AAMC Novel Coronavirus Update
December 2, 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.

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Today's Numbers

- World: 64,054,194 confirmed cases (1,484,164 deaths)
  - 4,079,530 new cases this week (4,142,963 new cases two weeks ago)
- United States: 13,751,282 (271,064)
  - 1,130,147 new cases this week (1,101,228 new cases two weeks ago)
  - 10,687 deaths this week (8,201 deaths two weeks ago)
  - 194,157,032 total tests
- U.S. Hot Spots
  - California: 81,140 new cases in last 7 days (3% change in daily cases)
  - Texas: 58,601 (-16%)
  - Illinois: 53,379 (-18%)
  - Ohio: 47,350 (-9%)
  - Florida: 46,490 (-3%)

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.
vaccine mRNA-1273. The Phase 3 study, called COVE, enrolled 30,000 participants and found 196 symptomatic cases of COVID-19 in the study population. 185 cases were seen in the placebo group and 11 cases were seen in the vaccine cohort—a vaccine efficacy of 94.1%. There were 30 severe cases of COVID-19, all in the placebo group. There was one COVID-19-related death in the placebo group. 7,000 enrollees were over 65 years old, and another 5,000 enrollees were deemed high risk for severe COVID-19. 11,000 enrollees were from communities of color. [Editor’s comment: Press releases are not the ideal way to learn study results, but in this case the outcomes were very positive. Both the Moderna and Pfizer mRNA vaccines look similarly efficacious, and both hold considerable promise to help ameliorate the pandemic. Production rate will be an issue, and demand can be predicted to exceed supply for a while.]

Treatment News

The checkered experience with immunomodulating agents in treating COVID-19 added another chapter when the FDA issued an EUA for the combination of Eli Lilly’s oral Janus kinase inhibitor baricitinib (Olumiant) and intravenous remdesivir in patients with advanced COVID-19 requiring supplemental oxygen, assisted ventilation, or extracorporeal membrane oxygenation. The FDA used the ACTT-2 study sponsored by the National Institutes of Health (NIH) as the basis for the approval. In ACTT-2, 1,033 patients with moderate or severe COVID-19 were enrolled—515 on baricitinib with remdesivir and 518 on placebo with remdesivir—and followed for 29 days. The study produced a one-day reduction in median recovery time in the baricitinib group. [Editor’s comment: While the full results have yet to be reported in a peer-reviewed journal, a median one-day improvement in a study enrolling more than 1,000 subjects is hardly persuasive. Baricitinib may ultimately prove to be beneficial, but the gains are at best marginal.]

In addition to the news about the mRNA vaccines, AstraZeneca has published results from a Phase 2 study with their chimpanzee adenovirus-based vaccine ChAdOx1, also known as AZD1222, demonstrating that the vaccine has good immunogenicity in volunteers age 70 and older. The control group for the study received a meningococcal vaccine. There were three cohorts: 18-55, 56-69, and 70 and up, all of whom received a two-dose prime-boost regimen. Median spike antibody titers were similar in all three groups. 99% of subjects had detectable neutralizing antibody titers after two doses, and there were fewer adverse experiences in the older cohort. AstraZeneca also announced interim results of one Phase 3 trial. 2,741 volunteers were accidentally given a half dose of the vaccine as the first administration, and 8,895 volunteers were given the actual planned first dose. All 11,636 received the full second dose. The low-dose cohort showed an efficacy of 90%, while the originally planned regimen had a 60% efficacy. Overall efficacy in the study was 70%. No vaccinated individuals had severe COVID-19. [Editor’s comment: Sometimes serendipity happens and good fortune follows. Sometimes what appears to be sloppy research is hard to believe. Is the low/high regimen meaningfully better? It’s hard to know given this press release, and I suspect the data will continue to be hard to interpret even when submitted for peer review. The AstraZeneca vaccine will likely be more readily available in the US, and the interim data are already being used to support emergency use. The concern is the low effective dose found in the first administration.]
patients given REGN-CoV2 with more advanced disease may, in fact, do worse than those given a placebo. [Editor’s comment: While supplies will be limited, REGN-CoV2 shows real promise for high-risk patients who are seen early in the course of COVID-19, as does the Eli Lilly monoclonal antibody, bamlanivimab, which has also received an FDA EUA.]

Pfizer and BioNTech submitted an EUA request to the FDA for their SARS-CoV-2 vaccine BNT162b2. The United Kingdom, meanwhile, has just issued an emergency authorization for the use of this vaccine. The British government said that 800,000 doses would be available for administration beginning next week.

Clinical News

Convalescent plasma has been proposed as a treatment for COVID-19. There has been a suspicion it would be most effective if used early in the course of the disease, which would be similar to the Eli Lilly and Regeneron monoclonal antibodies. A randomized placebo-controlled trial published in the New England Journal of Medicine confirmed a portion of that suspicion. 333 adult patients hospitalized with severe COVID-19 pneumonia were randomized 2-to-1 to a convalescent plasma or placebo group. The primary endpoint was the patients’ clinical status evaluated 30 days after enrollment. There were no significant differences between the two arms. [Editor’s comment: The common theme on antibody treatments is that their value is to shut down viral replication early. By the time an individual is making their own anti-SARS-CoV-2 antibodies, there is no point to layering on exogenous antibody supplements. The need for antibody treatments to be used in the early stages of disease reinforces the importance of early SARS-CoV-2 diagnostic testing with rapid turnaround on results.]

A case series at Parkland Hospital in Dallas of pregnant women infected with SARS-CoV-2 was reported in JAMA Open Network. The study monitored pregnancies between March 18 and Aug. 22, following 3,374 women. 252 women were infected with SARS-CoV-2 — 239 of whom showed mild or asymptomatic illness at initial presentation, and six developed severe disease. 14 women were hospitalized for COVID-19 — a rate similar to nonpregnant infected women. There were no adverse pregnancy outcomes.

Policy News

In a very clever study published by the Centers for Disease Control and Prevention (CDC) in the Morbidity and Mortality Weekly Report, epidemiologists evaluated the rates of COVID-19 infection in Kansas counties that had mask mandates in comparison to counties that did not. In the span of June 1 to Aug. 23, 2020, the 24 counties with mask mandates saw a 6% decrease in case rate per 100,000 people, while the 81 counties with no mask mandates had a 100% increase. [Editor’s comment: We have known for most of the pandemic that masks would reduce transmission; we now know they would also save lives.]
The CDC is expected to recommend a 10-day quarantine after exposure to COVID-19 instead of the 14 days currently recommended — and only seven days if the individual has a negative diagnostic test.

AAMC Calls for Implementation of Crisis Standards of Care to Address COVID-19 Surge

Coronavirus and Health Equity

Due to the disproportionate impact of COVID-19 on racial and ethnic minorities in the United States, the life expectancy gap between Black people and White people is expected to increase by as much as five years by the end of 2020 according to new research published ahead of peer review. The Latinx community will face the greatest lifespan reduction, effectively erasing the long-standing longevity advantage they have had: In 2017, Latinx life expectancy was more than three years greater than White life expectancy.

Various interviews, conversations, and articles have described the crucial role Marcella Nunez-Smith, MD, one of the co-chairs of President-elect Joe Biden’s advisory board on the coronavirus pandemic, will play in focusing the United States’ response to the pandemic on health equity and racial justice.


Healthcare IT News: COVID-19's Racial Health Inequities Call for a Novel Collaborative Approach

US News & World Report: From Tuskegee to a COVID Vaccine: Diversity and Racism Are Hurdles in Drug Trials

Research News

A report in Science described how two potent human neutralizing monoclonal antibodies interact with the spike protein of SARS-CoV-2. Using cryo-electron microscopy, the investigators were able to demonstrate that both antibodies engaged the virus spike protein and competitively blocked attachment to the ACE2 receptor on cells. One of the antibodies also locked the spike protein into a closed formation by binding onto two adjacent receptor binding domains, thus providing a second means of neutralization.

Investigators at the University of Washington performed simultaneous quantitative assays for IgG anti-SARS-CoV-2 nucleocapsid antibodies and measurements of the cycle numbers in a polymerase chain reaction (PCR) assay as a measure of viral load in 245
later in patients with severe COVID-19 compared to patients with mild-to-moderate disease, while the titers against spike and receptor binding domain became 1.5-fold higher in patients with severe disease during hospitalization. Lower antibody titers were associated with longer viral shedding.

*The Journal of Infectious Diseases: Monocyte CD169 Expression as a Biomarker in the Early Diagnosis of COVID-19*

### Testing News

*Nature: A Serological Assay to Detect SARS-CoV-2 Antibodies in At-home Collected Finger-prick Dried Blood Spots*

### Other COVID-19 News

*Nature: Why Emergency COVID-vaccine Approvals Pose a Dilemma for Scientists*

*KFF: States Are Getting Ready to Distribute COVID-19 Vaccines, What Do Their Plans Tell Us So Far?*

*Scientific American: Mysteries of COVID Smell Loss Finally Yield Some Answers*

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