AAMC Novel Coronavirus Update
October 14, 2020

To help filter through the large volume of news about the novel coronavirus, Ross McKinney Jr., MD, AAMC chief scientific officer, with assistance from his team in the Scientific Affairs unit at the AAMC, has initiated this science-focused newsletter.

This newsletter will be published once per week on Wednesdays.

Opt-in to receive future updates.

Contact AAMC Lead Science Policy Specialist Anu Dev, PhD, with any other questions or requests.

To access the latest AAMC updates and resources on COVID-19, visit aamc.org/coronavirus. For resources on COVID-19 medical research, read more here.

Please share/forward this newsletter freely.

Today's Numbers

- World: 38,215,510 confirmed cases (1,087,600 deaths)
  - 2,322,834 new cases this week (2,162,000 new cases last week)
- United States: 7,519,846 (211,343)
  - 357,264 new cases this week (309,000 new cases last week)
  - 4,963 deaths this week (4,872 deaths last week)
  - 117,357,626 total tests
- U.S. Hot Spots
  - Virginia: 7,919 new cases in the past week (46% increase in the past week)
  - New Mexico: 2,341 (43%)
  - Illinois: 20,263 (39%)
  - Montana: 4,147 (39%)
  - North Dakota: 4,090 (36%)

For the most up-to-date data, refer to the Johns Hopkins COVID-19 Map. Details of other U.S. hot spots can be found at the Washington Post's coronavirus data webpage.

The Institute for Health Metrics and Evaluation at the University of Washington Medicine is projecting hospital resource use in the United States based on COVID-19 deaths.

Lead News

The process of conducting a clinical trial that results in Food and Drug Administration (FDA) approval of a novel vaccine can be a long and winding road. Johnson & Johnson
placed an enrollment hold on their Phase 3 clinical trial after one subject developed an undisclosed illness of sufficient severity to justify a temporary halt. The specific condition has not yet been revealed to the public. [Editor’s comment: Two of the five major United States vaccine trials, from Johnson & Johnson and AstraZeneca, have been placed on hold. The AstraZeneca hold has persisted for several weeks in the United States, reportedly in response to a case of transverse myelitis in one of the trial participants. Both of these situations are reminders that rushing to FDA approval may not be a good thing.]

**Treatment News**

Eli Lilly and Regeneron have both requested emergency use authorizations (EUAs) for their monoclonal antibody preparations to be used in treatment or prevention of COVID-19. Notably, Eli Lilly requested an EUA for a single monoclonal, LY-CoV555, not their combination product, while Regeneron’s product is a combination of two monoclonal antibodies.

Last week, Eli Lilly provided additional details regarding their three-arm BLAZE-1 Phase 2 clinical trial for mild-to-moderately affected outpatients, some of whom received a single monoclonal (LY-CoV555), while others received a combination of two monoclonal antibodies (LY-CoV555 and LY-CoV016). 112 volunteers were given the combination antibody, and 156 were given a placebo. The primary endpoint was a decrease in viral load at day 11, which was achieved, although significant decreases were also seen at day 3 and day 7. The combination antibody also reduced symptoms and lowered the rates of hospitalizations and emergency room visits. However, ACTIV-3, another study using LY-CoV555 being done in collaboration with the National Institutes of Health (NIH), was placed on hold this week due to an adverse event. ACTIV-3 is a randomized, placebo-controlled trial in hospitalized patients, all of whom receive remdesivir in addition to the Eli Lilly monoclonal or placebo. [Editor’s comment: While drug discovery research is always fraught with surprises, the enrollment hold on ACTIV-3 is something of a surprise. Targeted monoclonal antibodies weren’t expected to have much in the way of off-target effects, but this episode again points out the need for careful clinical trials.]

An NIH-sponsored Phase 3 clinical trial studying the antiviral remdesivir in combination with neutralizing SARS-CoV-2 antibodies in hospitalized adults with COVID-19 has begun in the United States and nearly 20 other countries. The Inpatient Treatment with Anti-Coronavirus Immunoglobulin (iTAC) trial is co-sponsored by the NIH’s National Institute of Allergy and Infectious Diseases (NIAID). The main goal of the trial is to compare the combination therapy to remdesivir-only treatment on day 7. NIAID Director Anthony Fauci, MD, said, “The iTAC trial will examine whether adding anti-coronavirus hlVIG to a remdesivir regimen can give the immune system a needed boost to suppress SARS-CoV-2 early in the course of illness, nipping the infection in the bud.” [Editor’s comment: Both monoclonal antibodies and convalescent plasma will probably be useful only for patients early in their clinical course who have not yet developed their own neutralizing antibodies. In essence, these two classes of anti-COVID-19 drugs accelerate the immune response. Once someone already has antibodies, additional antibodies will probably have very little therapeutic role.]

An ACTT-1 placebo-controlled study evaluated intravenous remdesivir for the treatment of hospitalized patients with evidence of lower respiratory tract disease. The primary endpoint was time to discharge or retention in the hospital for infection-control reasons only. 1062 patients were randomized: 541 to remdesivir and 521 to placebo. The median time to recovery was 10 days for the remdesivir-treated patients and 15 days for placebo controls. Mortality by day 29 was 11.4% for the remdesivir group versus 15.2% for the placebo. [Editor’s comment: Remdesivir has limited benefits, although they are
measurable. The mortality benefits were not statistically significant but may still be real if not profound.]

The American Society of Hematology (ASH) issued guidelines on the use of anticoagulation in patients with COVID-19. The ASH recommendations were reviewed by Medpage Today.

NIH launched a study designed to determine whether certain approved therapies or investigational drugs in late-stage clinical development show promise against COVID-19 and merit advancement into larger clinical trials.

The NIH updated its page on the therapeutic management of patients with COVID-19.

**Clinical News**

A study in Science Immunology examined the antibody response to SARS-CoV-2 in saliva and its relationship to systemic antibody levels, and it found IgG antibodies against viral antigens in both serum and saliva to be maintained in the majority of COVID-19 patients for at least three months post-symptom onset, suggesting potential diagnostic value of saliva to detect both virus and antibody levels.

An article in the Lancet described an investigation of two instances of SARS-CoV-2 infection in the same individual, suggesting that previous exposure to COVID-19 may not guarantee protective immunity. This is the second known case of reinfection, and while it’s unclear if this is a generalizable occurrence, researchers note the public health implications of reinfection and subsequent need for continued social measures to stem viral spread.

A study in JAMA evaluating whether SARS-CoV-2 can be transmitted by breast milk found that in breast milk from 18 SARS-CoV-2 infected women, only one sample of 64 was positive for viral RNA, and that sample did not have detectable replication-competent virus. [Editor's comment: Obviously good news for breastfeeding infants. The authors hint that Holder pasteurization may also be helpful in special circumstances.]

In another study relevant to infants in JAMA Pediatrics, a cohort analysis of 101 infants born to COVID-19-infected women at a single institution found that two infants had positive tests for SARS-CoV-2, but neither had any clinical evidence of COVID-19. The lack of vertical transmission was despite the fact that rooming-in and breastfeeding were frequently practiced.

**Coronavirus and Health Equity**

A new nationwide survey by the Kaiser Family Foundation and the Undefeated exploring Black Americans’ views and experiences of the pandemic found that nearly half of Black Americans say they would probably or definitely not take a coronavirus vaccine even if it is free and scientists say it is safe. By comparison, two-thirds of White Americans and 60% of Latinx Americans say they would get vaccinated. Further, nearly 6 in 10 Black respondents say the health care system never or only some of the time does “what is right for their communities.”

*Lancet: COVID-19 and Mass Incarceration: A Call for Urgent Action*
Research News

Researchers in Japan published a study in *Clinical Infectious Diseases* evaluating the stability of SARS-CoV-2 on human skin. They found that while SARS-CoV-2 lasts significantly longer on skin (approximately nine hours) than influenza A virus (closer to two hours), it can be quickly deactivated with the use of an ethanol-based disinfectant, emphasizing the importance of hand hygiene in containing the virus.

Scientists in Germany evaluated the structure of the SARS-CoV-2 spike protein (S) as it exists on the virus, as compared to recombinant spike protein. They found that S is more heavily glycosylated and that it has three protein hinges along the stalk that allow the spike to be flexible. The glycosylation sites actually protect the hinges from antibodies, preserving that flexibility. The researchers proposed that the flexible hinges may enable the virus to interact more easily with the cell surface’s angiotensin-converting enzyme 2 (ACE2) receptor, the virus attachment site.

Central nervous system diseases and neurological symptoms are common manifestations in COVID-19 patients. An autopsy series in Hamburg, Germany, that was published in the *Lancet Neurology* found that while viral RNA and proteins were found in the brain tissue of patients who died from COVID-19, the extent of disease did not correlate well with the viral load. Instead, the degree of immune reaction seemed to be the critical factor. The researchers note, "The neuropathological alterations are most likely to be immune-mediated, and there does not seem to be fulminant virus-induced encephalitis nor direct evidence for SARS-CoV-2-caused central nervous system damage."

*Science: Contextualizing Bats as Viral Reservoirs*

*Science: A Call to Test New Vaccines Head to Head, in Monkeys*

Testing News

The FDA has announced it will no longer review EUA applications for COVID-19 laboratory developed tests (LDTs). This follows the announcement from the Department of Health and Human Services in August that the FDA could not require an EUA for LDTs, and it came as a surprise for those going through the EUA process on a voluntary basis. While the initial announcement represented regulatory relief from a process that some thought slowed down the test development process, losing the option to have FDA review of some tests may prevent them from being reimbursable under the Public Readiness and Emergency Preparedness (PREP) Act and may leave the developer without liability protection under the Coronavirus Aid, Relief, and Economic Security (CARES) Act that
requires an FDA authorization for the test. [Editor's comment: This is yet another turn in the years-old tension over the FDA oversight of LDTs. The correct amount of oversight for LDTs probably rests somewhere between a matador’s cape and a stone wall — the issue should not be a binary either/or.]

The use of rapid point of care (POC) SARS-CoV-2 antigen tests in screening asymptomatic individuals has proved controversial. The state of Nevada ordered nursing homes to stop using the tests after the identification of more than 20 false positive tests when the POC test results were compared to a polymerase chain reaction (PCR) assay. Critics of the restriction noted that true positives had been identified as well, which had significant epidemiological ramifications.

*Nature Scientific Data: Cross-country Database of COVID-19 Testing*

*Modern Healthcare: Huge Demand for COVID-19 Rapid Antigen Testing May Face Manufacturing Constraints*

### Other COVID-19 News

An evaluation of [COVID-19 mortality and the excess all-cause mortality rates in the United States and 18 other countries](https://www.cdc.gov/coronavirus/2019-ncov/covid-data/modeling-data.html) found that after peak mortality in the spring, the United States had higher rates of both COVID-19 and all-cause mortality than other countries, including those with high COVID-19 mortality rates. The researchers note that the United States’ population was younger but had more comorbidities than the comparison countries.

*Science: Researchers Face Hurdles to Evaluate, Synthesize COVID-19 Evidence at Top Speed*

*Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report: Characteristics Associated with Adults Remembering to Wash Hands in Multiple Situations Before and During the COVID-19 Pandemic — United States, October 2019 and June 2020*

*Scientific American: COVID-19 Is Now the Third Leading Cause of Death in the U.S.*

*AP: China Joins COVAX Coronavirus Vaccine Alliance*

*Science: Sweden's Gamble*

For questions, contact **Anu Dev**, PhD, AAMC lead science policy specialist.

Ross McKinney Jr., MD  
Chief Scientific Officer  
rmckinney@aamc.org

Anu Dev, PhD
Lead Specialist, Science Policy
adev@aamc.org

Stephen J. Heinig
Director, Science Policy
sheinig@aamc.org

Philip Alberti, PhD
Senior Director, Health Equity Research & Policy
palberti@aamc.org

Unsubscribe from this series of newsletters
Update Profile

© %xtyear% AAMC | Privacy Policy