What You May Have Missed at

AACC 2021

Vaccines, Variants and COVID-19 Test Enhancements Top Focus

In a hybrid virtual and in-person meeting based in Atlanta, GA, the American Association of Clinical Chemistry (AACC) met to share insights in laboratory medicine. The event coincided with the Clinical Lab Expo, which is an important showcase for IVD vendors. About 7,500 professionals attended the meeting, lower than other years but still impressive given how many professional meetings this year have not taken place.

This year there was a notable focus on variants, not surprising given the national attention and the status of AACC as the largest meeting of laboratory professionals in the U.S. and abroad. This year the association also tackled vaccines, taking advantage of clinical testing's ability to 'judge' results of widely circulated vaccines and speak about variants and used their platform to do that at the meeting.

Breaking The Virus "Tango" Urged

Dr. Liu: In Virus Tango, We Need to Lead, Not Follow

The combination of the SARS-CoV-2 virus and human behaviors associated with vaccines was compared to a tango dance in a plenary session by **Dr. Margaret Liu, CEO of PAX Therapeutics and Chairman of the Board of the International Society for Vaccines**. In other words, the problem, and it's ramifications on in vitro diagnostics, could be with us for some time unless measures not apparent currently are taken. Liu said the virus was like a tango dance where, "The leader gives the signals but then the follower responds." While the virus got the first step, and then we responded with vaccines, we also sent following signals through our lax behavior about using masks and distancing, and the virus responded with variants. Overall Liu insisted, we have been following too much and allowing the virus to lead. Liu indicated that while SARS-CoV-2 variants emerge in response to non-vaccination and non mask wearing behaviors, they have properties due to changes in viral protein. Delta variant benefits from

among other things, increased viral loads in asymptomatic individuals. And Liu warned more variants are poised to arise if we don't take action. Liu also asserted the vaccines are effective. Speaking to an assemblage of knowledgeable laboratory scientists, Liu insisted that while the news media often fixates on antibody responses to vaccines and the fact that antibody titers have been shown to decline over time, Liu noted that vaccines also activate T-cell responses against the virus. T-cell helpers produce cytokines that are the "vitamins of the immune response" and help stimulate antibody production and support another type of T-cell, the cytotoxic T-cells

COVID-19 Tests Enhancements Announced

More than 400 exhibitors used AACC Atlanta to showcase products and services. Notable among these are refinements to COVID-19 tests. While last year COVID-19 tests were manufactured and deployed as rapidly as possible, in 2021 there was time for improvements that meet the clinical need. In addition to speed and volume, severity detection and variant detection elements were added to some systems.

Siemens Unveils Severity Algorithm For Major Analyzer: At a pre-convention press conference, Siemens announced its Atellica COVID-19 Severity Algorithm new user interface for Atellica Solution. The system helps predict the likelihood of progression to severe COVID-19 disease and life-threatening multiorgan dysfunction. Algorithm is based on over 14,000 cases of COVID-19 and analyzes nine biomarkers. The company also announced plans for an Atellica Hematology Portfolio.

New PCR System from Seegene: South Korea-based Seegene unveiled a new assay "STARlet-AIOS" at the American Association for Clinical Chemistry in Atlanta. Seegene's AIOS integrated the company's liquid handler and real-time PCR instruments into a single system that can access a wide array of Seegene's syndromic assays. AIOS enables high-throughput, real-time PCR workflow that begins with nucleic acid extraction and continues through real-time PCR and the interpretation of results. The company says a key feature of AIOS is the modular design of its molecular diagnostics system, which is composed of independent, detachable modules that work with the company's software.

Bio-Rad's New Variant Testing Panels: Bio-Rad Laboratories has launched Bio-Plex immunoglobulin A (IgA) and IgM SARS-CoV-2 panels to detect IgA and IgM antibodies against

four SARS-CoV-2 antigens. The panels are for research use only. Bio-Rad's Bio-Plex Pro Human IgA SARS-CoV-2 S1/S2/N/RBD 4-Plex Panel and the Bio-Plex Pro Human IgM SARS-CoV-2 S1/S2/N/RBD 4-Plex Panel join Bio-Rad's existing Bio-Plex Pro Human IgG SARS-CoV-2 N/RBD/S1/S2 4-Plex Panel to complete the set of three separate qualitative multiplex I immunoassays that detect IgA, IgM, and IgG antibodies against four SARS-CoV-2 antigens, the company said. The panels can assist researchers in developing vaccines, as well as help public health researchers who perform seroprevalence studies based on serology specimens to identify individuals who may have been exposed to SARS-CoV-2, the company said.

Thermo Launches PCR Kits, Including Mu Variant: Thermo Fisher announced it is launching two new PCR-based kits, the Applied Biosystems TaqPath COVID-19 Fast PCR Combo Kit 2.0 and the Applied Biosystems TaqPath COVID-19 RNase P Combo Kit 2.0. The kits target eight genes across three regions of the virus that causes COVID-19. Additionally, the company announced that the Mu variant is now included in its existing Applied Biosystems TaqMan SARS-CoV-2 Mutation Panel. Thermo Fisher is also launching the new Thermo Scientific AcroMetrix SARS-CoV-2 Control for monitoring extraction, amplification and detection steps for SARS-CoV-2 assays. Earlier this month, the company launched its Applied Biosystems QuantStudio Absolute Q Digital PCR System, the first fully integrated digital PCR (dPCR) system designed to provide highly accurate and consistent results within 90 minutes.

Tecan Eyes Throughput: Tecan exhibited its COVID-19 product portfolio that is designed to boost throughputs, turnaround times and user safety of a variety of clinical and research workflows. Tecan presented its Trio RNA-Seq Library Preparation Kit – on the DreamPrep NGS workstation which the company says provides consistent, high throughput sample-to-sequence libraries for detection, surveillance and evolution studies in labs. Tecan also showcased its Revelo RNA-Seq Library Preparation Kit which offers highly sensitive detection and characterization of SARS-CoV-2 in nasal swab samples. Additionally, Tecan highlighted its solutions to scale up RNA extraction for SARS-CoV-2 on the DreamPrep NAP workstation featuring Zymo Research. It also demonstrated how labs can simplify nucleic acid extraction with preprogrammed workflows optimized for the Quick- DNA/RNA Viral MagBead kit, to purify up to 96 samples in under two hours.

Home Test Announced: Co-Diagnostics, Inc. (Nasdaq-CM: CODX) introduced its new at-home and point-of-care PCR device in a press conference at the recent 2021 AACC Annual Scientific Meeting & Clinical Lab Expo. The company's new device has not been reviewed by the U.S. Food and Drug Administration and is not available for sale.

Small Footprint COVID-19 Analyzer: LumiraDx introduced the LumiraDx Platform, a point of care diagnostic system that combines a small, portable instrument, advanced low cost test strip and digital connectivity to the Cloud and hospital IT systems. The LumiraDx Platform and tests are designed on the same principles as lab analyzer systems, to deliver accurate results compared to laboratory reference assays across a number of parameters, in a portable, easy-to-use point of care solution. The company said the LumiraDx COVID-19 antigen test has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) and achieved CE Mark. The LumiraDx Platform and COVID-19 antigen tests are also available in Japan and Brazil and are being rolled out in more than 60 countries globally.

COVID-19 Severity Stratification Test - MeMed has developed a rapid test that can predict with greater accuracy than other tests if a COVID-19 patient's condition will deteriorate, according to a September 29 poster presentation at the 2021 AACC annual meeting. The test can

give a response in 15 minutes and help signal if a patient may need lifesaving treatment. It measures the inflammatory biomarkers C-reactive protein, TNF-related apoptosis-inducing ligand, and interferon gamma-induced protein 10, and uses these values to calculate a COVID-19 severity score based on a scale of 0 to 100, with 100 indicating the highest likelihood of a severe outcome. To develop the test, MeMed researchers first used a rapid point-of-care instrument that the company previously built to measure the biomarkers in 518 COVID-19 patients, 113 of whom had a severe outcome. Next, they created a model using a machine-learning algorithm that serves as the basis for the COVID-19 severity score. The researchers, led by Dr. Niv Mastboim and Eran Eden, PhD, co-founder and CEO of MeMed, reported that the severity score has an area under the curve (AUC) of 0.86, outperforming other COVID-19 severity stratification tests in terms of accuracy, including the commonly used biomarker interleukin-6, which has an AUC of 0.77.

New Screening System Study: Scientists have created a new machine learning tool that could help healthcare workers to quickly screen and direct the flow of COVID-19 patients arriving at hospitals. Results from an evaluation of this algorithm, along with an artificial intelligence method that improves test utilization and reimbursement, were presented at the 2021 AACC Annual Scientific Meeting & Clinical Lab Expo.

It is important for clinicians to quickly diagnose COVID-19 patients when they arrive at hospitals, both to triage them and to separate them from other vulnerable patients who may be immunocompromised or have pre-existing medical conditions. This can be difficult, however, because COVID-19 shares many symptoms with other viral infections, and the most accurate PCR-based tests for COVID-19 can take several days to yield results.

A team of researchers led by Rana Zeeshan Haider, PhD, and Tahir Sultan Shamsi, FRCP, of the National Institute of Blood Disease in Karachi, Pakistan, has therefore created a machine learning algorithm to help healthcare workers efficiently screen incoming COVID-19 patients. The scientists extracted routine diagnostic and demographic data from the records of 21,672 patients presenting at hospitals and applied several statistical techniques to develop this algorithm, which is a predictive model that differentiates between COVID-19 and non-COVID-19 patients. During validation experiments, the model performed with an accuracy of up to 92.5% when tested with an independent dataset and showed a negative predictive value of up to 96.9%.

The latter means that the model is particularly reliable when identifying patients who don't have COVID-19. "The true negative labeling efficiency of our research advocates its utility as a screening test for rapid expulsion of SARS-CoV-2 from emergency departments, aiding prompt care decisions, directing patient-case flow, and fulfilling the role of a 'pre-test' concerning orderly RT-PCR testing where it is not handy," said Haider. "We propose this test to accept the challenge of critical diagnostic needs in resource constrained settings where molecular testing is not under the flag of routine testing panels."

Non-COVID Product Developments

There were some other developments at the meeting of note.

Post Hematology Analysis Aid from Mindray: Mindray used the week of the AACC meeting to announce it was launching MC-80, a new digital cell morphology analyzer that's designed to support morphological review of blood cells after hematology analysis, providing clearer images that capture cellular abnormalities in more detail, the company said. The company notes that most clinical laboratories must re-examine over 30% of their blood samples.

A Test for Professional Stress: Research presented at the 2021 AACC Annual Scientific Meeting & Clinical Lab Expo showed that a new test could identify healthcare professionals who are experiencing high levels of work-related stress and anxiety. A blood test for occupational stress could help to achieve this goal by making it easier to identify healthcare professionals who need mental health treatment. In an effort to find a biomarker that could be used for such a test, a team of researchers led by Hala Demerdash, PhD, of Alexandria University Hospitals in Egypt, set out to determine if blood levels of copeptin correlate with psychological stress. Copeptin is part of a precursor to the hormone arginine vasopressin (which is released in response to stress) that is more stable than the hormone itself. The researchers measured blood copeptin levels in 70 physicians and nurses who were treating COVID-19 patients in the ICU, and also gave the participants a psychological stress questionnaire at the same timepoints when their copeptin levels were measured.

Roche Showcases Alzheimer's Biomarkers: Alzheimer's disease is thought to begin 20 years or more before the onset of symptoms. Roche conducted a Biomarkers in Alzheimer's Disease session to learn about the clinical implications for early diagnosis and treatment. Roche offers Elecsys β-Amyloid(1-42) CSF II (AB42 2) which is an in vitro diagnostic immunoassay intended for the quantitative determination of the β-Amyloid(1-42) protein concentration in human cerebrospinal fluid (CSF).

Beckman Launches Urinalysis Workcell: (From LabPulse.com) Beckman Coulter aims to improve laboratory workflow for processing urinalysis samples with a new automated diagnostic system, DxU Iris, introduced at this year's American Association for Clinical Chemistry (AACC)2021 meeting. DxU Iris is designed to reduce manual sample processing in urinalysis lab workflow by reducing manual reviews to 4%. This can cut sample processing time by up to 78%, according to the company.

In launching the system at AACC 2021, Beckman Coulter noted that urinalysis samples make up 30% of all samples processed by clinical labs. A lab technician is often required to manually inspect the samples, such as confirming the analyzer's findings or identifying unique particle types. This can slow lab workflow. DxU Iris matches the company's DxU 850m Iris or DxU 840m Iris urine microscopy analyzer with its Arkray Aution Max 4030 urine chemistry analyzer. The system uses Beckman Coulter's digital flow morphology technology to isolate, identify, and characterize urine particles on the screen and its auto-particle recognition software to deliver standardized results with artificial intelligence technology.

Saliva Test: Researchers have developed a noninvasive test based on analysis of microRNA in saliva to detect prostate cancer, according to a September 28 poster presentation at the 2021 AACC annual meeting. The test distinguishes prostate cancer from benign prostatic hyperplasia (BPH), a benign enlargement of the prostate that can occur as men age. The test can detect eight different microRNAs that either support or suppress tumor growth, according to the researchers, who were led by Drs. Jamal Amri and Mona Alaee of the Tehran University of Medical Sciences. The researchers acquired saliva samples from 180 men between 45 and 50 years of age. Sixty of the subjects had been diagnosed with prostate cancer using standard methods, and 60 had been diagnosed with BPH.

EKF Launches New Ketone and Glucose Analyzer: EKF introduced its newest hemoglobin analyzer for the US market, the Hemo Control, which provides near patient hemoglobin and hematocrit results in one test as quickly as 25 seconds. EKF's team of point-of-care and central laboratory diagnostics experts at the event also highlighted the Lucica Glycated Albumin-L. Manufactured by Asahi Kasei Pharma, it is a specific test for glycated albumin ("GA") and is FDA cleared for sale in the U.S., where it is sold exclusively by EKF Diagnostics. This established test enables intermediate term glycemic monitoring of diabetics over the preceding 2-3 weeks. The STAT-Site WB and Lucica Glycated Albumin-L test were part of a suite of other diabetes care products that EKF showcased at 2021 AACC. These included its Beta-Hydroxybutyrate LiquiColor Assay (B-HB) and Nitro-Tab Ketone Tablets, both of which provide quick and simple tests for ketosis.

Concurrent with the AACC meeting, **Abbott** received FDA clearance for its i-Stat Chem8+ cartridge with its i-Stat 1 System. In two minutes, at the patient side, the system measure levels of sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, and total carbon dioxide.

Also **Roche** earned FDA approval for its Elecsys HCG Stat test measuring hCG, in serum and plasma for the early detection of pregnancy. This immunoassay runs on Roche's Cobas e 601 analyzer.

Ortho Clinical Diagnostics' Vitros Chemistry Products PHBR Slides gained FDA clearance. The product measures concentrations of phenobarbital in serum and plasma using the firm's automated Vitros 5600 Integrated System. The test detects the use or overdose of phenobarbital and can be used to monitor drug concentrations to ensure appropriate therapy.

Atlas Link Technology obtained 510(k) clearance for three over-the-counter pregnancy detection tests — the Atlas One Step hCG Urine Pregnancy Test (Strip), Atlas One Step hCG Urine Pregnancy Test (Cassette), and Atlas One Step hCG Urine Pregnancy Test (Midstream). All are urine-based lateral flow immunoassays.

BioMérieux achieved a clearance for use of its Vitek 2 Gram Negative Piperacillin/tazobactam for antimicrobial susceptibility testing of Gram-negative bacilli using its Vitek 2 and Vitek 2 Compact systems. Piperacillin and tazobactam is a combination penicillin antibiotic for numerous bacterial infections.

Siemens Healthineers achieved 510(k) clearance from the FDA for its N Latex FLC kappa and N Latex FLC lambda assays for monitoring multiple myeloma. The assays are confirmed to be highly precise and sensitive for free light chain quantification compared to the immunofixation method currently regarded as the reference method for detection of monoclonal immunoglobulins and its components.

Siemens Healthineers also unveiled its RAPIDPoint 500e Blood Gas System. The system uses a comprehensive series of analyzer functional checks and flagging mechanisms deliver accurate test results. Siemens says the system performs frequent quality and blood integrity checks before, during, and after every patient sample.

IVD Development Acceleration Laboratory Launched: 20/20 GeneSystems has launched an innovation acceleration clinical laboratory to assist developers of diagnostic tests in getting their products to market in the U.S. more quickly and cost-effectively by using a shared laboratory space. Called the **Clinical Lab Innovation Axcellerator (CLIAx)**, the laboratory gives diagnostic test developers access to instrumentation and staff. CLIAx comprises 3,000 sq ft of available lab space and testing equipment, including a polymerase chain reaction/molecular assay suite, as well as capabilities in next-generation sequencing, immunoassays, and clinical chemistry, according to 20/20 GeneSystems. GeneSystems also announced it has signed an agreement with Australian diagnostics firm Minomic International to use CLIAx. Minomic is developing MiCheck Prostate, a blood test that estimates an individual's risk of aggressive prostate cancer.

Moderna Vaccine Shows Greater Response, Says Dartmouth Study

Announced at the meeting was research comparing the different COVID-19 vaccine brands. Researchers led by Michael Kelliher, PhD, of Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire, have now shown how antibody responses and adverse reactions can differ in recipients of the Moderna and Pfizer COVID-19 vaccines. In 78 individuals who received Moderna and 70 individuals who received Pfizer, Kelliher's team collected blood samples before the second vaccine dose, 14 days after the second dose, and 30 days after. The study participants also took a survey where they rated the severity of adverse effects and symptoms after vaccination.

> "We can't claim Moderna is better than Pfizer based on these results … but it does seem there is more of a response from Moderna at least in terms of the assay that we used,"

Overall, individuals who received the Moderna vaccine showed a higher antibody response against the viral spike protein compared with those who received Pfizer (4,244 U/mL vs. 1,986 U/mL 30 days after dose two) and also reported stronger side effects.

Kelliher cautions these differences could arise from confounding variables such as the higher mRNA dosage in the Moderna vaccine. His team also found that antibody responses had dropped 30 days after the second dose, regardless of the vaccine given.

"We can't claim Moderna is better than Pfizer based on these results … but it does seem there is more of a response from Moderna at least in terms of the assay that we used," said Kelliher. "How that correlates with the total adaptive immune response is unknown, and there's still a decent amount of research that needs to be done on this topic."

Day Zero Diagnostics Wins Disruptive Award for Cultureless WGS Test

A suite of technologies that diagnose bloodstream infections and sepsis from Day Zero Diagnostics edged out two other companies -- one of which was co-founded by Nobel laureate Jennifer Doudna, PhD -- to win the Disruptive Technology Award on September 27 at the AACC annual meeting. Day Zero Diagnostics' technologies include whole-genome sequencing (WGS) to rapidly diagnose infections directly from clinical samples without the need for cultured growth, algorithms for species identification and drug susceptibility profiles, and a database of WGS and drug susceptibility profiles.

> "…there is an enormous unmet need for sepsis diagnosis, given that sepsis accounts for 1 in 3 hospital deaths, has a mortality rate between 10% and 40%, and generates $62 billion in care costs every year."

In his talk, CEO Jong Lee said that Day Zero's technology can provide a complete diagnosis directly from the blood in less than eight hours, enabling physicians to use a targeted treatment on day zero. For the first clinical application of its technology, Day Zero focused on bloodstream infections and sepsis. Lee noted that there is an enormous unmet need for sepsis diagnosis, given that sepsis accounts for 1 in 3 hospital deaths, has a mortality rate between 10% and 40%, and generates $62 billion in care costs every year. Day Zero's system delivers a sepsis diagnosis directly from the blood in less than 8 hours compared with the two to five days required by conventional diagnostics.

Also competing for the award were Mammoth Biosciences and MeMed, and executives from both firms made their pitch at the Atlanta conference. Mammoth Biosciences, co-founded by Doudna, in part specializes in CRISPR-based diagnostics. The company advanced as a finalist for its programmable CRISPR-based detection platform DETECTR, which searches samples for the presence of specific nucleic acids indicative of disease and provides actionable clinical information.

The AACC Disruptive Technology Award competition recognizes innovative testing and disruptive technology solutions that improve patient care through diagnostic performance or access to high-quality testing. It provides an opportunity for early to midstage startups in the medical device, diagnostic, or digital health/health IT spaces to showcase their technology to a large audience and a panel of judges. This year, the award highlighted developers of artificial intelligence and machine-learning technologies that are advancing medicine and pathology.

Study Compares Vaccinated and Naturally Infected Antibody Profiles

A research group led by Xiaochun Zhang, MD, PhD, of University Hospitals Cleveland Medical Center set out to define differences in antibodies against SARS-CoV-2 among vaccinated and unvaccinated individuals. The scientists tested for antibodies against the SARS-CoV-2 spike protein, receptor-binding domain (RBD), nucleocapsid protein, and the spike protein's S1 and S2 subunits in three study groups: 33 fully vaccinated healthcare workers, 52 healthcare workers who had recovered from natural infection, and 34 patients with active infections. The test results revealed that the fully vaccinated individuals had an average of 50-fold higher antibody levels than naturally infected, unvaccinated individuals.

> Antibodies from the vaccinated group also reacted far more strongly to the RBD and S1 viral antigens, suggesting that antibodies against these proteins could be the best targets for tests developed in the future.

Follow-up studies that profile changes in SARS-CoV-2 antibodies over time for vaccinated individuals and those with breakthrough infections could yield further insights, according to Zhang. "With the 3rd dose of mRNA vaccine on the horizon, this type of study may help identify a practical indicator in optimizing booster-dose planning if an association between antibody level and infection risk is proved," she said.

Model for AI in Diagnostics Seen in Amazon

(From LabPulse.com) There's a lot that healthcare can learn from online retail giant Amazon about how to integrate artificial intelligence (AI) into clinical care, Regina Barzilay, PhD, said during a September 26 plenary talk at the 2021 annual American Association for Clinical Chemistry meeting. In her talk, Barzilay discussed the current AI landscape in healthcare, doled out advice, and dispelled some myths. Barzilay is the distinguished professor for AI and health AI at the Massachusetts Institute of Technology (MIT) School of Engineering. What can the healthcare field learn from Amazon? Barzilay said that when Amazon gives a product recommendation to a consumer, for better or for worse, the platform aggregates all the

> Myth No. 1 was "the assumption that human judgment is the gold standard by which AI performance should be judged."

available data on that consumer before deciding what to recommend. She contrasted this "use-everything" approach with how clinical decisions are currently made based on biomarkers of dubious value and findings from clinical trials that enroll about 3% of the population.

Applying the Amazon approach, all the data known about a patient, including tests, history, and demographics, would be utilized in a flexible manner for each diagnosis. "In an ideal case, where I see the diagnostics moving is [providing] the same flexibility," said Barzilay. "The way I envision us moving forward is in taking all the information about the patient and from there predicting all the different outcomes that you can predict about the patient."

Next, Barzilay addressed an issue she is very familiar with: AI and cancer screening. Barzilay's group has successfully deployed machine-learning models for cancer detection. She is interested in the best approach to formulating machine-learning prediction tasks -- and these methods may not always align with what other clinicians think. Barzilay advocated removing humans from the loop and proceeding directly from the data to the outcome.

Specifically, Barzilay questioned using density in breast exams as a biomarker to predict a woman's risk of developing breast cancer. (That is, women whose breasts are dense have a higher risk of breast cancer versus women whose breasts are fatty.) In the U.S., a federal law requires that every woman who has a mammogram "needs to hear about density," Barzilay explained.

Common approaches to predicting a woman's risk of breast cancer include the classical risk model in which clinicians record data such as age, family, history, and prior medical breast procedures and incorporate that into a risk assessment score. In the classical risk model, where random guessing corresponds to an area under the curve (AUC) of 0.5, this added information provides a risk score with an AUC of 0.6. When the federally regulated density biomarker is added, the AUC moves to 0.63.

Barzilay questioned the assumption that human judgment is the gold standard by which AI performance should be judged.

She highlighted a study in which breast radiologists looked at the same set of patients, and some found dense breasts in 6.3% of the patients evaluated and others found dense breasts in 84.5% of the patients evaluated. Barzilay suggested moving away from the breast density biomarker and toward machine-learning models, which are not as inconsistent as humans and can learn from image outcomes -- the same way that face recognition systems can spontaneously learn what constitutes a face. "I very strongly advocate against using this kind of very rough biomarker," she said. "You can give images to the model and explain what happens to a patient in the next five years. Let the machine itself identify this pattern so you don't need to say how much [density] should be in the image."

Barzilay dispelled two of the most common myths about AI she has encountered. Myth No. 1 was "Humans provide the gold standard." Barzilay questioned the assumption that human judgment is the gold standard by which AI performance should be judged. In particular, she cited the American College of Radiology (ACR). In 2020, the ACR issued a statement in which it urged caution accepting the medical judgments of AI over human interpretation. While Barzilay admits that there are cases where machines make mistakes, she noted that human medical professionals make plenty of mistakes. Myth No. 2: "Every clinician can be an AI

researcher." The second myth that Barzilay dispelled involves the democratization of AI technology. Today, anyone can download code and train their own AI model. "We are just starting to see [the] increasing availability of tools to enable on-premises development of AI models by clinicians," she noted.

However, Barzilay cautioned that the results from a homegrown system will not be nearly as accurate as the results that can be obtained from an AI expert. To achieve the highest possible prediction performance, the model needs to be tweaked by a sophisticated AI practitioner with PhD-level training. "Don't be overconfident," she concluded.

Masked by COVID-19, Tuberculosis Threat Still Real

(From LabPulse.com) With approximately 25 percent of the global population infected, tuberculosis is one of the leading causes of death by an infectious disease. A third of infected people are in an asymptomatic, non-infectious dormant phase called “latent tuberculosis,” which, in a subset of people, can develop into active (symptomatic) disease if not treated. A session on Monday, “Advances in Tuberculosis Screening and Testing,” featured two speakers at the forefront of tuberculosis diagnosis and treatment. C. Robert Horsburgh, MD, discussed tuberculosis disease and treatment guidelines. He emphasized that non-drug-resistant tuberculosis infection can be treated if detected early. From Horsburgh, attendees learned that tuberculosis infection can develop into a latent form of the tuberculosis infection, where tuberculosis bacteria are sequestered in granulomas, and the host is not infectious. However, in a small subset of individuals with latent tuberculosis, the infection may progress to active disease. It is in this active form of the disease that people are infectious and can transmit to others.

The speakers also pointed out that during the COVID-19 pandemic, tuberculosis detection has dropped, likely due to a redirection of resources and testing toward COVID-19—and the two diseases’ overlapping symptoms

People with HIV and immunosuppressive conditions are at higher risk of developing active tuberculosis. In the US, active tuberculosis developed from the latent form is a significant public health concern. Delivering treatment to people infected with tuberculosis can stop the progression to disease and prevent transmission, but this is wholly dependent on the early diagnosis of tuberculosis infection. Here, laboratory testing plays a vital role.

L.V. Rao, PhD, FAACC, presented the latest advances in the diagnosis of and screening for tuberculosis infection. Currently, the tuberculin skin test and the interferon gamma release assays are used to detect tuberculosis infection, but they have limited availability in most parts of the world, he said. Also, both tests have limitations and considerations for test interpretation. Rao highlighted the urgent need for better tools to detect tuberculosis with faster turnaround times that allow the patient to receive results while at the clinic for a visit with their healthcare provider.

Technological advances include molecular, genetic, and rapid assays in development. Several of the newer tests being developed for diagnosis of tuberculosis infection incorporate antigen

detection. Rapid, sensitive, and easy-to-administer tests hold the promise to widen accessibility and increase screening for tuberculosis, especially in populations at high risk of infection.

The speakers also pointed out that during the COVID-19 pandemic, tuberculosis detection has dropped, likely due to a redirection of resources and testing toward COVID-19—and the two diseases' overlapping symptoms. Attendees at yesterday's session gained a deeper appreciation for the global threat of tuberculosis and the role we, as laboratorians, can play in implementing quality diagnostics. The burden of tuberculosis infection in the world is large and, in the US, most cases of tuberculosis disease are potentially preventable by diagnosing asymptomatic tuberculosis infection. Healthcare institutions should be prepared for increased demand for diagnosis of tuberculosis detection.

How scientists communicate with the public

Thorp noted that scientists are failing at the important task of communicating with the public. "I think it's fair to say that science got an 'A-plus' on the pandemic," Thorp said. "But when it comes to scientists doing social science and the humanities, we got an 'F,' because we didn't understand how to communicate our message beyond to each other."

Thorp cited masks, vaccines, systemic racism, and climate change as issues where scientists need to engage more effectively with the public. "We haven't got our message out about climate change," Thorp said. "And part of it is we've been doing the same thing for 75 years, thinking that if we just get everything right in the journals, eventually people will come around."

One problem is the tendency of scientists to hedge their conclusions with endless caveats that "bore people to tears," Thorp said. "In my opinion, we need a much more nuanced and sophisticated strategy," he said. "And one of the reasons why we need that is that the other side has a much more nuanced and sophisticated strategy."

Thorp wasn't shy about naming the purveyors of misinformation. "We're getting our lunch eaten by Ben Shapiro and Dan Bongino and ... Joe Rogan ... these guys are destroying us," Thorp said. "Because they have millions and millions of people who believe what they say no matter what, and we don't have very many people who believe what we say no matter what." Rather than try to beat the peddlers of misinformation at their own game, Thorp said scientists should focus on getting the science right and debating the science with colleagues. However, scientists should leave the messaging to allies who know how to navigate the public arena.

"You know, you hear this idea that every scientist is supposed to become a public communicator," Thorp said. "I don't believe that. People ask me all the time, 'How do I get my climate-denying uncle to believe in climate change?' Well, I can tell you the worst way would be to print out all my editorials and give them to him. I'm not the right person to do that. I write for other scientists. That is a totally different message."

The Worldwide Market for In Vitro Diagnostic Tests, 14th Edition

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Never before has in vitro diagnostics been so crucial. Tests for cancer and infectious disease detection, transplant success, and pharmaceutical selection have added healthcare value and improved outcomes. Genetic tests for rare diseases and prenatal assessment are increasingly utilized. And now, the COVID-19 pandemic has highlighted how important testing is in a way that could not be imagined.

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