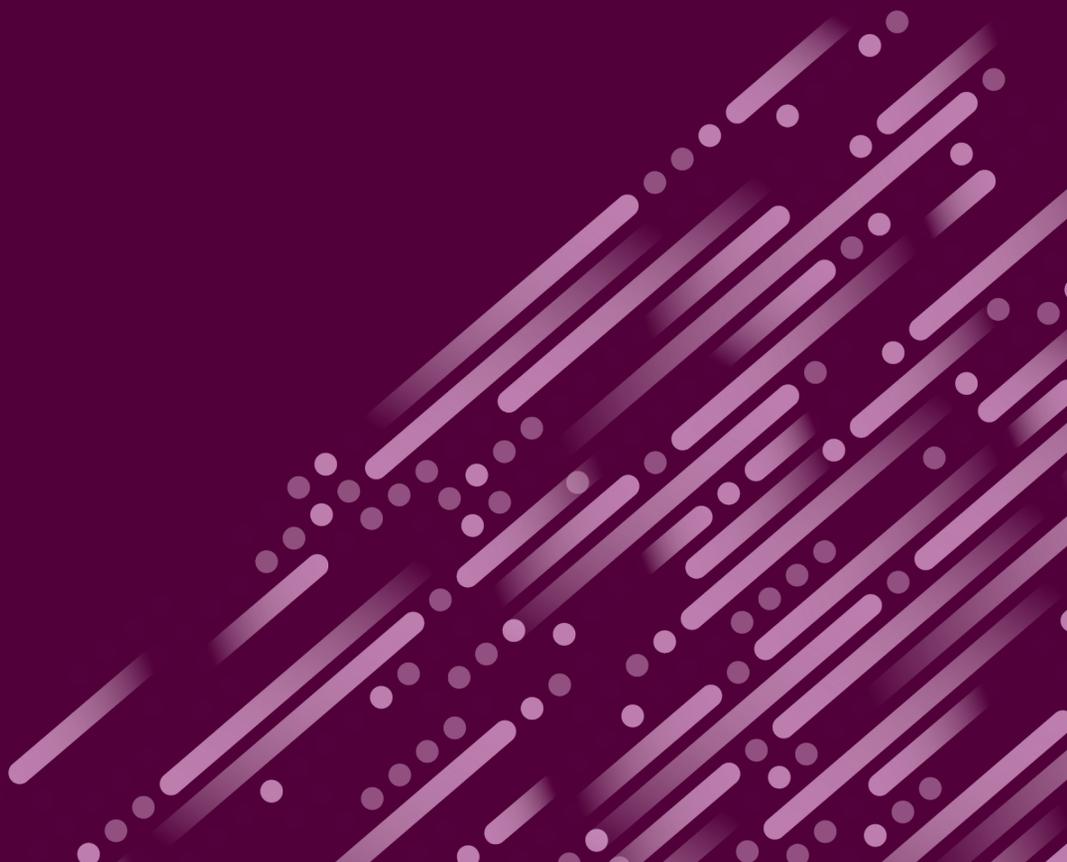


PharmaIntelligence  
Informa



# The Association of Molecular Pathologists (AMP) 2020 Annual Meeting

Coverage: November 18th, 2020



# AMP Annual Meeting

November 18th, 2020



There are few aspects of life that have not been dramatically altered by the coronavirus pandemic. An infectious diseases plenary session at the Association for Molecular Pathology (AMP) virtual meeting on November 18 dealt with this theme, providing an overview of the cases in various geographic regions around the world and bringing home the impact on minority populations in the U.S. Another highlight for the day detailed below was a panel session where experts debated the pros and cons of metagenomics. The day finished up with awards, followed by wine tasting – virtual of course.

## Pandemic update underscores ‘striking’ racial inequalities

Broadly speaking, the whole of the United States is grappling with rising rates of coronavirus cases, followed by hospitalizations and deaths, but the disease is taking the worst toll on minority populations, attendees heard during a pandemic update on November 18.

Carlos del Rio, M.D., professor of global health and epidemiology at the Emory Rollins School of Public Health, provided an overview of the global wreckage caused by the novel coronavirus this year. Worldwide, there have been more than 47 million cases and more than 1.2 million deaths reported.

The U.S. shares of the grim global totals are 9.5 million cases and 237,000 deaths. More than 100,000 cases are being reported daily. Hospitalization rates have reached record highs in half of U.S. states. And the number of daily deaths in the U.S. rose from 680 on October 15 to 1,049 on October 29, del Rio noted.

Del Rio also cited what he described as “startling” racial disparities in the U.S. Age-adjusted COVID-19-associated hospitalization rates have been vastly higher in minority populations, according to data from the U.S. Centers for Disease Control and Prevention (CDC). And according to the COVID Tracking Project, the death rate for Blacks is twice the rate of whites. These disparities are sometimes attributed to comorbidities, but del Rio noted that minority populations are more likely to need to work outside the home and to live in crowded environments.

# AMP Annual Meeting

November 18th, 2020



Obesity is a major comorbidity affecting disease severity; those with a body mass index (BMI) over 25 are at greater risk.

“Extra kilos make a big difference,” del Rio said.

There has been some good news on the prevention front as both Pfizer and Moderna recently reported that their messenger RNA (mRNA) vaccines are more than 90% effective, but both require refrigeration and as such are “not going to be available at your local Kroeger or CVS,” del Rio said.

Johnson & Johnson’s adenoviral-vector based vaccine does not require refrigeration and is eagerly awaited, but the product is further behind in development, he noted.

High-risk health workers and first responders, who account for 5% of the population, will be the first to get vaccinated and del Rio expects broad availability by next September or October.

Meanwhile, testing remains a critical part of coronavirus response. More than 149 million COVID-19 tests have been conducted to date in the U.S., but it’s still not enough, del Rio said. The first molecular test that can be self-administered and completed entirely at home received an emergency use authorization from the U.S. Food and Drug Administration on November 17. The Lucira All-in-One test is a rapid real-time loop mediated amplification reaction single-use product that will be made available by prescription. The FDA said in an announcement about the clearance that it is working with developers to make more at-home testing options available.

Asked about the new clearance at the AMP meeting, del Rio said that he supports a variety of testing options but added that he worries about potential for false negatives following experience with disease spread at White House meetings, despite rapid testing. Availability of at-home testing doesn’t mean that restrictions can be released, del Rio said. It’s also important to remember how much labs do to ensure quality testing, he added.

# AMP Annual Meeting

November 18th, 2020



## There's a time and place for metagenomics

Metagenomics has pros and cons for laboratories and health systems, and experience is growing with effective deployments. Experts hashed out the potential wins and losses during a Point/Counterpoint panel session on November 18.

Laying the ground rules for the panel session, moderator Erin Graf, Ph.D., of the Mayo Clinic Arizona, explained that for the discussion, metagenomics would be defined as “unbiased sequencing of DNA and in some instances RNA from a variety of patient sample types and for different clinical indications in order to determine presence of an possible infectious agent or agents.”

What could be the potential downsides of next-generation sequencing (NGS) for pathogens? Cost is a biggie. For example, if a sequencing test costs \$2,000 but 14 patients need to be screened to get one clinically meaningful or actionable result, that's a total cost of \$28,000, Graf posited. Most of these tests are being sent out and assuming no reimbursement, the lab would have to absorb the costs.

Taking the con side of the debate on metagenomics, the University of Pittsburgh's Stephanie Mitchell, Ph.D., said that her experience with the technology was that findings were typically negative and ultimately had no impact on care. The experience, however, did spur good conversations with clinicians about the advantages and limitations of sequencing in the context of infectious diseases. Mitchell also flagged disappointing specificity as a major limitation and noted the risk for false positives leading clinicians down a rabbit hole instead of paying attention to symptoms.

“We have been able to restrict testing at our institution,” said Mitchell, who is director of clinical microbiology at the Children's Hospital of Pittsburgh.

# AMP Annual Meeting

November 18th, 2020



When a new platform is introduced, testing protocols may not be in place yet for appropriate use, said Debra Palazzi, M.D., chief of pediatric infectious diseases at Texas Children's Hospital in Houston, which offers plasma-based metagenomics. Clinicians may be prone to ordering NGS when conventional testing is actually capable of delivering results and delivering them faster, she commented. And as opposed to substituting for other tests, the NGS is adding to the number of tests, she added. The effect on overall costs is an open question; from 3-50 tests have been ordered per month and staff are in the process of analyzing data, Palazzi said.

"We are learning a lot, but we have a lot of work to do," Palazzi added.

Although the session, which ran 90 minutes, included many pros and cons, a general message emerged that next-generation sequencing can be very valuable for some patients and that mastering appropriate use is a work in progress.

Palazzi recalled that testing helped solidify the diagnosis of brain abscess caused by *Bacillus megaterium* in a premature infant, which then enabled delivery of targeted therapy and a conversation with family about expectations for clinical outcomes.

Clinical utility really needs to be considered thoughtfully when ordering a test, said Steve Miller, M.D., Ph.D., director of the Clinical Microbiology Laboratory at the University of California San Francisco (UCSF), which has fully validated metagenomic sequencing, starting with cerebrospinal fluid samples. Ordering clinicians should make sure the patient has a high likelihood or a reasonable likelihood of having an infection, said Miller, adding that at UCSF, all test orders are reviewed to ensure they meet clinical criteria for best use.

Immunocompromised patients may be hard to diagnose, with hidden sources of infection they are unable to clear and could benefit from testing. A negative NGS result in an immunocompromised patient could also have a positive impact on patient care by ruling out certain classes of infections, allowing clinicians to investigate other causes of disease.

# AMP Annual Meeting

November 18th, 2020



There may also be clinical utility for detection of novel or re-emerging organisms. In one case, metagenomics enabled the diagnosis of a transplant patient with symptoms of encephalitis and meningitis as well as liver abnormalities with Saint Louis encephalitis, which was thought to be absent in California and Arizona, Miller said.

“We were able to show in fact that it has been reintroduced,” Miller said.

## AMP honors pathology leaders in awards session

Contributions to the molecular pathology specialty and AMP were recognized during a business meeting and awards session on November 18, with Jane Mann, M.D., Ph.D., and Ronald Przygodski, M.D. taking top honors.

The Jeffery A. Kant Leadership award was granted to Mann, who is medical director of the clinical laboratory at Grady Health System and professor of laboratory medicine at Emory University. Outgoing AMP president Karen Weck-Taylor, M.D., Ph.D., noted that Mann has served in many leadership capacities since becoming a member of the organization in 1999. Past posts include hematopathology subdivision chair, clinical practice committee chair, and secretary treasurer. Mann also served as the president of AMP in 2010.

Weck-Taylor credited Mann with contributions to the organization’s first strategic planning process, involvement in advocacy efforts, and for helping lead the development of evidence-based guidelines. Next-generation sequencing was emerging during the period of Mann’s presidency and AMP decided to embrace the new technology and shape its implementation into high-quality decision-making, Weck-Taylor said. Mann also presided over the initial expansion of AMP internationally; the first international membership grants were awarded in 2010.

# AMP Annual Meeting

November 18th, 2020



During the same session, AMP granted the Meritorious Service Award to Przygodski, who is director of genomic medicine implementation at the U.S. Department of Veterans Affairs. Przygodski has been a member of the editorial board of AMP's *Journal of Molecular Diagnostics* for more than decade and has been actively involved in a range of publications committees. He is also former chair of AMP's membership affairs committee.

Over the years, Przygodski has been recognized by the membership as being a very active reviewer of manuscripts, contributing astute and constructive comments, Weck-Taylor said.

Weck-Taylor is being succeeded as president of AMP by Antonia Sepulveda, M.D., Ph.D., chair of pathology at George Washington University.