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CAP Annual Meeting – A Review
Monday, October 12th 2020

Along with many other medical organizations, the College of American Pathologists (CAP) opted to hold its annual meeting virtually this year due to the COVID-19 pandemic, rather than gathering in Las Vegas as planned. CAP's online meeting, which is being held from October 10-14, features educational sessions, plenary lectures, networking events, industry workshops and satellite symposiums. Below, we present a notebook from Informa Pharma Intelligence recapping sessions held on Monday, October 12. Not surprisingly, highlights for this year include presentations about the impact the novel coronavirus has had on clinical laboratories.

Pathologists share COVID-19 lessons learned, get to grips with rapid testing advances

The COVID-19 pandemic has put pathologists and lab directors in the driver's seat on testing, a crucial part of crisis management. Experts shared their own experiences in managing testing and explored emerging trends in diagnostics during a scientific plenary presentation on Monday.

Reverse transcription polymerase chain reaction (RT-PCR) assays and antibody testing for gauging disease spread in the community have formed the cornerstone of testing during the pandemic. The key theme for laboratories this year has been overcoming challenges, said Dr. Benjamin Pinsky, PhD, associate professor of pathology and infectious diseases and medical director of clinical virology at the Stanford University Medical Center.

Based in Palo Alto, CA, Stanford health professionals faced some unique challenges – "apocalyptic wildfires" limited the ability to perform drive-through testing and record temperatures taxed the infrastructure at testing facilities. Some testing equipment did not work due to the heat and, consequently, mobile air-conditioning units had to be deployed to get the temperature down, Pinsky recalled.

Dr. Christina Wojewoda, associate professor of pathology and laboratory medicine at the University of Vermont Medical Center in Burlington, VT, said that she would characterize the pandemic as a series of supply chain issues – literally and figuratively – that pathologists have had to deal with. A range of supply shortages left labs scrambling, with some resorting to making their own viral transport media.

Due to restrictions associated with the emergency use authorization (EUA) process imposed by the U.S. Food and Drug Administration, initially, only certain labs were permitted to offer testing.

The University of Vermont found that it couldn't rely on the reference laboratories it usually used and needed to find new providers. It wound up contracting The Mayo Clinic in Rochester, MN, to do the work, sending the samples via private jets as commercial flight schedules had been disrupted. Over time, the Vermont center added its own inhouse capacity, but is still not confident about the availability of

reagents and test kits and requires additional staffing for COVID-19 services. As a result, the majority of testing is still sent out, but new staff are coming on board in a bid to ramp up inhouse services.

Due to the shortage of supplies, it's been important to be judicious about which patients to test, Wojewoda said. In the beginning of the pandemic, it was routine to test all asymptomatic patients who were pregnant or who were scheduled to undergo elective procedures. Some residents analyzed data and discovered that the positivity rate in asymptomatic patients was only .3% and that the majority of these cases involved exposure to a person known to have the coronavirus. Consequently, the center was able to pull back on asymptomatic testing, for example prior to elective procedures it is only indicated in when airway management is required, Wojewoda said. This allows the focus to be kept on patients who really need it, such as symptomatic inpatients and those who are immunocompromised.

In addition to COVID-related shortages, materials needed for other types of assays, such as tests for methicillin-resistant *Staphylococcus aureus* were in short supply, forcing staff to switch in some cases from automated to manual processes. The shift added stress and difficulty to what used to be rote parts of the job, she said.

"One public health issue is affecting another, with high demand and short supply," Wojewoda said.

COVID-19 has thrust pathologists into the limelight and an important part of Wojewoda's job is providing updates on testing, including the feasibility of speeding up the turnaround of results, the reliability of the supply chain, and the importance of conserving resources for the patients most in need. The Vermont Center has a good relationship with the state health department and has been leading the charge for testing, as a provider of services to smaller labs, Wojewoda explained.

Stanford's Pinsky also highlighted the growing role for pathologists amid the pandemic, in contrast with the pre-virus days where the specialty was more behind the scenes.

"This is a tremendous opportunity for pathologists," he said. "We are in much more high-profile situations, demonstrating our value to patient care and to our hospital systems. Nationally and globally we are the leaders in this pandemic. We should take the opportunity to show how valuable we are."

Meanwhile, the specialty is grappling with rapid and unprecedented changes in the landscape for testing. New options include rapid antigen testing at the point of care, though there have been questions about whether the sensitivity of these products is high enough. Pinksy said that his institution has put the assays to the test and determined that one model was as good or better as lab-based PCR, while the others had lower performance compared with lab PCR. Other new testing options include combination panels screening for the coronavirus along with influenza and other respiratory infections, and subgenomic RNA tests to assess whether patients are still infectious, Pinsky said.

Bearing in mind the supply chain issues, the University of Vermont is discouraging dual flu/COVID-19 testing in certain cases, such as symptomatic outpatients who are not immunocompromised and with no underlying heart and lung conditions, and instead guiding testing for COVID-19 alone. Staff worked with the state health department to issue an alert to this effect, Wojewoda said.

Pinsky said that he expects his hospital will find it difficult to prevent outpatients from getting flu testing and will therefore probably offer it.

Going forward, having the ability to measure immune response will be very important, he added.

"This is not over by a long shot and there are a lot of things going on as far as the diagnostics go," Pinsky said.

Meanwhile, there is a lot of interest in at-home testing options to broaden access, but the experts at the plenary session expressed reservations. Modeling looks very promising for frequent testing of asymptomatic people to identify outbreaks, but time will tell whether this is a practical and a cost-effective solution, Pinsky said. It's unclear how frequently testing needs to be done to overcome more limited performance characteristics and how good the tests are in the home setting with self-administration by consumers.

The modeling looks great for frequent and rapid antigen testing, but it's difficult to get people to even wash their hands correctly -- let alone to handle testing at the appropriate frequency, self-quarantine if necessary, and report positives to public health authorities, Wojewoda said.

"It's not just about testing itself," she explained. "It's about the whole social construct around that that I think we need to take into account."

Similarly, there are questions about the future of saliva as a specimen type instead of nasopharyngeal swabs, though the concept has the appeal of convenience among the general public.

Everybody is "chomping at the bit for saliva," but Wojewoda said that it doesn't make much sense to switch to a lower standard of specimen unless swabs are not available. For testing, from 3-5 milliliters of saliva is needed, which is a lot and may be difficult to achieve in practice, she also noted.

"We have other options that are available," Wojewoda said.

The data on saliva testing has been quite mixed, with some centers reporting excellent performance but other data suggesting poor performance, resulting in the need for repeat testing, Pinsky pointed out. Antigen tests in particular don't work well with saliva.

"I think the jury is still out on saliva," Pinsky said.

CAP unveils junior member poster winners

CAP announced the top five winners of its junior member abstract program during the scientific plenary session on COVID-19 on Monday.

Announcing the winners, CAP President Dr. Patrick Godbey noted that the five were selected out of a total of 645 abstracts spanning 24 areas of pathology. The winners were chosen by an editorial panel of CAP's peer-reviewed journal *Archives of Pathology and Laboratory Medicine*. In first place was Dr. Ayesha Siddique, of the Hartford Hospital in Hartfield, CT, for research on the prediction of lymph node metastases in patients with colon cancer following polypectomy. Here are the top 5:

1. Ayesha Siddique, MD, Department of Pathology and Laboratory Medicine, Hartford Hospital
   Does international tumor budding consensus conference criteria and depth of submucosal invasion proposed by the Japanese Society for Cancer of the Colon and Rectum really predict lymph node metastasis in endoscopic resected polypectomies with pT1 malignant colorectal polyps?
2. Brad Zehr, MD, Department of Pathology, The Ohio State University Wexner Medical Center
   Characterization of two distinct types of ERBB2 mutations in lung carcinomas
3. Devin R. Broadwater, MD, Department of Pathology, San Antonio Uniformed Services Health Education Consortium
   Development and validation of ultrarapid periodic acid–Schiff stain for use in identifying fungus on frozen section

4. Ibrahim Abukhiran, MBBS, Department of Pathology, University of Iowa Hospitals and Clinics
   Comparison of the performance of specimens from core needle biopsy, cell block, and cytology smears on molecular oncology testing by next-generation sequencing
5. Rahaf Alkhateb, MD, Department of Pathology, University of Texas–San Antonio
   Alloimmunization and transfusion reaction rate among the recipients of low-titer O-positive whole blood at an academic community-based Level I trauma center

New pulmonary pathology guidance helps optimize testing outcomes

New guidance from CAP in consultation with other medical organizations is designed to provide a roadmap for pathologists in taking samples from the thorax, with the goal of enabling the performance of multiple studies using small biopsy specimens.

The guidance on collection and handling of small biopsy and cytology specimens for ancillary services was recently published in *Arch Pathol Lab Med.* The collection of 16 recommendations was created by CAP, working with the following organizations:

- American College of Chest Physicians
- Association for Molecular Pathology
- American Society for Cytopathology
- American Thoracic Society
- Pulmonary Pathology Society
- Papanicolaou Society of Cytopathology
- Society of Interventional Radiology
- Society for Thoracic Radiology

A session at the CAP virtual annual meeting on Monday featured an analysis of the need for the new recommendations and the process of review and revision by coauthor Dr. Sinchita Roy-Chowdhuri, PhD, associate professor of pathology at the University of Texas MD Anderson Cancer Center.

Roy-Chowdhuri described the process for creating the guidelines as a multi-organization effort that included pathologists, radiologists, and pulmonologists. The main focus was to help ensure the collection of specimens are adequate for any testing needed to make a definitive diagnosis and for patient management. An expert panel considered ancillary studies for lung cancer as well as for infectious diseases but most of the data was related to biomarker testing in oncology. Beyond the diagnosis of lung cancer, it is important to have information about a variety of biomarkers, without the need to send a patient back for another biopsy, she explained. Research suggests that in from 10%-20% of biopsies, the specimen is inadequate for all the testing desired, she noted.

“What can we do as pathologists working with our clinical colleagues to ensure that we are collecting a good specimen that will be adequate for all tests needed?” the clinician asked.

Overall, a literature review turned up 3,101 studies, of which experts used data from 202 to inform their recommendations. There are multiple ways to get a specimen, most of which involve image guidance, with computed tomography (CT) or ultrasound.

The number 1 recommendation is to use endobronchial ultrasound guided transbronchial needle aspiration (EBUS TBNA), where this technique is available, for making the initial evaluation. Furthermore, the guidance advises use of 10-, 21-, or 22-gauge needles for these procedures.

The guidelines had been published in draft form on CAP's website and members had the opportunity to comment. Most of the recommendations were generally accepted. However, a sizeable fraction took issue with recommendations to use rapid onsite evaluation (ROSE) with EBUS TBNA, transthoracic needle procedures, and transbronchial needle aspirations.

ROSE can help ensure adequate sampling and appropriate triage, maximizing the benefit during a procedure, Roy-Chowdhuri noted. Those who disagreed with recommending ROSE cited challenges with reimbursement, lack of infrastructure, and longer timeframes. Some also felt that ROSE was not necessary. Roy-Chowdhuri mentioned that the guidelines do not advise ROSE for every case, but rather for specimens where it is likely that additional testing will be needed. The literature is clear that ROSE is associated with getting a better sample for ancillary studies/biomarker testing, so CAP opted to stick with its recommendations, she explained.

The recommendations also provide advice for facilities that do not have access to ROSE.

The expert panel found limited information to make conclusions outside of oncology. However, there were a small number of studies that enabled development of recommendations for handling patients with tuberculosis and three of the 16 recommendations address this disease.

"When collecting pleural fluid for diagnosis of extrapulmonary tuberculosis, specimens should be submitted for microbiology culture studies for mycobacteria using liquid media protocol," the 16th recommendation advises.