

November 16, 2020

Summary

The United States has 11,147,299 confirmed COVID-19 cases and 246,854 reported related deaths. During the week ending November 15, the United States averaged 150,265 new cases per day, an 81% increase over the average from two weeks prior. On November 13, President-elect Biden issued a statement urging President Trump to take aggressive steps to slow the spread of the virus. Moderna announced that preliminary, non-peer reviewed data from its COVID-19 vaccine trials indicates that its vaccine candidate is 94.5% effective. Moderna plans to apply for an emergency use authorization for its vaccine within the next few weeks and says it will be able to produce enough doses for 10 million people by the end of 2020. Dr. Fauci said that the country will likely begin deploying COVID-19 vaccines in December but warned that even with vaccines, an additional 200,000 people could die by the Spring if Americans do not comply with public health measures such as mask wearing. More than 130 Secret Service agents are quarantining after testing positive for the virus or coming in contact with an infected person.

Last week, California became the second state to top 1 million confirmed COVID-19 cases following Texas. Oregon governor Kate Brown announced sweeping restrictions, limiting restaurants to takeout service only, and placing restrictions on other gathering places similar to the Stay Home order issued in March. Idaho governor Brad Little announced that he would roll back into stage 2 of his state's re-opening plan and mobilize the National Guard to help combat the pandemic by assisting with mobile testing, facility decontamination, and more, as cases threaten to overwhelm the state's healthcare system. Washington governor Jay Inslee criticized Little's decision not to impose a mask mandate after imposing tighter restrictions in his own state, which include ordering restaurants to shut down indoor service and limiting outdoor service to parties of five or fewer.

New York reported 25 deaths, 1,968 hospitalizations, and 391 COVID-19 patients in intensive care on Sunday, November 15. Approximately 3,490, or 2.8% of the 124,565 tests administered in New York on November 15 were positive for COVID-19. New York launched a new mobile application, in partnership with Google and motivated by a rise in new welfare recipients as a result of the pandemic, to improve access to state-funded welfare benefits. The New York Office of Court Administration has suspended civil and criminal jury trials due to rising infection rates; bench trials and in-person conferences will continue to be held. After warning that in-person learning may be shut down last Friday, the New York City Department of Education declined to close schools on Monday, as positivity rates remain below the 3% threshold.

Presidential updates

- [*President-Elect Biden Calls on President Trump to Take More Aggressive Steps to Address Surge*](#), November 13
 - President-elect Biden issued a statement urging President Trump to mount a more aggressive effort to slow the spread of the virus as cases rise across the country.
 - In his statement, Biden called the federal government’s pandemic response “woefully lacking” and opined that the recent surge in COVID-19 cases, which is killing more than 1,000 Americans per day, requires a “robust and immediate federal response.”
 - Shortly after Biden released his statement, President Trump discussed the pandemic during his first public address since Biden was declared President-elect.
 - Trump [said](#) that Pfizer’s COVID-19 vaccine candidate will receive emergency use authorization (EUA) “extremely soon.” He vowed not to implement a national lockdown but did not outline a plan for addressing the surge.
- [*President-Elect Biden Continues Planning Pandemic Response But Delayed Transition May Jeopardize Vaccine Distribution Efforts*](#), November 16
 - President-elect Biden and his transition team continue preparing to manage the federal government’s pandemic response. On November 15, Biden’s chief of staff Ron Klaine [said](#) that transition officials will meet this week with drugmakers developing coronavirus vaccines.
 - However, Biden’s transition team cannot begin working with current government officials or accessing nonpublic data until Government Services Administration (GSA) certifies Biden as the President-elect. GSA has heretofore refused to do so.
 - Both [Klain](#) and Dr. [Fauci](#) recently expressed concern regarding the effect the delay will have on the Biden Administration’s pandemic response.
 - During an interview with the press, Klain [explained](#) that it is important that transition officials begin working with Department of Health and Human Services (HHS) “as quickly as possible” to ensure there is no disruption in COVID-19 vaccine distribution when Biden takes office in January, noting that vaccine distribution will be “a giant logistical project.”
 - The incoming administration’s ability to plan for vaccine distribution may be especially important, given that state leaders have [repeatedly](#) expressed concern about their ability to distribute COVID-19 vaccines absent additional federal support.
- [*COVID-19 Outbreak Sidelines Secret Service Agents*](#), November 13
 - The media [reported](#) that more than 130 uniformed Secret Service agents are quarantining after testing positive for the virus or coming in contact with an infected person.
 - Officers in the uniformed Secret Service are different from the agents that protect senior officials and their families. The uniformed service provides security for physical locations such as the White House and the Vice President’s residence and for public events.
 - Members of the uniformed Secret Service may have been exposed at the White House, which recently saw a new [wave](#) of COVID-19 infections, or while traveling to provide security at campaign events hosted by President Trump and/or President-elect Biden.

- The media reported that some uniformed Secret Service agents expressed concern about the [lack](#) of mask wearing at the White House and the risk of contracting the virus during campaign [travel](#).
- The uniformed Secret Service employs 1,300 agents, which means roughly ten percent of its agents have been sidelined by the outbreak.
- An agency spokesperson said, “We continuously assess the requirements necessary to operate during the pandemic and ensure we remain prepared and fully staffed to carry out our critical integrated protective and investigative missions, neither of which has been degraded by the pandemic.”
- However, a former senior Secret Service supervisor [told](#) the media that “being down more than 100 officers is very problematic...that does not bode well for White House security.”

World Health Organization (WHO)

- [WHO COVID-19 Updates](#), November 16
 - WHO published technical [guidance](#) on technical specifications of personal protective equipment (PPE) for COVID-19, intended for procurement agencies, occupational health departments, infection prevention and control departments, health facility administrators, biomedical and materials engineering, PPE manufacturers, and public health authorities.
 - WHO published technical [guidance](#) on national deployment and vaccination planning for COVID-19 vaccines, intended to help countries develop their distribution plans.

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

- [CDC Interpretation of Forecasts of New Deaths and Hospitalizations](#), November 13
 - CDC [consolidated](#) data from 36 models projecting the COVID-19 death rate. Predicted rates of increase differ among the forecasts, depending on assumptions about the prevalence and rigor of social distancing behaviors.
 - CDC’s national ensemble forecast indicates that deaths will increase over the next four weeks. CDC predicts that the number of cumulative COVID-19 deaths will be between 260,000 and 282,000 by December 5.
 - CDC [consolidated](#) data from nine models projecting the number of daily COVID-19 hospitalizations. Three models predict an increase in daily hospitalizations over the next four weeks, one model predicts a decrease, and two models are uncertain about the direction of the trend. The forecasts estimate 3,200 to 19,000 new COVID-19 hospitalizations per day by December 7.
- [COVIDView Weekly Surveillance Summary of U.S. COVID-19 Activity](#), November 13
 - CDC summarized key COVID-19 disease indicators for the week ending November 7.
 - The national average of respiratory specimens testing positive for COVID-19 increased from 8.4% to 10.5% from October 31 to November 7.
 - The percentage of respiratory specimens testing positive for COVID-19 increased in all parts of the country.
 - The overall cumulative hospitalization rate is 217.2 per 100,000, up from 207.1 per 100,000 during the previous week. Weekly hospitalization rates among children have had a two-week sustained increase from October 24 to November 7.

- Based on death certificate data, the percentage of total deaths attributed to pneumonia, influenza, or COVID-19 decreased 3.4% from October 31 (12.3%) to November 7 (8.9%). 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 16
 - New York reported 25 deaths, 1,968 hospitalizations, and 391 COVID-19 patients in intensive care on Sunday, November 15.
 - Approximately 3,490, or 2.8% of the 124,565 tests administered in New York on November 15 were positive for COVID-19.
 - On November 16, Governor Cuomo [announced](#) the release of a new mobile application, developed in partnership with Google, that will assist users in accessing social services. The application was designed to assist the large number of new welfare recipients as a result of the pandemic.
 - On November 13, the New York Office of Court Administration [announced](#) that criminal and civil jury trials would be postponed until further notice as a result of rising positivity rates. Bench trials (in which the verdict is rendered by a judge, rather than a jury) will continue virtually, and in-person court conferences will continue.

New York City

- [New York City COVID-19 Updates](#), November 16
 - After [warning](#) parents on Friday that schools may be closed beginning today, Mayor de Blasio [said](#) Sunday that classrooms would remain open for now after the city's infection data remained below the threshold for closing schools. The city's seven-day positivity rate was 2.57%, which was below the 3% threshold for shutting down in-person learning. The city's teachers union has urged the New York City Department of Education (NYC DOE) to honor its agreement to end in-person learning when the citywide seven-day rolling average surpasses 3%.
 - Since the beginning of the pandemic, the NYC DOE has [conducted](#) an air quality review of 1,400 school buildings across the city, and, where necessary, conducted renovations to remediate the air quality issues in an effort to reduce virus spread. For example, the Martin Luther King, Jr. Educational Complex in Manhattan, which houses six New York schools, required \$4.2 million in renovations to the complex's ventilation system. The Murry Bergtraum High School for Business Careers (Manhattan) and the Herman H. Lehman High School (Bronx) also required ventilation system upgrades.
- [New York City Restaurants in Precarious State as Winter Nears](#), November 16
 - Restauranters fear that impending lockdowns due to the rise in coronavirus cases throughout the state will strike a death blow to businesses that have struggled to stay afloat.
 - In a recent survey, the NYC Hospitality Alliance found that 88% of restaurants could not pay their full October rent, and 30% paid no rent at all. The alliance has lobbied state officials to increase indoor dining capacity.

- Yet indoor dining had been banned until September 30, at which point New York City restaurants were allowed to allow 25% indoor capacity, while upstate restaurants could maintain 50% capacity.
- Still, restaurants fear that New York will roll back indoor dining as infection rates rise. They see the 10 p.m. curfew, which was imposed last week, as a warning sign that additional restrictions will follow as infection rates continue to increase.
- Some restaurants have attempted to prepare outdoor dining spaces for the colder winter months by installing outdoor heaters. But FDNY has issued 172 violations for faulty setups. Though FDNY has not imposed monetary penalties for these regulatory violations, the noncompliant purchases have cost some restaurants sorely needed cash. Other restaurants, assuming that patrons will be too cold despite the newly installed heating systems, have spent thousands to update ventilation systems; one restaurant has installed a greenhouse on an outdoor patio to increase capacity.

Other Related Updates

- [*Moderna Vaccine Shows Promising Interim Results*](#), November 16
 - An independent data and safety monitoring board overseeing the Phase 3 trial of Moderna's COVID-19 vaccine candidate [shared](#) its interim analysis, which suggested the vaccine is safe and has an efficacy rate of 94.5%.
 - The interim analysis included 95 cases of symptomatic COVID-19. Of those 95 cases, 90 occurred in the placebo group and just five occurred in the vaccinated group. There were 11 severe COVID-19 cases, all of which occurred in the placebo group. The findings were statistically significant.
 - The trial includes more than 30,000 participants at 100 clinical research sites in the United States. Investigators worked to enroll a diverse pool of participants in recognition of the disproportionate impact of the epidemic on minority populations. 37% of trial volunteers are racial or ethnic minorities.
 - The vaccine was co-developed by Moderna, Inc., based in Cambridge, Massachusetts, and the National Institute of Allergy and Infectious Disease (NIAID), part of the National Institutes of Health. The Phase 3 trial was part of Operation Warp Speed, the federal government's vaccine acceleration initiative.
 - The announcement comes one week after interim results from Pfizer's vaccine trial indicated Pfizer's vaccine candidate is safe and more than 90% effective.
 - Neither study has [released](#) detailed data for peer review, so the results cannot be considered conclusive.
 - Both candidates use a synthetic version of coronavirus mRNA to program a person's cells to produce fragments of the virus. The virus fragments activate the immune system, providing protection against the real virus.
 - mRNA vaccines are being tested for a variety of other illnesses and cancers, but none have yet been approved or marketed. The success of the Pfizer and Moderna candidates indicates that mRNA vaccines may be a promising way of creating new vaccines quickly for other ailments.
 - Both vaccines must be stored at low temperatures and require two doses, presenting logistical challenges. However, while the Pfizer vaccine must be stored at -94 degrees Fahrenheit, the Moderna vaccine can be stored at -4 degrees Fahrenheit.

- Researchers must still determine how long immunity will last, whether the vaccines work equally well in older and younger people, and whether the vaccine prevents vaccinated individuals from spreading the virus or merely protects them from symptoms.
 - Both companies said they expected to apply within weeks to the Food and Drug Administration for emergency use authorization (EUA).
 - Moderna said it can produce 20 million doses by end of 2020, enough for 10 million people. Pfizer can produce 50 million doses by end of 2020, enough for 25 million people.
- [Study Identifies Nebulized Interferon Beta-1 as Possible COVID-19 Treatment](#), November 12
 - Nebulized (inhaled) interferon beta-1a was associated with higher odds of clinical improvement in hospitalized COVID-19 patients according to a Phase 2 industry-funded study published in the medical journal The Lancet.
 - The study included roughly 100 adults admitted to the hospital with confirmed COVID-19, who were randomized to receive either daily inhaled interferon beta-1a via a nebulizer or a placebo for 14 days.
 - At days 15-16, odds of clinical improvement were twice as high in the interferon group. At day 28, they were three times greater. The treatment group had a 79% lower risk of developing severe disease or dying. Treatment had no effect on discharge time.
 - Commentators wrote that few antiviral drugs effective against SARS-CoV-2 have been identified, and that the findings in this study are promising and should be promptly evaluated in large randomized clinical trials.
 - [FDA COVID-19 Updates](#), November 16
 - At FDA’s request, the Department of Justice (DOJ) filed a civil [complaint](#) against Natural Solutions Foundation and two associated individuals seeking to permanently enjoin them from distributing Dr. Rima Recommends™ Nano Silver 10PPM as a prevention or treatment for COVID-19 and other diseases.
 - FDA issued a consumer [update](#) urging consumers to avoid fraudulent flu products and offering tips on how to spot them.

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-Pandemic](#), November 10
- [New HHS Advisory Opinions Support Broad Application of PREP Act Immunity for COVID-19 Response](#), November 3

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