AAMC Coronavirus Update
March 17, 2021

To help filter through the large volume of news about the 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 Senior Science Policy Specialist Julia Omotade, 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: 120,917,739 confirmed cases (2,674,151 deaths)
  - 3,069,485 new cases this week (2,385,777 cases last week)
- United States: 29,556,707 confirmed cases (537,123 deaths)
  - 383,212 new cases this week (402,049 cases last week)
  - 17,915 deaths this week (11,541 last week)
  - 375,491,000 total tests
- U.S. Hot Spots
  - New York: 47,393 new cases in last 7 days (-7% change in daily cases)
  - Florida: 31,692 (-9%)
  - Texas: 31,468 (-20%)
  - New Jersey: 26,204 (+12%)
  - California: 18,818 (-34%)
- U.S. COVID-19 Vaccine Distribution and Administration
  - Total doses delivered: 147,590,615
  - Total doses administered: 113,037,627

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. Overall U.S. COVID-19 vaccine distribution and administration data can be found at the Centers for Disease Control and Prevention (CDC) COVID Data Tracker.

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

A frequent question for vaccinators has been, “If I’ve already had documented COVID-19, do I need two doses of one of the mRNA vaccines?” Fortunately, there is now data that speaks to that important issue. Investigators at Icahn School of Medicine at Mount Sinai published data in the New England Journal of Medicine on comparisons of vaccine-produced SARS-CoV-2 antibody responses by 67 seronegative and 43 seropositive adults. 88 volunteers received the vaccine from Pfizer and its German partner BioNTech and 22 volunteers received the Moderna vaccine. Seronegative individuals had a slower and more variable antibody rise, while previously infected individuals had a rapid and more uniformly high response (10 to 45 times as high as the responses of seronegative people). There was no increase in antibody titers in seropositive individuals after a second dose of vaccine. [Editor’s comment: The study is small enough that it’s not a definitive statement, but it’s reasonable to expect that eventually there will be recommendations that people who had documented COVID-19 should receive only one dose of an mRNA vaccine as a boost. Essentially, actual SARS-CoV-2 infection acts like the “prime” in the prime-boost package used by the mRNA vaccines. The data looks interesting, but I await confirmation from the CDC and/or the Food and Drug Administration (FDA) regarding the recommendation for only a single dose after confirmed infection.]

Treatment News

In the back and forth regarding whether the anti-IL-6 receptor drug, tocilizumab, is an effective adjunctive treatment for COVID-19, Roche announced in a press release that the addition of tocilizumab to remdesivir did not shorten the time to hospital discharge in patients admitted with COVID-19 pneumonia. The study, called REMDACTA, was a phase 3, multicenter, international, placebo-controlled study of adding tocilizumab or placebo to a regimen containing the antiviral remdesivir. Study participants were patients who had been hospitalized with COVID-19 pneumonia, and the primary endpoint was the time of hospital discharge (out to 28 days). Mortality was assessed as a secondary endpoint. No benefit was observed in either assessment (time of hospital discharge or mortality). [Editor’s comment: Studies of tocilizumab have produced variable results. A study published in the NEJM earlier this year demonstrated that in underrepresented and minority populations admitted with COVID-19, tocilizumab reduced the progression to a composite endpoint of mechanical ventilation or death. The bottom line is probably that it might be marginally helpful in some patients, though it’s hard to know which.]

GSK and Vir Pharmaceuticals announced the results of a study of their novel monoclonal antibody VIR-7831 in patients with mild to moderate COVID-19. The study, called COMET-ICE, infused VIR-7831 or placebo as a monotherapy in adults at high risk for hospitalization with early documented COVID-19. The drug produced an 85% decrease in hospitalization or death, and as a result, the companies stated they were planning to apply to the FDA for an emergency use authorization (EUA). Aware that one of the largest concerns with monoclonal antibodies is that viral variants like B.1.351 are resistant, the companies noted that neutralizing activity was retained against the B.1.1.7, B.1.351, and P.1 variants in in vitro studies. The authors attribute that finding to the fact that VIR-7831 binds to a highly conserved region of the spike protein.
Clinical News

In the *NEJM*, researchers from South Africa published the results of their studies of the AstraZeneca (ChAdOx1 nCoV-19) COVID-19 vaccine against the B.1.351 variant first detected in South Africa. As has been well-publicized, the results were clear and unfavorable for the vaccine. Participants were 18-65 years old, which limited the ability of the study to speak to prevention of severe disease, with 2,026 HIV-negative adults randomized 1-to-1 to vaccine or placebo. Efficacy was measured as laboratory-confirmed symptomatic COVID-19 14 or more days after the second dose of vaccine. Mild to moderate COVID-19 developed in 23 of 717 placebo recipients and in 19 of 750 vaccine recipients. The efficacy was 21.9%. 92.9% of the cases were caused by the B.1.351 variant, and against this variant, the efficacy was 10.4%. [Editor’s comment: While this outcome was well-publicized before it was published, the results are fairly stark for the AstraZeneca vaccine. The vaccine is effective against the original SARS-CoV-2 virus and the B.1.1.7 variant, but the lack of potency against B.1.351 (and presumably the kindred P.1 variant) is not favorable news. In other studies, vaccines have proved effective for prevention against severe disease, but because this study enrolled only relatively low-risk volunteers (i.e., people younger than 65 years old), this analysis wasn’t available.]

In contrast to the less than ideal news for AstraZeneca, Novavax announced the results of its efficacy studies in the United Kingdom and South Africa in a press release. The Novavax vaccine is a combination of an adjuvant and purified spike protein produced in cell-culture systems using ovary cells from the fall armyworm. The U.K. study evaluated 15,000 volunteers who were between the ages of 18 and 84, with 27% being over the age of 65. The endpoint was symptomatic, PCR-confirmed COVID-19 seven days or more after the second dose of vaccine. Efficacy was 96.4% against the original SARS-CoV-2 virus (D614G) and 89.7% against the B.1.1.7 variant. There were five cases of severe disease, which were all in the placebo group. In the over-65 age group, 90% of the cases were in the placebo group. In South Africa, Novavax reported results on both HIV negative and positive individuals. There were 147 PCR-positive symptomatic cases. 96 of the cases were in the placebo group and 51 were in the vaccinated group, which resulted in an efficacy of 48.6%. The efficacy in HIV-negative volunteers was 55.4%. [Editor’s comment: The Novavax vaccine, while late to the party, shows promise, and the fact that it has some effect against B.1.351 is good news. The fact that it has less effect against B.1.351 than the original virus is probably an inducement to develop boosters that incorporate the variant spike proteins in the future.]

As schools reopen to in-person classrooms, the issue of COVID-19 vaccination for children has become increasingly important. The *New York Times* reported that Moderna has announced that they are currently enrolling 3,000 children between the ages of 12 and 17 in a study of adolescent vaccination, which will hopefully have results by this summer. Likewise, Moderna has just begun a 6,750-participant study for children who are 6 months to 11 years old. The younger children’s study includes two phases: a dose-finding component followed by a more traditional placebo-controlled study. In the dose-finding study, children who are 6 months to 1 year old will receive two 25, 50, or 100 microgram doses spaced 28 days apart. The 50 and 100 microgram doses will be tested in children ages 2 to 11. After the dose is selected, the second phase of the study will introduce a placebo control arm. The primary endpoints are safety and antibody titers, with efficacy as a secondary endpoint. [Editor’s comment: Given the falling rate of community spread, the value of a placebo-controlled efficacy study in this population seems low, primarily because there won’t be enough endpoints to evaluate. That being said, the main utility of this study seems to be identifying the proper doses and balancing the need to elicit adult-like antibody titers with control of the side effect profile.]
In a clever observational study, the CDC evaluated the Pfizer vaccine in residents of two skilled nursing facilities and published the results in the Morbidity and Mortality Weekly Report (MMWR). The question being asked was how quickly the first dose of the vaccine affected the spread of SARS-CoV-2 in the nursing home. The efficacy of the vaccine from 14 days after the first dose to seven days after the second dose was 63%. The take-home message is good news: The vaccine quite quickly begins to offer protection, even in a situation with fragile elderly patients.

**Moderna Announces First Participants Dosed in Study Evaluating COVID-19 Booster Vaccine Candidates**

**Policy News**

On March 11, President Joe Biden signed a $1.9 trillion coronavirus pandemic relief bill to address the economic damage caused by the pandemic. This legislation has huge implications for the scientific community and will allocate billions of dollars to bolster vaccine distribution, coronavirus testing and tracing, and pandemic-related research. Notably, the bill allocates $1.75 billion to sequence and track SARS-CoV-2 variants and nearly $1 billion in research funding for federal organizations such as the National Science Foundation and the U.S. Fish and Wildlife Service.

On March 11, the Biden administration released details of an accelerated vaccination plan to make every adult in the United States eligible for vaccination no later than May 1, including plans to increase the number of vaccination sites and the number of personnel providing vaccines.

**Coronavirus and Health Equity**

A new issue brief from the Assistant Secretary for Planning and Evaluation (ASPE) described stark racial/ethnic inequities in COVID-19-related vaccination, testing, infection rates, hospitalizations, and deaths. The ASPE also suggested various policy solutions to these inequities, including improving our public health data infrastructure and expanding access to health care and social services.

A new poll from AP-NORC found that while 25% of all adults in the United States reported being laid off during the pandemic, that proportion rose to 29% for Black adults and 38% for Latino adults. Additionally, while 30% of adult Americans said their current household income was lower than it was pre-pandemic, that figure rose to 40% for adults under the age of 30 — a group hit particularly hard by the recession.

The Biden administration announced a $250 million funding opportunity aimed at “Advancing Health Literacy to Enhance Equitable Community Responses to COVID-19.” Up to 73 awards of $3 million to $4 million each will be made to local municipalities. Applications are due on April 20, 2021.

**New York Times: L.G.B.T.Q. People Face Increased Risks From Covid, but Many Don’t Want the Vaccine**

**Fronteras: The Navajo Nation Took A Hard Stance Against COVID-19; Experts Say It**
Research News

2020 saw the emergence of multiple variants of SARS-CoV-2, including B.1.1.7, a variant first detected in the United Kingdom in September 2020 that has now spread to multiple countries worldwide. Emerging SARS-CoV-2 variants have been the subject of much attention — both in the media and on the scientific benchtop — and for good reason. Almost immediately, a sleuth of studies began examining if these “variants of concern” harbor mutations that might lead to enhanced transmission and/or virulence. Though studies have established B.1.1.7 as more transmissible, a recent manuscript by Davies et al., “Increased Mortality in Community-tested Cases of SARS-CoV-2 Lineage B.1.1.7,” analyzed datasets from B.1.1.7-derived COVID-19 deaths in England from September 2020 to February 2021, demonstrating that B.1.1.7 is not only more transmissible but also may lead to greater disease severity (approximately a 61% higher hazard of death associated with B.1.1.7). Like many others, this study adds to the growing body of work that reflects researchers’ expeditious drive to characterize how “variants of concerns” affect transmission, diagnostics, and future therapeutics.

In addition to increased virulence and/or transmission, perhaps one of the most pressing questions about the evolution of SARS-CoV-2 is whether the existing variants can evade antibody-mediated immunity generated by the currently available vaccines. A comprehensive review by Altman et al. put a spotlight on recent research articles that examine this million-dollar question: Can existing vaccines mount an immune response that sufficiently confers protection against the SARS-CoV-2 variants? In a recent Science article, Muik et al. examined the B.1.1.7 variant, which harbors amino acid changes in the viral spike glycoprotein (spike protein/spike) — a change previously shown to increase the affinity of the SARS-CoV-2 spike protein for its cellular target. The primary question that the authors asked was: Might this variant also escape recognition by neutralizing antibodies conferred by the Pfizer mRNA vaccine? To address this question, the authors tested the “Wuhan reference strain” and the “B.1.1.7 lineage” spike protein with sera from 40 subjects who were previously vaccinated with the mRNA-based Pfizer vaccine (previously shown to have a high efficacy for eliciting neutralizing antibodies to the spike protein). Interestingly, the authors found that the immune sera from the subjects “had slightly reduced but overall largely preserved neutralizing titers against the B.1.1.7 lineage pseudovirus” — indicating that the B.1.1.7 lineage will likely not evade immune protection mounted by the Pfizer vaccine. Despite some limitations of their study, the authors concluded that the current Pfizer vaccine provides “a significant cushion” of protection against the B.1.1.7 variant — welcome news as researchers continue to investigate how and if variants respond to the currently available vaccines.

Initial entry of SARS-CoV-2 is mediated by the spike glycoprotein, making the spike protein a key target for vaccine design (a mechanism for current vaccines is to elicit neutralizing antibodies that block spike and prevent viral infection). This week’s editions of Cell Host & Microbe and Cell features three articles that use distinct but complementary in vitro and in vivo methods to examine if mutations in the SARS-CoV-2 spike receptor binding domain escape vaccine-mediated anti-spike neutralizing
responses.

**Cell: Potent SARS-CoV-2 Neutralizing Antibodies Directed Against Spike N-Terminal Domain Target a Single Supersite**

**medRxiv: Are Vaccines Safe in Patients With Long COVID? A Prospective Observational Study.**

**CDC MMWR: COVID-19 Vaccine Second-Dose Completion and Interval Between First and Second Doses Among Vaccinated Persons — United States, December 14, 2020–February 14, 2021**


**JAMA: Immunogenicity of a Single Dose of SARS-CoV-2 Messenger RNA Vaccine in Solid Organ Transplant Recipients**

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### Testing News

With the recognition that screening tests are going to be particularly important in safely reopening schools and workplaces, the FDA [announced its intention](https://www.fda.gov) to provide a more streamlined path to EUAs for screening tools and to increase consumer access to COVID-19 tests. A [supplemental template](https://www.fda.gov) for developers of molecular and antigen diagnostic COVID-19 tests describes how to seek EUAs for tests intended for serial screening (testing the same individual multiple times over a few days). This approach could potentially affect the development of at-home tests. The FDA stated that “in certain circumstances, a POC test or an at-home test could be authorized for over-the-counter (OTC) use without the need for validating its use in asymptomatic individuals prior to authorization. The FDA believes that evidence of a test’s strong performance in symptomatic patients combined with serial testing can mitigate the risk of false results when testing asymptomatic individuals.” A concurrently released fact sheet, [Screening for COVID-19: Deciding Which Test to Use When Establishing Testing Programs](https://www.fda.gov), is intended to assist schools, workplaces, communities, and others in the selection of specific tests and establishment of a screening program.

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### Other COVID-19 News

**AAMCNews: One Year Into COVID, Scientists Are Still Learning About How the Virus Spreads, Why Disease Symptoms and Severity Vary, and More**

A recent *Science* article discussed the impact of the pandemic on the academic medicine enterprise, [examined the disproportionate effect on researchers from underrepresented groups](https://www.sciencemag.org), and posited strategies to combat loss of productivity.

As we mark the one-year anniversary of the declaration of the COVID-19 pandemic, National Institutes of Health Director Francis Collins, MD, PhD, reflected on [what the scientific community has learned and achieved](https://www.nih.gov) in these unprecedented times and what it will take to successfully combat the next worldwide pandemic.
For questions, contact Julia Omotade, PhD, AAMC lead science policy specialist.

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