COVId-19 Testing Needs More Research, Experts Say

Additional research is needed to determine if and to what extent a positive antibody test means a person may be protected from reinfection with SARS-CoV-2, according to attendees of the COVID-19 Serology Studies Workshop. Convened by experts from the U.S. Department of Health and Human Services, including scientists at NIAID, NHLBI, CDC, Biomedical Advanced Research and Development Authority, and the Department of Defense, the workshop aimed to assess efforts to better understand the implications of serology test results, to produce and validate test kits, and to quantify undetected cases of SARS-CoV-2 infection.

Until more data is available on what a positive antibody test means for SARS-CoV-2, serology tests should not be used as a standalone tool to make decisions about personal safety related to SARS-CoV-2 exposure, experts say. Researchers are now pursuing studies in humans and in animal models to better understand SARS-CoV-2 immunity. Attendees noted that such understanding could help identify optimal donors of convalescent plasma that potentially could be used to help treat those with severe COVID-19.


AMA Survey Reveals Health Insurance Industry ‘Failure’

More than two years after a consensus statement signaled insurers were open to reforming the arduous prior authorization process, their subsequent inaction has translated into stalled progress and ongoing burdens for patients and physicians, says an AMA press release. New survey data released by the AMA reveals that physicians say prior authorization continues to interfere with patient care and can lead to adverse clinical consequences, with 16% of physicians reporting that the process has led to a patient’s hospitalization. Physicians see little, if any, progress toward easing agreed-upon burdensome barriers to patient care, highlighting the need for legislative action to address a problem affecting patients across the country, the press release stated.

“These new survey results highlight that practices continue to devote significant time—an average of nearly two business days per week per physician—navigating prior authorization’s administrative obstacles. Even more concerning, this process can harm our patients,” said AMA President Susan R. Bailey, MD. “Almost two and a half years after our consensus statement, the sad fact is little progress has been made toward the reform goals. The health insurance industry’s failure to achieve agreed-upon improvements illustrates a clear need for legislation like The Improving Seniors’ Timely Access to Care Act, H.R. 3107, to rein in prior authorization practices that adversely affect patient health.”

H.R. 3107, bipartisan legislation introduced by Reps. Suzan DelBene (D-WA), Mike Kelly (R-PA), Roger Marshall, MD (R-KS), and Ami Bera, MD (D-CA), would improve care delivery for America’s seniors by requiring Medicare Advantage plans to abide by many of the concepts outlined in the consensus statement, such as streamlining and standardizing prior authorization and improving transparency of health insurer programs. A bipartisan majority of more than 219 members of the House of Representatives has already sponsored the bill.

In January 2018, the AMA and other national organizations representing pharmacists, medical groups, hospitals, and health plans signed a joint consensus statement that outlined five key areas for industry-wide improvements to prior authorization processes and patient-centered care. The shared commitment was signed by two trade organizations representing payers: America’s Health Insurance Plans and the Blue Cross Blue Shield Association.

The newly released AMA survey results reflect the limited progress that health plans have made toward implementing each of the five areas of prior authorization reform outlined in the consensus statement, including selective application of requirements, adjustment of the volume of requirements, improved transparency, protection for continuity of patient care, and automation through standardized processes.

Technology

App Mutually Beneficial for Patients, Physicians

CareSense, provided by MedTrak Inc., a third-party vendor, is a cloud-based platform designed to help hospitals engage, educate, communicate, and guide patients through their episode of care. Using automated phone calls, text messages, emails, and app notifications, it delivers critical information to patients in a timely way. Patients can be provided reminders about appointments, medications, and exercises. Benefits to the patient are reduced missed appointments, lower surgical cancellations, increased compliance with clinician-recommended medications and exercises, enhanced patient education, and improved patient satisfaction. Clinicians can track patient progress, answer patient questions, receive alerts about potential problems from patients that could jeopardize patient safety, and increase their chances to cancel their procedure. Also, clinicians can provide custom videos and daily emails to educate their patients on their condition and the procedure they are having. Benefits to clinicians include reduction in readmission, the ability to track outcomes, saving the clinician’s time as well as lower post-acute care costs.

This platform collects and analyzes patient-reported outcomes, satisfaction data, marketing information, and research. Institutions can utilize this platform to facilitate their participation in bundled payment programs such as CMS’ Comprehensive Care for Joint Replacement (CJR) Model. The CJR Model is a bundled payment program for hip and knee replacements that holds hospitals financially accountable for the quality and cost of a comprehensive joint replacement episode of care while creating incentives to increase the coordination of care among hospitals, physicians, and post-acute care providers. This platform can help standardize the care pathways patients experience by assisting all members of the care team to better adhere to an established protocol. More adherence to an established protocol has been demonstrated to increase the overall quality of care, improve patient satisfaction, and reduce costs.

ReActiv8® Neurostimulation System Receives FDA Approval

Mainstay Medical announced FDA approval of the company’s Premarket Approval (PMA) application for ReActiv8®, its implantable neurostimulation system to treat intractable chronic low back pain. The FDA approval grants Mainstay the right to market ReActiv8® in the United States as an aid in the management of intractable chronic low back pain associated with multifidus muscle dysfunction, as evidenced by imaging or physiological testing in adults who have failed therapy, including pain medications and physical therapy, and are not candidates for spine surgery.

The approval is primarily based on results from the ReActiv8-B clinical study, a pivotal 204-patient, international, multicenter, prospective, randomized, active sham-controlled, blinded trial with one-way cross-over, conducted under an investigational device exemption (IDE) from FDA.