Letter from the President

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 to test the Zika virus at the Texas Children's Hospital in Houston, 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 laboratory'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, has only authorized state public health laboratories and the domestic and international laboratories belonging to the World Health Organization's Emergency R&D Group. AMP members have petitioned for their RT-PCR assay. The public health laboratory network, while important and necessary, is not sufficient to provide patient care on the scale and speed required. Clinical laboratories offer a fast and necessary way to expand the ability to develop their own or purchase new, high-throughput, low-cost, high-throughput, and point-of-care tests.

During the H1N1 outbreak a few years ago, AMP members Karen Kaul and Jan Nowak wrote an editorial in JMD titled "The Role of Community Molecular Diagnostic Laboratories in the H1N1 Pandemic" where they describe the important role of community diagnostic 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.

AMP 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. The FDA asked at the JMD meeting to monitor FDA approval activity related to LPD 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, thus the current activity by FDA, reminds us of the oversight that would be a very bumpy road. We will soon distribute a survey to members to obtain feedback on what steps AMP should provide to assist in a possible new era of FDA regulation.

Sincerely,
Charles E. Hil, MD, PHO
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, 2016 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 care providers and improve communication between MACs and providers. Our recommendation focused on stakeholder engagement critical to ensuring that MACs are successful in their endeavors to appropriately and fairly make coverage assessments and provide specific recommendations including that CMS should exercise its authority over 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 of quality and service. CMS should assess the MACs adherence to the gapfill process as a measurement of quality of service; and that MACs should be held accountable for data and valid data that are to be used in determining outcomes and payment.

AMP Releases Results from 2015 Genomic Sequencing Procedure Microcosting and Health Economic Cost-Effectiveness 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-analysis, sequencing, bioinformatics, and interpretation of genomic sequencing procedures (GSPs). AMP was assisted in the project by the Healthcare Advances. 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-Effectiveness Analysis: A Report of the Association for Molecular Pathology Microcosting Task Force." The report includes detailed cost information and provides a comprehensive cost analysis for several different sequencers. The report provides a roadmap for understanding the costs associated with implementing these technologies.

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://journals.sagepub.com/doi/abs/10.1177/1556819616614443?journalCode=jmd


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 John M. McLean, Robert Klees, and Madhuri Hegde. Robert Klees presented public comment on behalf of AMP. The webinar of this meeting is available here:

http://www.fda.gov/AboutFDA/NewsEvents/WorkshopsConferences/cm600467.html#agenda

Subsequently, AMP provided written comments to this topic on AMP. This expression that issues surrounded validation of NGS assays on oncology applications have been taking place in the professional community for years and 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 previous test systems. The workshop provided different clinical scenarios such as well patient/pediatric tests, acute disease tests, and chronic disease tests. Eric Konnick presented public comments on behalf of AMP. The webinar of the meeting is available here:

http://www.fda.gov/AboutFDA/NewsEvents/WorkshopsConferences/cm578341.htm

On March 31, 2016, AMP provided written comments to this workshop; they expressed deep concern about the scope of the workshop as framed by AMP as part of its contribution to the Precision Medicine Initiative, but the workshop’s discussion focused on reporting research results, rather than clinical test results, and AMP concluded that comments submitted will be used by the agency in regards to clinical protocols for future testing to allow for sample sharing among practice professional societies, stakeholder conveners such as the Institute of Medicine, and other forms of continuing medical education that might be helpful for the development of more robust protocols for consideration for future clinical tests.

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 perspectives on receiving potentially medically actionable, but not yet validated genetic test results. FDA will provide information on what test results patients can expect to receive, how those results should be returned, and what information is needed to understand the results in the event that they could effectively be used in the medical care of the patient. Patients provided different clinical scenarios such as well patient/pediatric tests, acute disease tests, and chronic disease tests. Eric Konnick provided public comments on behalf of AMP. The webinar of the meeting is available here:

http://www.fda.gov/AboutFDA/NewsEvents/WorkshopsConferences/cm578341.htm

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Finally, 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 are clearly within the scope of practice of medicine and are beyond the purview of the FDA. The comments are available here:

http://www.fda.gov/AboutFDA/NewsEvents/WorkshopsConferences/cm578341.htm

EAG Webinar

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

Last month, The Economics Affairs Group (EAG) 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/Workinars/index.htm

Join AMP on the Hill!

While I am new a member of AMP's Professional Relations Committee, I am not new to advocating on Capitol Hill for patients and the medical 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 staff members each year, and we have been able to hit the ground running. Several years ago was still established myself as a trusted voice for any 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. Monson's remarks in the last AMP on the Hill newsletter, that Congressional offices really value these meetings and are very interested in better understanding the concerns and role of those who participate.

I've been a member of AMP since 1989 and have been involved with AMP, and Washington D.C. please do not hesitate to contact Tara Burke at t Burke@amp.org to 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 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 strategic direction and goals at the National Cancer Institute (NCI) for the Vice President of the United States, 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 extensive experience in this field. In 2012, Dr. Downing received the Award for Molecular Diagnostics, AMP’s highest honor.