

November 23, 2020

Summary

The United States has 12,314,229 confirmed COVID-19 cases and 257,095 reported related deaths. Pfizer announced that it has applied to FDA for an emergency use authorization (EUA) for its COVID-19 vaccine candidate, which FDA could grant as early as mid-December. AstraZeneca released preliminary, non-peer reviewed data from its COVID-19 vaccine trials that indicates that its candidate is 90% effective when administered via an initial smaller dose and then a second larger dose two weeks later. Operation Warp Speed Chief Slaoui said that the federal government initially plans to distribute COVID-19 vaccine supplies to states in proportion to their populations; states will decide how to distribute the vaccines among their citizens. CDC will release guidance to help the states prioritize groups for vaccination. President-elect Biden met with House Speaker Pelosi and Senate Minority Leader Schumer to discuss passing a stimulus package during the lame duck session; Biden is reportedly pressuring Democratic lawmakers to make a deal with Republicans to stave off a double-dip recession.

The national total of COVID-19 hospitalizations has hit new highs every day since November 11, approaching 84,000 total patients on November 22. According to NPR, about one-fifth of U.S. hospitals are now short-staffed. Nevada Governor Steve Sisolak announced a new three-week “statewide pause” in effect on November 24 that will strengthen the state’s mask mandate, limit private gatherings to ten people and two households, and tighten restrictions on various businesses. Kentucky Governor Andy Beshear imposed new restrictions on restaurants, bars, gyms, and social gatherings from November 20 through December 15, and announced schools will end in-person learning. Elementary schools may reopen on December 7, but middle and high schools will remain closed until January. Minnesota Governor Tim Walz closed indoor dining, gyms, entertainment, and swimming pools, and limited capacity in retail stores, barbershops and salons from November 20 to December 18.

New York reported 33 deaths, 2,724 hospitalizations, and 545 COVID-19 patients in intensive care on Sunday, November 22. Approximately 5,906, or 3.08% of the 191,489 tests administered in New York on November 22 were positive for COVID-19. On November 22, Governor Cuomo sent a letter to Congress requesting additional federal stimulus relief for unemployed Americans, noting that New York had already provided \$55 billion in unemployment benefits during the pandemic. Hundreds of bodies of coronavirus victims whose next of kin have not been identified or cannot pay for a private burial remain in storage in freezer trucks along the Brooklyn waterfront. The New York Department of Homelessness is preparing to return homeless individuals to temporary shelters in city hotels as it prepares for a second

wave. Mayor de Blasio mentioned that he would “likely” close gyms and indoor dining in the coming weeks.

Presidential updates

- [President-Elect Biden, Congressional Leaders Discuss Second Round of Stimulus Spending](#), November 20
 - President-elect Biden met with House Speaker Nancy Pelosi and Senate Minority Leader Chuck Schumer to discuss passing a stimulus package during the lame duck session.
 - Biden and his aides have public and privately called for Congress to pass a second round of stimulus spending as soon as possible. However, any package proposed during the lame duck session will need to be approved by the Republican-controlled Senate. In the months leading up the election, the House and Senate reached an impasse regarding stimulus spending, with House Democrats proposing trillions of dollars in additional aid and Senate Republicans favoring a much smaller package.
 - Biden transition adviser Jen Spsaki [told](#) Politico that Biden will be “working in lockstep” with Democratic lawmakers on the issue of stimulus spending.
 - However, the media is [reporting](#) that Biden and his aids have begun pressuring Democratic lawmakers to reach a quick stimulus deal with Senate Republicans to avoid a “double dip [recession](#).”
 - Extending the [expanded](#) unemployment benefits established by the CARES Act may be particularly important to the Biden team. Unless Congress acts, 12 million Americans are set to lose their jobless benefits at the end of the year. An anonymous member of Biden’s transition team [told](#) Politico that Democrats may have to make some concessions to Senate Majority Leader Mitch McConnell because they “simply have to” extend unemployment aid.
 - According to the media, Biden’s team is also considering other options for fighting a renewed economic downturn, including announcing that Biden will sign executive order on his first day in office extending moratoriums on evictions and foreclosures and deferrals of student loan payments.

World Health Organization (WHO)

- [WHO COVID-19 Updates](#), November 23
 - WHO [published](#) Therapeutics and COVID-19 Living Guideline to provide guidance on drug use to treat COVID-19.
 - Most notably, the guidelines [recommend](#) against the use of remdesivir in hospitalized patients with COVID-19, regardless of disease severity. WHO studies indicate that remdesivir has “possibly no effect” on mortality and other important outcomes. This guidance conflicts with current US guidance.

U.S. Centers for Disease Control and Prevention (CDC)

- [COVIDView Weekly Surveillance Summary of U.S. COVID-19 Activity](#), November 20
 - CDC summarized key COVID-19 disease indicators for the week ending November 14.
 - The national average of respiratory specimens testing positive for COVID-19 increased from 10.8% to 11.9% from November 7 to November 14.

- Regionally, the percentage of respiratory specimens testing positive for COVID-19 increased in nine of ten regions.
- The overall cumulative hospitalization rate is 228.7 per 100,000, up from 217.2 per 100,000 during the previous week.
- Based on death certificate data, the percentage of total deaths attributed to pneumonia, influenza, or COVID-19 decreased 3.7% from November 7 (14.4%) to November 14 (10.7%). However, the percentage remains above the epidemic threshold and will likely increase as more death certificates are processed.

New York State

- [New York State COVID-19 Updates](#), November 23
 - New York reported 33 deaths, 545 hospitalizations, and 545 COVID-19 patients in intensive care on Sunday, November 22. Approximately 5,906, or 3.08% of the 191,489 tests administered in New York on November 22 were positive for COVID-19.
 - On November 22, Governor Cuomo [sent](#) a letter to Congress calling for the renewal and expansion of federal support programs for unemployed Americans whose benefits will expire soon after Christmas. Since the beginning of the pandemic, New York has provided more than \$55 billion in unemployment benefits to 3.8 million New Yorkers, which represents more than 26-typical-years' worth of benefits.
 - On November 20, New York administered 207,909 COVID-19 tests, a new record high.

New York City

- [New York City COVID-19 Updates](#), November 23
 - Hundreds of bodies of coronavirus victims whose next of kin cannot be located or cannot afford a proper burial [remain](#) in storage in freezer trucks on the Brooklyn waterfront. Normally, the bodies would have been buried in a gravesite for the indigent on Hart Island, but Mayor de Blasio stopped the practice after criticism in April. Although New York City increased its burial assistance to \$1,700 from \$900 in May, many families still cannot afford a private burial.
 - The New York City Department of Homelessness is [preparing](#) for a second wave of infections among the City's homeless population. The homeless were hit hard by the virus at the outset of the pandemic, but positivity rates dropped to 0% from July until October, when it climbed to 1.3%. The City is expected to return homeless individuals to city hotels, as they did earlier this year, despite pushback from neighborhood residents.
 - Following last week's school [closures](#), Mayor de Blasio [said](#) that gyms and indoor dining were "likely" to close within the next two weeks as a result of increasing positivity rates. Under the state's micro-cluster approach, areas of New York City would reach "orange" status—requiring the closure of gyms and indoor dining—if the seven-day average for positivity rates exceed 3% for 10 consecutive days and the area reports 10 or more new daily cases per 100,000 residents for seven days.

Other Related Updates

- [*AstraZeneca Announced Interim Vaccine Results Showing 62-90% Efficacy*](#), November 23
 - AstraZeneca [announced](#) an early analysis of its late-stage clinical trials in Britain and Brazil that showed its COVID-19 vaccine candidate was up to 90% effective and did not identify any serious safety events related to the vaccine.
 - Trial data includes two different dosing regimens: A half dose, followed by a full dose two weeks later, resulted in 90% efficacy, but a full dose followed by a full dose two weeks later resulted in only 62% efficacy, for an average of 70% across the trials. Researchers have not determined why the lower initial dose was more effective, but the result could benefit distribution as less vaccine will need to be produced.
 - The vaccine is designed to genetically alter an adenovirus found in chimps so that it harmlessly mimics the coronavirus and provokes an immune response. A vaccine deploying that technology has never won approval to date.
 - The interim results show that AstraZeneca's vaccine is somewhat less effective than Pfizer and Moderna's vaccines, but can be stored in ordinary refrigeration for up to six months a significant advantage for ease of distribution..
 - The Pfizer vaccine must be stored at -112 degrees Fahrenheit, and while Moderna's vaccine can remain stable at refrigeration temperatures for up to 30 days, it must be transported or stored long-term at -4 degrees Fahrenheit. The need for cold storage may complicate distribution to poor or rural populations, where the health care infrastructure may not have equipment needed to achieve the extreme cold.
 - AstraZeneca's vaccine will be priced at \$3 to \$4 per dose, a fraction of some other potential vaccines.
 - AstraZeneca has [pledged](#) to make the vaccine available at cost around the world at least until July 2021, and in poorer countries in perpetuity.
 - AstraZeneca indicated it can begin supplying vaccines by the end of this year, and produce up to 3 billion doses in 2021.
- [*Pfizer Files COVID-19 Vaccine Application to U.S. FDA*](#), November 20
 - Pfizer applied to U.S. regulators on November 20 for emergency use authorization (EUA), becoming the first vaccine manufacturer to seek approval for its vaccine.
 - The application comes just days after Pfizer and German partner BioNTech reported final trial results that showed the vaccine was 95% effective in preventing COVID-19 with no major safety concerns.
 - FDA will host a meeting on December 10 for members to discuss the vaccine. The agency declined to predict how long its review will take, but both Pfizer and HHS Secretary Alex Azar have said the FDA could grant an EUA in mid-December.
 - Moderna will likely be the next company to seek an EUA for their COVID-19 vaccine after an initial analysis showed the vaccine was 94.5% effect. Final results and safety data are expected from Moderna in the coming days.
- [*Operation Warp Speed Chief Slaoui Discusses COVID-19 Vaccine Distribution Plan*](#), November 22
 - During an [interview](#) with the press, Operation Warp Speed Chief Slaoui outlined the federal government's plan for distributing COVID-19 vaccines. The federal government plans to begin shipping vaccines to the states within 24 hours of FDA

approval, with a goal of enabling states to begin administering vaccines within 48 hours of approval.

- Because initial vaccine supply will be limited, the federal government will allocate vaccine doses among the states in proportion to their population, and the states will decide how and where to distribute their doses.
 - Within a day of FDA approval, CDC will issue recommendations regarding which groups states should vaccinate first. Advisory Committee on Immunization Practices (ACIP), a committee of medical and public health experts who develop recommendations on the use of vaccines in the United States, will draft the CDC's prioritization recommendations and submit them to the CDC Director for approval. ACIP has not yet finalized its recommendations regarding vaccine prioritization.
 - According to the CDC website, ACIP is [considering](#) four groups for prioritization: (1) health care workers; (2) workers in essential and critical industries; (3) people with certain underlying medical conditions; and (4) adults aged 65 years or older. However, the media previously [reported](#) that ACIP members had formed a consensus that health care workers should be first in line for vaccination.
 - In formulating its recommendations, ACIP is considering input from other groups, such as The National Academies of Sciences, Engineering, and Medicine, Johns Hopkins Bloomberg School of Public Health, and WHO Strategic Advisory Group of Experts, which have already released their own prioritization [frameworks](#).
- [*NIH Expands Research to Improve COVID-19 Testing Among Vulnerable Populations*](#), November 20
 - National Institutes of Health (NIH) [awarded](#) nearly \$45 million to expand the research network of the Rapid Acceleration of Diagnostics Underserved Populations ([RADx-UP](#)) program, adding 20 institutions and seven states and territories.
 - RADx-UP aims to enable and enhance COVID-19 testing of populations disproportionately affected by the disease, including African Americans, Native Americans, Latinos/Latinas, Native Hawaiians, older adults, pregnant women, and homeless or incarcerated people.
 - This second round of funding brings the total investment in RADx-UP programs to more than \$283 million at 55 institutions across 33 states and territories and the Cherokee Nation.
 - The new grants bolsters two components to address testing deficiencies: 1) research on cultural and historical factors, attitudes, expectations and preferences for testing, and interpersonal and institutional (e.g. health systems) factors that affect access to testing, and 2) a collaborative network of community-engagement projects with established programs that have adequate capacity, infrastructure, and relationships with underserved communities.
 - [*FDA COVID-19 Updates*](#), November 23
 - Food and Drug Administration [issued](#) an emergency use authorization (EUA) for baricitinib, in combination with remdesivir, for the treatment of suspected or laboratory-confirmed COVID-19 in hospitalized adults and pediatric patients two years or older requiring supplemental oxygen, invasive mechanical ventilation, or

extracorporeal membrane oxygenation (in which a patient's blood is pumped into a heart-lung machine that removes carbon dioxide and oxygenates the blood)

- FDA [issued](#) an EUA for casirivimab and imdevimab, which are monoclonal antibodies, to be administered together for treatment of mild to moderate COVID-19 in adults and pediatric patients with positive COVID-19 tests who are at high risk for progressing to severe COVID-19. Those at high risk include adults over 65 and those with certain chronic medical conditions.
- FDA announced a [meeting](#) of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) on December 10 to discuss the request for EUA of Pfizer-BioNTech's COVID-19 vaccine.

Other recent events covered in detail elsewhere:

- [SBA Proposes Detailed New Questionnaire to Evaluate Post-Hoc the Good Faith of PPP Applicants' Prior Certifications of Loan "Necessity"](#), November 11
- [Ethical Challenges in Clinical Research During the COVID-19 Pandemic](#), November 10

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