequately in the past; therefore, considering the role of genomics under CER will be critical.”

Dr. Nowak continued to say that in order for CER to be a success, it will be essential to train experts in diagnostics (including molecular diagnostics) in current health services research methods as well as to train health services researchers in the technical areas they will assess. This cross training will be essential to ensure that the research methods are technology appropriate.

“There is much less experience in assessing the role of the diagnostic test itself in appropriate and cost effective management of individual patients,” wrote Dr. Nowak. “Therefore, AMP encourages the Coordinating Council to invest in the cross-training of researchers and diagnostics experts as well as to build the infrastructure within the agencies to understand and review data from different types of technologies.”

The AMP letter recommends the development of a model process for CER regarding clinical laboratory tests. This model should include the creation of a panel of experts consisting of physicians and scientists, including laboratorians with molecular diagnostics expertise, economists, and reimbursement specialists; the creation of an electronic clearinghouse for information on CER projects similar to www.clinicaltrials.gov; the development and adoption of standards for the collection and storage of data from genetic testing laboratories in order to facilitate interoperability among databases; and a requirement that data from technologies and tests being assessed be generated from CLIA-, CAP-, ISO-, or FDA- certified institutions.

Additionally, AMP wrote that in order to routinely incorporate information that relates patient outcomes to genetic variations into clinical care, there is a need to jointly fund large, carefully designed comparative effectiveness trials for molecular tests with

observational comparative effectiveness studies that complement the randomized controlled trials by including patients who do not necessarily meet the inclusion criteria for traditional prospective trials.

AMP's comment letter also called for measures for the evaluation of genomic tests and clinical molecular diagnostics laboratories. For the public to reap the benefits of effective molecular tests, it is critical that all laboratories meet high performance standards and participate in proficiency testing programs utilizing appropriate reference and control materials. Specifically the letter recommends funding a program to develop new reference materials to aid the continued advancement of quality measures in laboratory medicine; the development of proficiency testing methods as alternatives to distributing surrogate test specimens; and, the development of appropriate quality assurance measures for new technologies such as whole genome sequencing.

Finally, as Dr. Nowak wrote, "Despite the possibility of saving the healthcare system thousands of dollars per patient and improving the quality of care, diagnostics have been historically under valued. AMP hopes that any CER activities will include research to explore the value, beyond simply cost, of diagnostic tests to patients, providers, payers and the larger health care system."

Full text of the AMP comment letter can be found at www.amp.org.

About AMP

The Association for Molecular Pathology is an international medical professional association dedicated to the advancement, practice, and science of clinical molecular laboratory medicine and translational research based on the applications of molecular biology, genetics and genomics. Through the efforts of an enthusiastic membership from across the United States and around the world, AMP continues to grow in numbers and influence. The organization is divided into the scientific subdivisions of genetics, infectious diseases, hematopathology, and solid tumors. Each subdivision addresses issues, identifies goals, shapes policy, and provides member benefits specific to that particular discipline. The AMP membership includes individuals from academic medical centers, independent laboratories, government, and industry, including physicians, laboratory directors, scientists, medical technologists, and trainees. AMP members populate the majority of clinical molecular diagnostic laboratories in the United States. AMP members are at the forefront of the development and implementation of novel molecular diagnostic tests, whether these are laboratory developed or commercially developed. AMP promotes molecular testing that is consistent with the highest standards established by CLIA, the College of American Pathologists (CAP), the American College of Medical Genetics (ACMG), and FDA. AMP members proudly accept their responsibilities in assessing the analytical validity, clinical validity, clinical utility, and the clinical utilization of molecular tests for each specific patient.

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