AAMC Novel Coronavirus Update
September 16, 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 Senior Science Policy Specialist Amanda Field, 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.

The AAMC Coronavirus Update editors are taking a break next week. The next issue will be on 9/30.

Today's Numbers

- World: 29,656,504 confirmed cases (938,905 deaths)
  - 2,221,000 new cases this week (1,821,000 new cases last week)
- United States: 6,607,955 (196,254)
  - 293,000 new cases this week (253,000 new cases last week)
  - 6,270 deaths this week (5,040 deaths last week)
  - 89,987,708 total tests
- U.S. Hot Spots
  - Vermont: 46 new cases in the past week (133% increase in the past week)
  - Puerto Rico: 2,777 (85%)
  - Connecticut: 1,160 (63%)
  - Wisconsin: 8,348 (45%)
  - Wyoming: 287 (41%)

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 Centers for Disease Control and Prevention (CDC) reported on the analysis of an outbreak of COVID-19 in three day care centers in Salt Lake City, Utah. Twelve children from two of the centers are believed to have been infected in the centers, and three of those children were asymptomatic. Those twelve children went on to infect twelve people outside of the center, including parents and siblings, and one of the parents had to be hospitalized. Two of the asymptomatic children were confirmed to be transmitters. [Editor’s comment: There has been discussion about whether children are likely to be a source of infection in families, with some European studies suggesting they aren’t. This study raises more concerns and makes it clear children can introduce infection into a family from a day care or school.]

Treatment News

AstraZeneca has reopened its UK-based SARS-CoV-2 vaccine study after a pause to evaluate an unspecified serious adverse event. They have not yet reopened their other 30,000-subject study being performed in the United States and elsewhere. The company has not publicly disclosed the type of serious adverse event, nor how they are evaluating the possibility of a causal relationship with the vaccine, but during a discussion with investors, they revealed that the problem was a female volunteer who developed transverse myelitis, a spinal cord inflammation. [Editor’s comment: As this newsletter noted last week, transverse myelitis has been associated with viral infections as a post-infectious phenomenon. Even when a study enrolls a large number of volunteers, rare but serious adverse experiences may not be detected, which means it will be critical to continue post-marketing surveillance after the study is complete. This story also illustrates the importance of transparency in the vaccine development process in order to achieve the needed level of trust in the vaccine’s safety and efficacy.]

New York Times: Halt of Coronavirus Trial Is 'Safety Valve' at Work: Fauci

Pfizer and BioNTech announced that they would expand their SARS-CoV-2 vaccine study from 30,000 volunteers to 44,000. However, they did not provide an explanation of the reason for the expansion. [Editor’s comment: This situation again illustrates why transparency would be useful as multiple companies develop vaccines during a time of deep public interest. One likely explanation for the expansion is that the event rate (new COVID-19 cases) has fallen, which means it will take longer to show efficacy of the vaccine than Pfizer wanted. However, it appears the public will only learn in retrospect whether that was the explanation.]

The National Institutes of Health (NIH), as part of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) initiative, has launched three Phase 3 trials to evaluate the use of blood thinners to treat blood clotting associated with COVID-19. The ACTIV-4 Antithrombotics trials will be conducted globally on COVID-19 patients who have not been hospitalized, who are currently in the hospital, and who have been discharged from the hospital.

In a non-peer-reviewed preprint, Eli Lily found that their anti-inflammatory drug baricitinib shortened COVID-19 hospitalizations by one day when given in combination with remdesivir. [Editor’s comment: Another very small step for mankind.]

The NIH updated its COVID-19 treatment guidelines.

The Department of Health and Human Services authorized state-licensed pharmacists and pharmacy interns to order and administer COVID-19 vaccinations to people over the age of 3 in order to enhance access to a vaccine once one is available. Pharmacists must
satisfy requirements to be able to do so, including vaccination training, adhering to recordkeeping and reporting requirements, and administering Food and Drug Administration (FDA)-authorized or licensed vaccines.

*Nature*: Researchers Highlight ‘Questionable’ Data in Russian Coronavirus Vaccine Trial Results


*Nature*: The Underdog Coronavirus Vaccines That the World Will Need If Front Runners Stumble

*Undark*: The Overlooked Logistics of Covid-19 Vaccine Distribution

**Clinical News**

The CDC performed a case-control study of people infected with SARS-CoV-2 to evaluate behavioral risk factors for transmission. Sadly, the most significant finding was that people who ate at locations that offered on-site eating and drinking were twice as likely to catch COVID-19 as people who did not eat at on-site restaurants. The on-site options incorporated indoor, patio, and outdoor seating. There was no significant increase in risk from exposures through “shopping, gatherings with ≤10 persons in a home; going to an office setting; going to a salon; gatherings with >10 persons in a home; going to a gym; using public transportation; going to a bar/coffee shop; or attending church/religious gathering.” [Editor’s comment: Case-control studies have many serious deficiencies. Some findings are limited by the sample size. In this study, if a large number of people went out to eat at restaurants, then the data on restaurant dining would be more sensitive and able to produce a signal for higher risk with this activity. Alternatively, if fewer people went out to bars, there might not be enough cases to demonstrate a statistically significant increase in risk, even if there is one. This study does not indicate that going out to bars is now safe, but it does suggest we’re stuck with carryout…]

The CDC released a study evaluating COVID-19 deaths among 121 Americans less than 21 years old prior to July 31, 2020. To start, the article was published in the morbidity and mortality weekly report (MMWR) at a time when there had been 150,000 COVID-19 deaths in the United States, which once again makes it clear that children are much less likely to get seriously ill than adults. 70% of the deaths were in children ages 10 to 20. 45% of the deaths were in Hispanic children, 29% were in Black children, and 4% were in American Indian children. Of the children who died, 75% had a preexisting medical condition. [Editor’s comment: As the MMWR noted, Hispanic, Black, and American Indian children are disproportionately represented in deaths among children. Fortunately, the mortality rate for children is low in all racial and ethnic categories.]

In a study of 3,222 young adults (ages 18 to 34) admitted with COVID-19 to hospitals that are part of the Premier Healthcare Database, obesity was a very common issue. 37% of the patients were obese, and 25% were morbidly obese. Minority status was also an issue — 57% were Black or Hispanic. 21% required intensive care, and 2.7% died. 65% of those who died or were ventilated were male, and 41% were morbidly obese.

A report in *Nature Communication* demonstrated that the number of confirmed COVID-19 cases in the United States is undercounted and does not “capture the total burden of the pandemic because testing has been primarily restricted to individuals with moderate to severe symptoms due to limited test availability.”
NIH Director’s Blog: Months After Recovery, COVID-19 Survivors Often Have Persistent Lung Trouble

*Nature* reported on the symptoms that COVID-19 long-haulers continue to suffer months after infection, including lasting damage to the lungs, heart, immune system, brain, and more, as well as chronic fatigue. Symptoms could be due to the infection, a continuing immune response, or damage from intensive treatments. Several studies have already begun to track these long-term symptoms in order to be able to create clinical guidelines to treat them.

*New York Times: How the Coronavirus Attacks the Brain*

*NIH: Substance Use Disorders Linked to COVID-19 Susceptibility*

*Science: Why Obesity Worsens COVID-19*

*Science: As Evidence Builds That COVID-19 Can Damage the Heart, Doctors Are Racing to Understand It*

**Policy News**

The U.S. government announced adjustments to its policy regarding entry strategy for international air passengers who were recently in certain countries. Rather than focusing on entry health screenings for passengers, which studies indicate have limited effectiveness since many cases have no or mild symptoms, “resources will instead be dedicated to more effective mitigation efforts that focus on the individual passenger,” including health education, voluntary collection of contact information, testing, country-specific risk assessments, and training for workers at ports of entry.

A perspective in the *New England Journal of Medicine* discussed the reasoning behind the decisions *Operation Warp Speed* makes to support candidate therapeutics (as opposed to the criteria for vaccines): the therapeutics must in clinical testing by the fall, the science must be sound, and the therapeutics must be able to be manufactured at scale during 2020.

*Nature: How the FDA Should Protect Its Integrity From Politics*

**Coronavirus and Health Equity**

Data from the Commonwealth Fund’s 2020 International Health Policy COVID-19 Supplement Survey revealed that more than 50% of Black and Latinx respondents reported some kind of COVID-19-related economic challenge, compared to 1 in 5 White respondents. At the same time, nearly 40% of women reported mental health struggles, compared to 1 in 4 men.

A team of researchers from Harvard Medical School and the City University of New York found that individuals who stayed home from work in April and May 2020 due to probable COVID-19 symptoms (but who did not receive a formal diagnosis) were more likely to be people of color, uninsured, less well-educated, and people with lower incomes — mirroring now well-documented racial, economic, and social inequities in diagnosed coronavirus cases and COVID-19-related deaths.
A commentary in *Nature Reviews Immunology* discussed the very complex concept of herd immunity in COVID-19 and drew several important conclusions. The authors’ most optimistic model suggests that herd immunity will not be reached until at least half of the population has been infected. Achieving herd immunity in the United States by disease alone would mean 500,000 to 2.1 million deaths. They make the point that vaccines are a far more advantageous method to achieve herd immunity, but the level of protection from vaccines won’t be known until there are clinical trial results.

A study in *Cell* found a human antibody that binds to membrane-associated S glycoprotein, interfering with the coronavirus’s ability to bind the ACE2 receptor and enter the cell. The study showed that this antibody had potent neutralization activity and therapeutic efficacy at low doses in mice and hamsters. The antibody also cross-reacted with SARS-CoV-2 mutants, which could be helpful for continuing protection as the coronavirus mutates in the real world. [Editor’s comment: As always, while promising, studies in rodents must be validated in humans before effectiveness can be determined. This study comes with an additional caveat — the antibody was administered to hamsters six hours after infection, before peak infection, and since the antibody works by preventing the coronavirus from entering a cell, it may be less effective if administered later in the infection after many cells have already been infected.]

COVID-19 has had a profound effect on recruitment for a wide variety of clinical trials, with sites reporting 80% fewer new patients in April 2020 than April 2019. However, according to *Nature Reviews Drug Discovery*, there was some evidence of clinical trial recovery by June and July. The article discusses some of the strategies used by clinical sites to maintain patients in studies and resume more effective volunteer recruitment after the spring peak of COVID-19 activity.

A study that originally followed 4,500 college students from 2014 to 2018 to find which students contracted mononucleosis and subsequently developed chronic fatigue syndrome is now being used to help understand why some COVID-19 patients develop chronic fatigue. Because both illnesses appear to have similar long-term symptoms, researchers are hoping the “extensive baseline data and biological materials” from the mono study can elucidate if there are genetic, physiological, or behavioral characteristics that lead to chronic fatigue after an acute viral illness — particularly for COVID-19.

*Science: A Molecular Pore Spans the Double Membrane of the Coronavirus Replication Organelle*
STAT: Early Research from 23andMe Strengthens Link Between Blood Types and COVID-19

University of Pittsburgh: Tiny Antibody Component Highly Effective Against COVID-19

Testing News

The FDA developed a reference panel of standardized clinical samples for SARS-CoV-2 diagnostic assays and then sent the panel to 137 developers of authorized assays. The reference panel had one sample with a known virus amount and four other samples where the FDA knew the virus amount but the testing facility did not. When the results were returned to the FDA, they demonstrated a substantial range of sensitivity for the tests. According to the FDA, the results allow laboratory directors to compare the assays and make an appropriate selection.

The CITI Program is offering a course on remote contact tracing to “train individuals to conduct remote contact tracing for COVID-19 according to an established protocol and using evidence-based practices.”

New York Times: It’s Not Easy to Get a Coronavirus Test for a Child

Modern Healthcare: COVID-19 Test Charges Range from One Cent to $14,750, Study Finds

Other COVID-19 News

Ed Yong for the Atlantic discussed several intuitive thinking traps that have kept Americans in a pandemic spiral, arguing we must stop thinking this way and trust evidence-based solutions as the cold season begins.


Washington Post: Maine Wedding ‘Superspreader’ Event Is Now Linked to Seven Deaths. None of Those People Attended.

Washington Post: Italy’s Bergamo Is Calling Back Coronavirus Survivors. About Half Say They Haven’t Fully Recovered.

Wall Street Journal: Israel to Enter Lockdown Again as Second Coronavirus Wave Hits


AP: Scarcity of Key Material Squeezes Medical Mask Manufacturing

STAT: The Lessons We’ve Learned From the COVID-19 Response, According to Anthony Fauci


CDC: What to Do If Your Pet Tests Positive For the Virus That Causes COVID-19
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