THE ChAMPion

AMP update on U.S. policy issues affecting molecular diagnostics.

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Letter from the President

Dear AMP members,

Mosquito season is arriving in the U.S. and laboratories across the country are working hard to develop accurate diagnostic procedures as soon as possible. In March, Texas Children's Hospital and Houston Methodist created a laboratory developed procedure (LDP), which by identifying virus-specific RNA sequences, is able to provide a diagnosis in a few hours. Immediately after the announcement, FDA sent the AMP-member physicians who developed this test an "It Has Come to Our Attention Letter" asking to review the LDP's design, validation, and procedure information. As of April 12, there are no FDA-approved tests for Zika. Further, the only Emergency Use Authorizations (EUA) have been solely provided to CDC, who, to date, have only authorized state public health laboratories and the domestic and international laboratories belonging to the Laboratory Response Network. CDC's announcement noted that no U.S. hospitals would receive authorization on their RT-PRC assay. The public health laboratory network, while important and necessary, is not sufficient to provide patient care on the scale or turn-around time needed. Clinical laboratories that have the necessary expertise should be able to develop their own Zika LDPs. These LDPs need to exist beyond testing from the public health laboratories, and must be available to all Americans across the country, particularly in Southern states.

During the H1N1 outbreak a few years ago, AMP leaders **Karen Kaul** and **Jan Nowak** wrote an editorial in JMD titled "The Role of Community Molecular Diagnostics Laboratories in the H1N1 Pandemic," where they describe the important role of community diagnostics laboratories during the H1N1 pandemic and issued a call for better planning in the future. Their points reverberate today as the importance of a community molecular diagnostic laboratory continues.

FDA has stated their intention to finalize the guidance on LDPs in 2016. Under FDA's proposed framework, laboratories will likely experience FDA correspondence similar to the Texas hospitals recent letter and be forced to comply in order to avoid enforcement action for the LDPs they provide. AMP continues to monitor FDA and congressional activity related to LDP regulatory oversight very closely and will continue to update the membership as things progress. The emergence of widespread Zika infection and its devastating co-morbidities, plus the recent activity by FDA reminds us that FDA oversight of LDPs would be a very bumpy road! We will soon distribute a survey to members to obtain feedback on what services AMP should provide to assist in a possible new reality of FDA regulation.

Sincerely,

Charles E. Hill, MD, PhD
AMP President

Advocacy News

AMP Provides Comments to CMS on the Awarding and Administration of Medicare Administrative Contractor Contracts

AMP submitted comments on February 19, 2106 to a request for information from CMS regarding awarding and administration of Medicare Administrative Contractor (MAC) contracts. AMP provided a number of recommendations to CMS in order for MACs to best serve as primary operational contacts between the Medicare fee-for-service program and providers across the country. AMP stated that transparency and stakeholder engagement are critical to ensuring that MACs are successful in their endeavors to appropriately and fairly make coverage assessments and provided specific recommendations including that CMS should exercise its authority to oversee the work of the MACs in a timely and transparent manner; MACs should be assessed on their transparency and public engagement as a measurement of their level and quality of service; CMS should assess the MACs adherence to the gapfill process as a measurement of quality of service; and that MACs should be evaluated based on the relationships with healthcare providers within their jurisdictions. AMP's comments are available here: http://amp.org/publications_resources/position_statements_letters/documents/AMPcomments-MAC-RFI-CMS1653NC-FINAL.pdf

AMP Releases Results from 2015 Genomic Sequencing Procedure Microcosting and Health Economic Cost-Impact Analyses

In 2014, AMP worked with nine labs to analyze over a dozen next generation sequencing protocols to determine costs associated with assay validation, pre-analytics, sequencing, bioinformatics, and interpretation of genomic sequencing procedures (GSPs). AMP was assisted in the project by Boston Healthcare Associates. On April 11, 2016, *The Journal of Molecular Diagnostics (JMD)* published the results in a manuscript titled "Genomic Sequencing Procedure Microcosting Analysis and Health Economic Cost-Impact Analysis: A Report of the Association for Molecular Pathology." The *JMD* report includes aggregated cost and personnel time data from nine laboratories performing 13 GSPs. In addition, payer cost-impact models for three clinical scenarios were generated with assistance from key opinion leaders: impact of using a targeted gene panel in optimizing care for patients with advanced non-small-cell lung cancer, use of a targeted multi-gene panel in the diagnosis and management of patients with sensorineural hearing loss, and exome sequencing in the diagnosis and management of children with neurodevelopmental disorders of unknown genetic etiology. Each model demonstrated economic value by either reducing health care costs or identifying appropriate care pathways.

A major objective of the project was to provide laboratories with tools to accurately estimate the cost of performing GSP services. New CPT codes for GSPs went into effect January 1, 2015. The release of the tools coincided with the Centers for Medicare and Medicaid Services' (CMS) gapfill timeline for the GSP codes and was available as a resource for labs providing cost information to their local Medicare Carrier.

The *JMD* manuscript is available here: http://jmd.amjpathol.org/article/S1525-1578%2816%2900053-2/fulltext
The models are available for download here: http://amp.org/committees/economics/NGSPricingProject.cfm

AMP Provides Comments on the Recent FDA Public Workshop on Next Generation Sequencing-Based Oncology Panels

The workshop was held on February 25, 2016 and consisted of a number of panel discussions that focused on the challenges of conducting next generation sequencing oncology (NGS) procedures including analytical, pre-analytical, and clinical claims challenges. The panelists included numerous AMP members including, **Dara Aisner, John Pfeifer, Robert Klees,** and **Madhuri Hegde. Roger Klein** presented public comment on behalf of AMP. The webcast of this meeting is available here: http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm480046.htm#agenda

Subsequently, AMP provided written comments to FDA on this topic. AMP expressed that issues surrounding validation of NGS assays for oncology applications have been taking place in the professional community for years and urged FDA to explore the consensus that professional organizations have already reached. AMP also advised FDA to use caution with any regulatory approaches to NGS test systems since NGS is quite different than FDA's historical work, which lent itself to a review of tests in narrow, well-defined contexts. AMP communicated that validation of the performance characteristics of NGS instruments and reagents, and assays themselves, must inherently rely on a method-based approach that is reflective of the nature and types of variants likely to be seen in clinical practice. Thus, AMP recommended that FDA exercise enormous flexibility, in order to support the accuracy and reliability of tests, without harmfully interfering with the introduction of new NGS assays. The comments are available here:
http://www.amp.org/publications_resources/position_statements_letters/documents/AMPcomments-NGS-based-oncology-panels-FDA-2015-N-4990-FINAL.pdf

AMP Responds to Recent FDA Public Workshop on the Return of Genetic Test Results and Interpretations

FDA intends that the workshop, held on March 2, 2016, will assist the Agency to understand patient and provider perspectives on receiving potentially medically relevant genetic test results. The topics focused on better defining the specific information patients and providers prefer to receive, how those results should be returned, and what information is needed to understand the results in the event that they could effectively aid in medical decision making. Panel discussions were divided among different clinical scenarios such as well patient/predictive tests, acute disease tests, and chronic disease tests. **Eric Konnick** presented public comments on behalf of AMP. The webcast of the meeting is available here: http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm478841.htm

On March 31, 2016, AMP provided written comment to FDA on this workshop; they expressed deep concern about the scope of the workshop. FDA framed the workshop as part of its contribution to the Precision Medicine Initiative, but the workshop's discussions did not focus on returning research results, but rather clinical test results, and AMP concluded that comments submitted will be used by the agency in regards to clinical testing, which may have very significant consequences for patient access to diagnostics. AMP expressed that activities by clinical practice professional societies, stakeholder conveners such as the Institute of Medicine, and other forms of continuing medical education that examine, educate, and provide recommendations and guidelines for practice are the best mechanisms for consideration on how to best return genetic test results. Most importantly, AMP stated in its comments that the activities that occur in the practice of laboratory medicine and pathology, including the performance and interpretation of findings from numerous laboratory procedures, are professional medical services that fall clearly within the scope of practice of medicine and are beyond the purview of the FDA. The comments are available here: http://amp.org/publications_resources/position_statements_letters/documents/AMPcomments-genetictestresults-FDA-2015-N-4809-FINAL.pdf

Join AMP on the Hill!

While I am a new member of AMP's Professional Relations Committee, I am not new to advocating on Capitol Hill for patients and the molecular professionals who serve them. My recent visit to Washington D.C. allowed me to join AMP on the Hill to meet with congressional staff from the state of Washington. This last series of meetings was my fifth visit to the Hill since 2014, and with Senator Cantwell and Representative McDermott offices, I have met with the same staffers each time. My intention for starting the process several years ago was to establish myself as a trusted source for my congressional delegation, which would provide an important perspective on how to improve the care of patients in Washington State and nationally. Establishing and maintaining these relationships is invaluable, especially when AMP needs to communicate concerns to congressional staff on a particular issue. Congressional offices rely on their constituents to provide input and guidance on issues, and becoming known to the staff members through repeated contact will enhance communication with the office. I echo Dr. Monzon's remarks in the last ChAMPion newsletter, that congressional offices really value these meetings and are very interested in better understanding the concerns and role of those who practice personalized medicine. If you are visiting Washington D.C., please do not hesitate to contact Tara Burke at tburke@amp.org to help set up a day on Capitol Hill.

-Eric Konnick, MD
Member, Professional Relations Committee

In the News

James Downing Named to National Cancer Institute Blue Ribbon Panel

Congratulations to AMP member, **James Downing**, President and Chief Executive Officer of St. Jude Children's Research Hospital. He has been selected to serve on a Blue Ribbon Panel that will inform the scientific direction and goals at the National Cancer Institute (NCI) for Vice President Joe Biden's National Cancer Moonshot Initiative. Dr. Downing knows the critical role that molecular diagnostics plays in the fight against cancer and the panel will benefit from his genomic medicine expertise. In 2012, Dr. Downing received the AMP Award for Excellence in Molecular Diagnostics, AMP's highest honor.

EAC Webinar

Miss the Recent Webinar on the Basics of Molecular Coding, Coverage, and Reimbursement?

Last month, The Economics Affairs Committee (EAC) held a webinar titled "Molecular Coding, Coverage, and Reimbursement 101," where EAC Chair, **Sam Caughron** provided an overview of these processes with a focus on Centers for Medicare and Medicaid Services' (CMS) methods used by the Medicare Administrative Contractors (MACs) to make coverage assessments. To view the archived webinar visit:
http://amp.org/Webinars/index.cfm

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