AAMC Novel Coronavirus Update
September 9, 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.

Today's Numbers

- World: 27,628,190 confirmed cases (898,757 deaths)
  - 1,821,000 new cases this week (1,865,000 new cases last week)
- United States: 6,334,158 (189,972)
  - 253,000 new cases this week (269,000 new cases last week)
  - 5,040 deaths this week (6,289 deaths last week)
  - 83,964,567 total tests
- U.S. Hot Spots
  - Delaware: 759 new cases in the past week (38% increase in the past week)
  - New Hampshire: 185 (33%)
  - Wisconsin: 5,463 (19%)
  - Illinois: 15,273 (15%)
  - Alaska: 469 (13%)

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 first vaccine to run into an operational concern appears to be the AstraZeneca-Oxford University vaccine. The study, which only recently began enrolling 30,000 volunteers in
the United States for its Phase 3 trial, has been placed on hold while the company evaluates a single serious adverse event of transverse myelitis — an inflammatory condition of the spinal cord. The vaccine, labelled AZD1222, uses a chimpanzee adenovirus as a vector with SARS-CoV-2 spike protein incorporated. [Editor’s comment: The nature of the specific serious adverse event, which occurred in the United Kingdom, is similar to Guillain-Barré syndrome, which was triggered by the swine flu vaccine of 1976. The affected study volunteer is reported to be recovering. The situation highlights the concern that some of these vaccines may have unanticipated and uncommon side effects that could become a problem when moving them into wide distribution, and that approving vaccines without adequate safety data could be problematic (see the Russian vaccine story below).]

**Treatment News**

Since the British National Health Service’s Randomised Evaluation of COVID-19 Therapy (RECOVERY) trial demonstrated that dexamethasone decreased COVID-19 mortality for patients treated while intubated (29.3% mortality on dexamethasone, 41.4% mortality with usual care), there has been a question about whether this effect is general for all corticosteroids. A meta-analysis in *JAMA* from seven randomized, controlled clinical trials showed that the benefits can also be achieved by other steroids, including hydrocortisone and methylprednisolone. There were 222 deaths from among 678 patients randomized to steroids, as opposed to 425 deaths in 1025 patients randomized to placebo or usual care, for a statistically significant odds ratio of 0.66. [Editor’s comment: This is an important contribution because generic steroids are widely available and familiar to most physicians.]

Amid questions as to whether the Food and Drug Administration (FDA) can resist political pressure to expedite an Emergency Use Authorization (EUA) for one of the vaccines, nine vaccine companies agreed to wait until there is adequate evidence that their vaccine is both safe and effective before they submit for regulatory approval. [Editor’s comment: Historically, the FDA has been the judge of when a product is safe and effective and ready for marketing. Because vaccine manufacturers are concerned that the FDA is perceived to be falling short of its obligations, the companies agreed to work against short-term self-interest and toward longer-term trust-building in order to improve the trust of the public in the new COVID-19 vaccines — and, for that matter, other vaccines.]

**Pfizer has enrolled about 23,000 people for its Phase 3 coronavirus vaccine trial** so far. The company reports that initial results could be ready as early as late October, and if they are positive, Pfizer will ask the FDA to authorize the vaccine right away. [Editor’s comment: If Pfizer does see an adequate efficacy signal and request authorization, probably through an EUA, the safety data will necessarily be short-term and incomplete. In addition, there will be no way to know what the durability of immunity will be.]

The Russian government published the results of the two adenovirus-based SARS-CoV-2 vaccine trials that led to approval of their vaccine. One study used a lyophilized (freeze-dried) preparation of the vaccines, while the other used a frozen preparation. The Russian vaccine is a combination of two adenovirus vector recombinants — Ad26 and Ad5 — that have both been modified to contain the spike protein and are intended to be given sequentially in a so-called ”Prime-Boost” strategy. In Phase 1, they gave 38 volunteers a single dose of the rAd26-s (recombinant adenovirus 26 with spike) or rAd5-s (recombinant adenovirus 5 with spike) vaccine and monitored them for side effects. In phase 2, they gave 38 volunteers the rAd26-s vaccine first, followed by the rAd5-s after 21 days. Antibodies were measured as well as adverse experiences. The adverse events included injection site pain (58%), fever (50%), headache (42%), and asthenia (28%). Antibody
production appeared to be good. [Editor’s comment: While the Russian government decided to approve this vaccine, it should be noted that it has only passed Phase 1/2 testing stages — meaning that safety has only been demonstrated in fewer than 80 volunteers and that it is not yet known if it is clinically effective.]

A nanoparticle vaccine candidate from Novavax was shown to be safe and elicit an immune response in its Phase 1/2 trial, as published in the New England Journal of Medicine.

An article in JAMA explained the advantages of mRNA vaccines.

Nature Reviews Drug Discovery: Evolution of the COVID-19 Vaccine Development Landscape

STAT: ‘An Unchartered Situation for All of Us’: From Shipping Containers to Security Concerns, a COVID-19 Vaccine Supply Chain Takes Shape

STAT: Experts See a Chance for a COVID-19 Vaccine Approval This Fall — If It’s Done Right

Clinical News

Researchers at the Gladstone Institutes in San Francisco, California, found that SARS-CoV-2 disrupted cardiac cell fibers (sarcomeres) in vitro. According to a non-peer-reviewed preprint, the appearance of fragmented sarcomeres was similar to that seen in autopsy specimens from COVID-19 patients. They also noted that cardiac dysfunction is found in as many as 50% of COVID-19 patients and posited that direct cardiac damage can be produced by the virus.

The Lancet published a systematic review of 39 observational studies and 662 children with multisystem inflammatory syndrome in children (MIS-C). The essential findings were that a high proportion (71%) of children required intensive care, but the condition was fatal in only 1.7% of cases. Fever, abdominal pain, diarrhea, and vomiting were the most common symptoms. 581 children were given an echocardiograph, in which cardiac disease was found in 262 (54%). Of the patients with cardiac disease, the most common finding was depressed ejection fraction.

The Centers for Disease Control and Prevention (CDC) has been tracking reported cases of MIS-C and has received reports of 792 confirmed cases and 16 deaths as of Sept. 3, with further cases under investigation. Most cases are in children between 1 and 14 years old (with an average age of 8 years) and developed two to four weeks after infection, and 70% of cases have been in Latinx or Black children. The CDC has a page explaining how it is addressing MIS-C, including working with partners, preparing health care providers and health departments, conducting research, tracking cases, and keeping caregivers informed.

A meta-analysis of 77 studies on pregnant and recently pregnant women with suspected or confirmed COVID-19 in the BMJ found that they are less likely to manifest COVID-19 symptoms than nonpregnant women, but they are more likely to need intensive treatment care if they do have symptoms.

With flu season approaching, there is growing concern in public health about the possibility of interaction between the flu virus and SARS-CoV-2. Little is known about their
interaction, but a small number of cases of people infected with both is beginning to surface. It also may be the case that there is little interaction between the two or that the combination may limit transmission.

*New York Times: How the Aging Immune System Makes Older People Vulnerable to COVID-19*

*Wall Street Journal: The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic*

*Medpage Today: One in Four Americans Report Depression During Pandemic*

*Undark: When Children’s Covid-19 Symptoms Won’t Go Away*

### Policy News

The CDC advised public health officials in all 50 states to be prepared for distribution of a potential COVID-19 vaccine to limited populations, including health workers and other high-risk groups, *by late October or early November*. The timeline appears to be very rapid and may reflect external pressures. It may not account for necessary time to ensure public health and safety concerns.

The CDC, Department of Defense, and other agencies have been working with California, Florida, Minnesota, North Dakota, and Philadelphia, Pennsylvania, to **create “plans to transport and store vaccine and prioritize who will get the first doses,”** possibly by this fall. The plans, which will consider local racial and ethnic distribution, will be shared with other states to help them do the same. Two top issues are the lack of -70 degrees Celsius freezers required to store some vaccine candidates and the need to create a plan to identify priority populations.

The AAMC submitted a letter to the National Academies of Science, Engineering, and Medicine in response to their request for public comment on the *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine*. "Given the significant health, social, and economic injustices laid bare by the pandemic, the AAMC was pleased to see the emphasis on mitigating inequities in vaccine access and the related foundational principles of fairness, equal regard, and transparency,” said Ross McKinney, MD, and Philip Alberti, PhD, both editors of this newsletter.

The CDC updated its [considerations for restaurants and bars](https://www.cdc.gov/parasites/tuberculosis/considerations_for_res landmark/).

The American Academy of Pediatrics issued a policy statement on recommendations for preventing flu infections in children. Because of the similarity of symptoms to COVID-19, it states it is more important than ever that everyone over 6 months old is vaccinated against the flu by the end of October.

Writers at STAT [reviewed the status of Operation Warp Speed](https://www.statnews.com/2020/10/27/warp-speed-coronavirus-vaccine/) and considered the progress that has been made thus far.

*Washington Post: The U.S. Is Facing a Crisis of Confidence in Our Government Scientists*

*Chronicle of Higher Education: Health Experts Warn Colleges Not to Send Students Home. But What if Quarantine Spaces Run Out?*
Coronavirus and Health Equity

New data compiled by the Color of Coronavirus project show COVID-19-related death rates in the United States are rising more steeply for racial and ethnic minorities than for White people. During the last two weeks of August, per capita deaths rose from 80 to 88 per 100,000 population for Black Americans and from 46 to 54 per 100,000 for Latinx Americans, while it rose from 36 to 40 per 100,000 for White Americans.

According to new analyses by Kaiser Family Foundation, there have been significant increases in COVID-19 cases and deaths among residents and staff of assisted living facilities. The report is based on data for only 19 states, as fewer than half of U.S. states report information from such facilities.

Researchers from Geisinger Health System found that risk factors for coronavirus infection are not the same as risk factors for COVID-19 death. Specifically, while “counties with more diverse demographics, higher population, education, income levels, and lower disability rates were at a higher risk of COVID-19 infection ... [those] with higher proportion with disability and poverty rates had a higher death rate.”

A new study underway at Grady Memorial Hospital seeks to understand whether people with a single copy of the sickle cell mutation — but don't have the disease itself — might be more vulnerable to COVID-19 illness and severity. Currently, the CDC notes that sickle cell disease is one condition that places people at higher risk for severe illness from COVID-19.

Nature published an article reviewing what is known about SARS-CoV-2 mutations over time. Most RNA viruses mutate frequently, but SARS-CoV-2 is clearly the exception. One mutation, D614G, which was not part of the original consensus sequence, is now virtually ubiquitous. It’s still not clear what role it plays in either spread or virulence, although it appears likely any role is small. [Editor’s comment: The lack of mutation is good news for vaccine developers, since it makes it more likely they will be targeting a relatively
consistent spike protein. This should make the vaccines more useful for a longer period of time.

An international consortium called 4CE that is comprised of 96 hospitals across five countries is using data from electronic health records to establish “a framework to capture the trajectory of COVID-19 disease in patients and their response to interventions.”

**Science:** Structural Basis for Translational Shutdown and Immune Evasion by the Nsp1 Protein of SARS-CoV-2

**Robert Wood Johnson Foundation: The Impact of Coronavirus on Households Across America**

**Science:** A Molecular Trap Against COVID-19

**Nature:** What the Immune Response to the Coronavirus Says About the Prospects for a Vaccine

**NIH Director’s Blog:** Citizen Scientists Take on the Challenge of Long-Haul COVID-19

**NIH Director’s Blog:** Genome Data Help to Track COVID-19 Superspreading Event

### Testing News

The National Institutes of Health (NIH) announced $129.3 million in funding to nine companies to scale up and manufacture new SARS-CoV-2 tests as part of the Rapid Acceleration of Diagnostics (RADx) initiative. The newest awards will fund tests that include portable point-of-care tests and high-throughput tests with a 24-hour turnaround time.

Leaders from several NIH institutes and centers outlined the importance of widespread SARS-CoV-2 testing, including that testing saves lives, testing can be easy and fast, and testing matters most in the communities most affected by COVID-19.

Schools and sleepover camps have been challenged to deal with the spread of SARS-CoV-2. The CDC reported on four camps in Maine that relied on the use of nonpharmaceutical interventions to minimize spread. The camps used a combination of strategies: pre-arrival quarantine, testing before and after arrival, implementation of cohorts, use of face coverings, physical distancing, regular surface hygiene, and maximal outdoor programming. Despite more than 1,000 campers and staff from across the country, there were only three cases detected after the start of camp — each of which triggered a period of quarantine for contacts. [Editor’s comment: The contrast with the story from a Georgia camp with no face coverings and widespread COVID-19 that the CDC reported a few weeks ago could hardly be more stark. Camps can create “pods” of safety if the appropriate precautions are taken.]

**New York Times:** New York Will Test the Dead More Often for Coronavirus and Flu

**NPR:** Florida Cuts Ties With Large Coronavirus Testing Lab, Citing 75,000 Delayed Results

**Modern Healthcare:** Feds to Ship Fast COVID-19 Tests to Assisted-living Sites
Other COVID-19 News

A potential fall wave of COVID-19 cases could result in an additional 1.9 million deaths globally with 410,000 in the United States by year’s end, according to a new forecast from the Institute for Health Metrics and Evaluation at the University of Washington. While cases are declining, there are fears in the public health community that colder weather could make the virus more viable for transmission.

The CDC updated its travel recommendations by destination, indicating the known risk level of every country. The risk remains high to travel to most of the world.

Washington Post: Pandemic Seems to Be Leveling Off in U.S., but Numbers Remain Troublingly High, Experts Say

Washington Post: ‘Worst Case Scenarios’ at Sturgis Rally Could Link Event to 266,000 Coronavirus Cases, Study Says

Medpage Today: Nurses Survey: N95 Mask Shortages Still the Rule

Washington Post: How to Sneeze During a Pandemic

Science: Can You Catch COVID-19 From Your Neighbor’s Toilet?

Washington Post: Deep Cleans and Disinfecting Mists Might Not Keep Us From Getting the Virus, but They Sure Make Us Feel Better

Wall Street Journal: ‘Really Diabolical’: Inside the Coronavirus That Outsmarted Science

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