Pharma Intelligence
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The Association of Molecular Pathologists (AMP) 2020 Annual Meeting

Coverage: November 17th, 2020

AMP Annual Meeting

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The Association for Molecular Pathology (AMP) Annual Meeting & Expo – held in a virtual format this year from November 16-20 – features a good mix of scientific sessions, workshops, and advocacy sessions targeting pocketbook issues at the heart of laboratory medicine practice during the COVID-19 pandemic. Below, Informa Pharma Intelligence provide highlights from November 17, including abstracts flagged by meeting organizers for their significance to clinical practice and discussion about where the field is headed under a new U.S. administration in 2021.

Cautious optimism for fresh start on COVID in 2021

A new administration in the White House under President Joe Biden could bode well for clinical laboratories, experts said during a panel session November 17 organized by the AMP's Economic Affairs Committee.

The panel session focused on lab economics amid COVID-19. The public health emergency declared by the U.S. Department of Health and Human Services (DHHS) is set to expire on January 20, following a 90-day extension. That end-date will likely be extended again based on the current state of the pandemic, with reports of mounting cases and hospitalizations around the country at the cusp of the holiday season. Even after the public health emergency ends, there will be likely be a need to extend coverage and payment policies for several months, said session moderator Erika Miller, senior vice president and counsel at CRD Associates, in Washington, D.C.

Moving forward, we know President-elect Biden is committed to science and evidence-based policies and this can be expected to factor heavily into decisions about extensions, said Miller, adding that it's not going to be like "flicking the light switch" off. Miller also expects a different and more pro-testing posture from Biden compared with the last four years.

In a plan to combat COVID-19 published on his website *joebiden.com*, the president-elect called for an urgent and robust national response to the pandemic and placed heavy emphasis on testing. Among other things, the plan Backs "wide availability of free testing" and the "elimination of all cost barriers to preventive care and treatment for COVID-19".

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The meaning of "free" is likely that testing is available, with no constraints on supply and for patients in getting screened, said Jay Patel, M.D., vice chair of new codes and pricing on the Economic Affairs Committee. Supply chain issues could still benefit from greater coordination and payers may face pressure to maintain open coverage policies, said Patel, who is also executive director, clinical trials and PharmaDx, at ARUP Laboratories in Salt Lake City.

Miller sees a lot of opportunities for change in the new year. The AMP has been heavily focused on coding and reimbursement issues during the pandemic and it would like to see a change to a new U.S. Centers for Medicare and Medicaid Services (CMS) policy on COVID testing reimbursement. As of January 1, a new healthcare common procedure coding system (HCPCS) policy for high throughput COVID-19 testing is set to take effect – to qualify for a higher rate, the majority of a lab's tests must be turned around within 48 hours of specimen collection. Panelists noted that supply chain issues make the turnaround time target difficult to achieve and that there are also administrative burdens associated with compliance. There will now be an opportunity to weigh in on this with a new administration, Miller said.

Similarly, Pranil Chandra, D.O., vice chair of coverage decisions on the Economic Affairs Committee, said that he sees an opportunity to start fresh and focus on areas that are working well but also on opportunities for better coverage and pricing policies. Issues need to be framed in a manner that demonstrates the impact on patient care as well as effects on laboratories doing testing around the country, said Chandra, who is chief medical officer of genomic and clinical pathology at PathGroup in Brentwood, TN.

A number of different options should be made available to clinicians, including panel tests that incorporate COVID-19; larger combination assays have faced challenges to reimbursement in the past. The pandemic provides an opportunity for education on the value of these tests and to promote better coverage policies, Chandra said.

Abstract G13

Universal genetic testing broadens catch in cancer patients

Universal genetic testing has the potential for detection of findings beyond what is possible through screening based on selection criteria enshrined in clinical guidelines, Memorial Sloan Kettering researchers reported in a study presented on November 17.

The study was featured in a session highlighting four abstracts that were determined to have significant value by the AMP's leadership in genetics. Researchers compared two different approaches to testing in patients evaluated for cancer at the Memorial Sloan Cancer Center between 2015 and 2020, with a range of tumor types represented (breast, ovarian, colorectal, pancreatic, and prostate).

In one cohort of 4,120 patients, selection for genetic testing was done in the traditional way, that is based on clinical and family history, and screening focused on a set of known genes. In the other cohort, which included 9,341 cancer patients, all underwent testing for 76 or 88 genes known to be associated with predisposition for a wide array of cancer types.

Researchers compared the positivity rates associated with the two approaches and noted additional findings that surfaced through broader genetic testing. Results were reported at the AMP meeting by Ozge Ceyhan Birsoy, PhD, a clinical molecular geneticist at Memorial Sloan Kettering.

Researchers reported similar positive rates for most tumor types, for example the positivity rate for pathogenic or likely pathogenic variants in breast cancer patients was 7.5% and 9.6% with broad, unselected testing. Birsoy noted during her presentation that there were differences in patient numbers. For example, when it came to breast cancer, 3,341 patients had targeted testing compared with 2,249 who had the universal approach. But for colon cancer, only 252 had targeted testing compared with 2,060 universal.

In the cohort of 9,341 patients who had universal testing, researcher reported that 9.1% had pathogenic or likely pathogenic variants that would not have been picked up in a targeted panel test. And of those with additional findings beyond a targeted panel test, 4.6% had variants in a gene of high or moderately high penetrance, Birsoy reported. In a small number of cases, patients had findings on broad testing that could lead to changes in treatment, that is for prophylactic treatment.

The results come at a time of growing debate about how broad testing should be in cancer patients and when universal, unselected testing is appropriate. However, questions still remain about how viable universal testing is from an economic point of view and how to address the risk of detecting and acting upon variants of unknown significance.

Comparison of genetic testing approaches for pathogenic, likely pathogenic variants		
Tumor type	Targeted panel positive rate	Broad testing positive rate
Breast cancer	7.5%	9.6%
Ovarian cancer	17.4%	14.4%
Colorectal cancer	13.5%	7.6%
Pancreatic cancer	8.8%	9.6%
Prostate cancer	7.5%	5.5%
***Source*: Birsoy et al, AMP 2020**		

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Abstract ID27

Blood test helps pinpoint cause of pneumonia

A microbial cell-free DNA sequencing blood test was helpful for diagnosing invasive mold infections in pneumonia patients, with potential to cut down on invasive procedures, researchers with the test's manufacturer reported on November 17

The test is an iteration of a microbial cell-free DNA sequencing test for more than 1,000 pathogens developed at Karius, of Redwood City, CA. During an AMP session highlighting four abstracts deemed to be particularly significant by infectious disease leadership at the meeting, Karius Chief Scientific Officer Timothy Blauwkamp, PhD, explained that the test had been optimized for diagnosing invasive mold infections, which present challenges for detection.

Blauwkamp presented data for a subset of 68 hematopoietic stem cell transplant patients with pneumonia from a previously reported study. Standard workup for pneumonia patients with suspected mold infections includes invasive bronchoalveolar lavage (BAL) procedures or lung biopsies that pose risk for complications in immunocompromised patients.

The retrospective study compared the blood test on stored samples to results from a range of BAL tests individually and as a composite. They also tested specificity using in 19 controls with pneumonia caused by bacteria or viruses as well as blood from 684 donors presumed to be healthy.

In the 68 patients, 191 invasive tests had been conducted, or about 2.8 per patient. The blood test gave the same result as findings from up to eight invasive tests in 72% of patient cases. Sensitivity was similar to that of each BAL test individually. Specificity for the blood test was 100% in the control patients and 97.4% in the reference dataset.

Turnaround time for the blood test is 48 hours, whereas the results from multiple BAL and culture tests can take a week or more to receive, he noted.

“That way you get patients on etiologically-directed therapy much, much faster, than if you would be able to when you spend the time first scheduling the procedure and then waiting for results,” Blauwkamp said.

There are also potential cost savings if invasive procedures could be reduced, considering that they involve specialized surgical care, anesthesia, and operating room time.

“It can add up to thousands and thousands of dollars just to obtain the specimen to do the diagnostic test,” Blauwkamp said.

However, the exec also acknowledged that a lot more data are needed to prove the hypothesis that redundant invasive tests could be eliminated. The company is currently evaluating the test in a prospective multicenter study of pneumonia in immunocompromised patients.