

COVID – 19 Research and Advisory Team: Report and Recommendations #40 November 13, 2020

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This report contains a summary of updates on the status of Covid-19 that are more evident since our last report. Sources include: CDC, WHO, SFDPH, CA DPH, Science Journal, Nature Journal, New England Journal of Medicine, Journal of the American Medical Association, Scripps Research Institute, Johns Hopkins Coronavirus Resource Center, UCSF Medical Grand Rounds, STAT, Institute for Health Metrics & Evaluation, the Covid Tracking Project, other clinical journals, reports from public health professionals, and news media. This report is not intended to provide personal advice – for that please consult with your health care providers.

RECENT FINDINGS

1) What seniors can expect when Covid-19 vaccines become available

The first candidates, from Pfizer and Moderna, could arrive before Christmas, according to Alex Azar, who heads the US Department of Health and Human Services. Both vaccines are notably effective in preventing illness due to the coronavirus, according to information released by the companies, although much of the data from clinical trials is still to come. Both have been tested in adults age 65 and older, who mounted a strong immune response. So far, summary results disclosed in news releases indicate that Pfizer's vaccine, produced in partnership with BioNTech, has an overall efficacy rate of 95% and efficacy of 94% in people 65 and older. Moderna's overall efficacy is 94%, with 87% efficacy in preventing moderate disease in older adults.

Seniors in nursing homes and assisted living centers will be among the first Americans vaccinated, following recommendations this week by a federal advisory panel. Older adults living at home will need to wait a while longer. This recognizes the extraordinary burden of Covid-19 in long-term care facilities. Although their residents represent fewer than 1% of the U.S. population, they account for 40% of Covid deaths — more than 100,000 deaths to date. The commission's decision comes despite a lack of evidence that Pfizer's and Moderna's vaccines are effective and safe for frail, vulnerable seniors in long-term care. Vaccines were not tested in this population.

Hospitals and physicians may try to identify older adults who are at the highest risk of becoming seriously ill from Covid-19 and offer them vaccines before other seniors. A study of more than 500,000 Medicare beneficiaries age 65 and older provides new evidence that could influence these assessments. It found the conditions that most increase older adults' chances of dying from Covid-19 are sickle cell disease, chronic kidney disease, leukemias and lymphomas, heart failure, diabetes, cerebral palsy, obesity, lung cancer and heart attacks, in that order.

Both the Pfizer and Moderna vaccines require two doses, administered three to four weeks apart. The companies have said about 40 million

doses of their vaccines should be available this year, enough to fully vaccinate about 20 million people. After that, 50 million doses might become available in January, followed by 60 million doses in both February and March, that translates into enough vaccine for another 85 million people and should be sufficient to vaccinate older adults in addition to medical personnel on the front lines and many other at-risk individuals.

Advocates have a big job ahead of them. According to a recent poll from the University of Michigan, only 58% of older adults (ages 50 to 80) said they were very or somewhat likely to get a Covid-19 vaccine. A significant number of older adults, 46%, thought they'd get the vaccine eventually but wanted others to go first. Only 20% wanted to get it as soon as possible.

As Pfizer's and Moderna's vaccines are rolled out, a very vulnerable group may have difficulty getting them: 2 million seniors who are homebound and another 5.3 million with physical impairments who have problems getting around. The reason: handling and cold storage requirements. Pfizer's vaccine needs to be stored at minus 70 degrees Celsius, calling for special equipment not available in small hospitals, clinics or doctors' offices. Moderna's vaccine needs long-term storage at minus 20 degrees Celsius.

2) Britain warns of allergic reactions to vaccine

British regulators directed hospitals not to administer the new coronavirus vaccine to people with a history of "significant" allergic reactions after two people who got the shot had problems. In a briefing with reporters Wednesday, Moncef Slaoui, science adviser for the White House's Operation Warp Speed vaccine task force, said he assumes the FDA will consider possible allergic side effects in its review of the Pfizer vaccine.

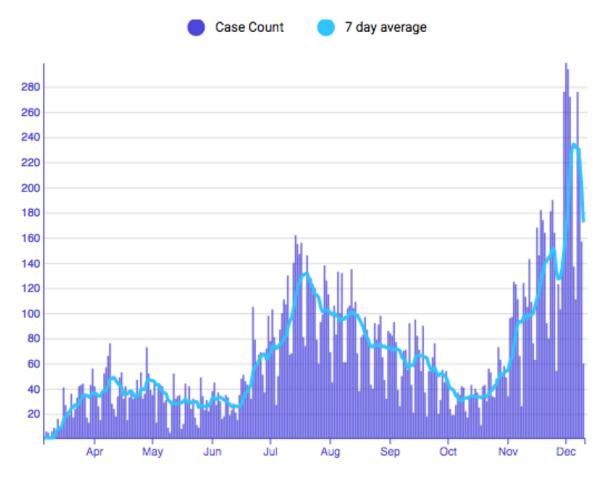
"Subjects with known severe allergic reactions should not take the vaccine until we understand exactly what happened here," Slaoui said, referring to the adverse reactions in two British health workers who were among the first to get the vaccine. Two staffers with Britain's National Health Service manifested symptoms of "anaphylactoid reaction" after receiving the vaccinations at a hospital Tuesday.

The Pfizer data showed that about 0.6 percent of people had some form of allergic reaction to the vaccine in the clinical trials (although 0.5 percent also exhibited a reaction to the placebo). The FDA found slightly more adverse events "potentially representing allergic reactions" in its review of the Pfizer data. There were 137 "hypersensitivity-related" reactions to the vaccine, compared with 111 such events in the placebo group.

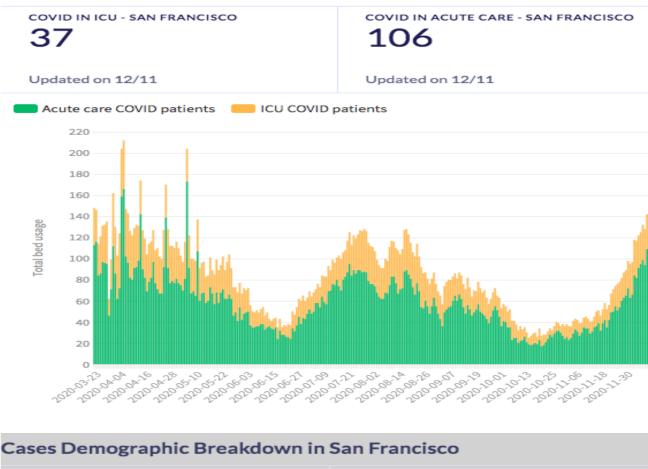
SAN FRANCISCO

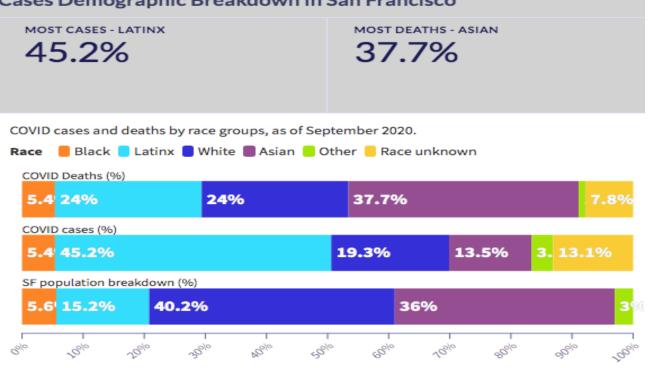
Total Cases: 18,326 Deaths: 167

R Number: between 1.3 and 1.4 (R Number refers to the reproductive rate of a disease. To control and eliminate the spread of a disease, an R Number of <1 is required. 1.4 indicates the virus is rapidly increasing)



SF Hospitalizations





Percentage

1) San Francisco Hits Record High in Covid Hospitalizations

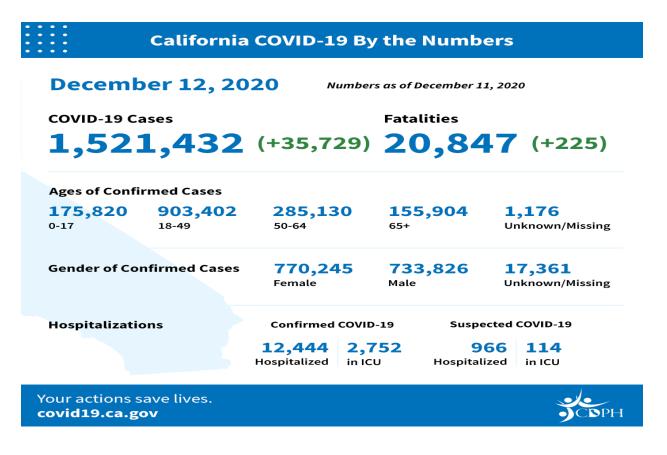
The Bay Area saw a single-day jump of COVID hospitalizations of 6.1% on Tuesday, and San Francisco is seeing more seriously ill COVID patients in hospitals at one time than at any other time during this pandemic. The predicted surge in COVID cases hitting hospitals is happening just as local public health experts predicted it would, with case numbers rapidly rising and the severely ill beginning to occupy more and more available ICU beds across the region.

In San Francisco, the number of confirmed COVID patients in hospitals is higher than during previous surges in the spring and summer. On Wednesday, SF Dept. of Public Health Director Dr. Grant Colfax gave another in a long series of stern and stark press briefings, warning San Francisco residents that if the curve doesn't bend in the coming weeks, the number of hospitalizations — and likely the number of COVID deaths in the city — will skyrocket to unmanageable levels. "To be blunt, we have one chance to turn this serious surge around and that chance is right now. But our window is narrowing and closing fast," Colfax said.

As ICUs become overwhelmed, patterns in other parts of the country have shown that more deaths occur as doctors and nurses are stretched too thin to properly attend to every patient. And Colfax said that we could be looking at a ten-fold increase in deaths by late winter if the trends continue unabated — with upwards of 1,500 deaths, when we have seen 165 in the city to date since March. The worst-case scenario sees a ten-fold increase in hospitalizations, to around 1,410 patients simultaneously needing hospital care in SF.

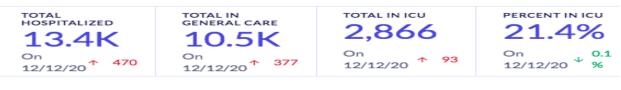
San Francisco continues to have more ICU beds available than most other Bay Area counties, but that could change quickly. The hospital system in the city currently has 72% of its intensive-care beds filled, with 28%, or 81 total ICU beds available. Additionally, acute-care beds are 81% filled, and there were 305 available as of Tuesday.

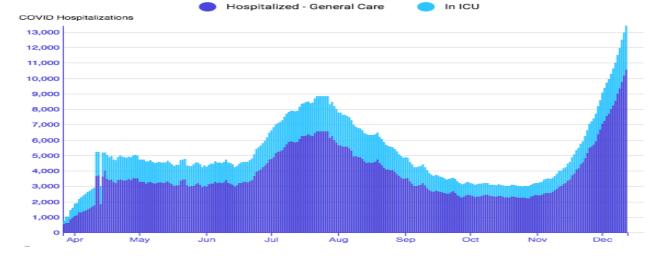
CALIFORNIA



California COVID Hospitalizations and ICU Usage

Data Updated Sunday 12/13 at 10:59 AM PST





1) California Covid-19 Update: New Infections Jump 20% In Single Day; Record Number Of Hospitalizations, ICU Patients And Deaths This Week

The number of daily new Covid-19 cases in California jumped 20% in the past 24 hours to a new all-time high of 35,468. It's the third record number of new cases in the past week. The state has also seen records fall in terms of deaths — that was 220 yesterday — and hospitalizations — at 12,940 on Friday — and ICU capacity — with just 9% left statewide.

California hit 30,000 daily new cases on Sunday. The state seems to now be seeing a surge on top of that surge. A rise to say 40,000 new cases daily would mean over a quarter of a million new infections each week. Conservatively, 10% of those people would end up in the hospital, which would mean 28,000 over a one-week period. That's unsustainable, given that the state only has about 72,000 beds. Health officials have long warned of this surge on top of a surge scenario. The "nightmare" situation they say would be to see yet another surge from infections transmitted at December holiday gatherings.

Certain areas in the state were even worse off. The hard-hit San Joaquin Valley had just 4.5% of its ICU beds left. The state's adjusted metric showed remaining ICU capacity in Orange County at just 2.3% on Friday. The number for all of Southern California was 6.2%. ICUs in San Diego and Santa Clara Counties are projected to reach capacity next week.

2) California vaccinations could start Monday, but it won't slow COVID-19 crisis imperiling hospitals

California will begin providing the COVID-19 vaccine as early as Monday, but officials warned the initial shipment of roughly 327,000 doses won't alter the rapidly deteriorating conditions in state hospitals as the virus rages out of control.

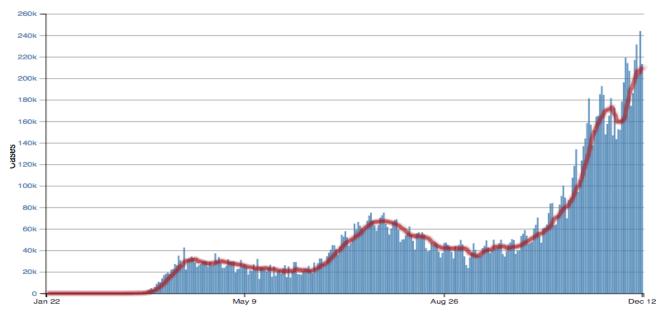
Medical workers were expected to get the first doses of vaccine through a limited number of hospitals in California that include Cedars-Sinai Medical Center, UCLA Health and Rady Children's Hospital in San Diego. Officials expect to get more doses of the vaccine later this month and again in early January. "While vaccines are around the corner, they will not be here in time to prevent compromising care for seriously ill individuals at our hospitals," Barbara Ferrer, L.A. County's health director, said.

The state Department of Public Health selected at least seven hospitals to receive the first batch of vaccines based on their storage capacity, the relatively high risk of their healthcare populations and their ability to distribute the vaccine in the community once it becomes widely available. In Northern California, designated hospitals include UC San Francisco Medical Center, Mercy Medical Center in Redding and UC Davis Health in Sacramento. Officials at hospitals slated to receive the vaccines said they were working to distribute the first doses equitably and in accordance with guidelines issued by federal and local health authorities.

A second vaccine, created by the pharmaceutical company Moderna in partnership with the National Institutes of Health, could be granted emergency use authorization next week, said Schechter of the California Department of Public Health. In total, California expects at least 2 million doses of COVID-19 vaccines by the end of December and approximately 6 million by the end of January, he said.

UNITED STATES

Total Cases: 16,136,675 Deaths: 298,569



Daily Trends in Number of COVID-19 Cases in the United States Reported to CDC

1) Single-Day U.S. COVID-19 Deaths Top 3,000, More Than D-Day Or 9/11

Just when the U.S. appears on the verge of rolling out a COVID-19 vaccine, the numbers have become gloomier than ever: Over 3,000 American deaths in a single day, more than on D-Day or 9/11. One million new cases in the span of five days. More than 106,000 people in the hospital. The crisis across the country is pushing medical centers to the breaking point and leaving staff members and public health officials burned out and plagued by tears and nightmares. All told, the crisis has left more than 290,000 people dead nationwide, with more than 15.5 million confirmed infections.

The U.S. recorded 3,124 deaths Wednesday, the highest one-day total yet, according to Johns Hopkins University. Up until last week, the peak was 2,603 deaths on April 15, when New York City was the epicenter of the nation's outbreak. The latest number is subject to revision up or down. Wednesday's toll eclipsed American deaths on the opening day

of the Normandy invasion during World War II: 2,500, out of some 4,400 Allied dead. And it topped the toll on Sept. 11, 2001: 2,977. New cases per day are running at all-time highs of over 209,000 on average. And the number of people in the hospital with COVID-19 is setting records nearly every day.

2) I.C.U. Beds Near Capacity Across U.S.

More than a third of Americans live in areas where hospitals are running critically short of intensive care beds, federal data show, revealing a newly detailed picture of the nation's hospital crisis during the deadliest week of the Covid-19 epidemic. Hospitals serving more than 100 million Americans reported having fewer than 15 percent of intensive care beds still available as of last week. One in 10 Americans — across a large swath of the Midwest, South and Southwest — lives in an area where intensive care beds are either completely full, or fewer than 5 percent of beds are available. At these levels, experts say maintaining existing standards of care for the sickest patients may be difficult or impossible. Sharp increases in Covid-19 patients can overwhelm smaller hospitals,

Survival rates from the disease have improved as doctors have learned which treatments work. But hospital shortages could reverse those gains, risking the possibility of increasing mortality rates once again as patients cannot receive the level of care they need. Thomas Tsai, an assistant professor of health policy at Harvard University, said that when resources are critically constrained, healthcare workers already facing burnout are forced to make emotionally wrenching decisions about who receives care.

3) Model still forecasts 500,000 deaths by April

More than 500,000 people in the United States will have died from Covid-19 by April, a model from the Institute for Health Metrics and Evaluation forecasts. The death toll could reach 502,000 by April 1, but it will be lower if more people wear masks, the researchers said. A worst-case scenario, predicated on states easing health orders, forecasts 598,000 deaths by April. A composite forecast from the US Centers for Disease Control and Prevention projects a total of 332,000 to 362,000 Covid-19 deaths by January 2. That forecast combines modeling from 40 independent research groups. 72% of Americans wear masks, and 56,000 fewer people would die if mask use rises to 95%.

Covid-19 vaccines are a "really significant light at the end of the tunnel, But the US probably won't see any significant impact from vaccines until well into 2021 -- and that's only if enough people choose to get vaccinated," said Dr. Anthony Fauci, director of the National Institute for Allergy and Infectious Diseases. "Let's say we get 75%, 80% of the population vaccinated. I believe if we do it efficiently enough over the second quarter of 2021, by the time we get to the end of the summer ... we may actually have enough herd immunity protecting our society that as we get to the end of 2021, we could approach ... some degree of normality that is close to where we were before."

4) FDA issues emergency use authorization for Pfizer/BioNTech Covid-19 vaccine

The US Food and Drug Administration has authorized the first Covid-19 vaccine for emergency use in the United States. Millions of doses of the Pfizer and BioNTech coronavirus vaccine, which has been found to be 95% effective, will be soon shipped around the country so vaccinations can begin within days.

An emergency use authorization means a medical product gets special authorization by the FDA to be used during an emergency -- but it is short of a full approval. Pfizer would have to file a separate application for its vaccine to be fully licensed by the FDA. Today's action follows an open and transparent review process that included input from independent scientific and public health experts and a thorough evaluation by the agency's career scientists to ensure this vaccine met FDA's rigorous, scientific standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization.

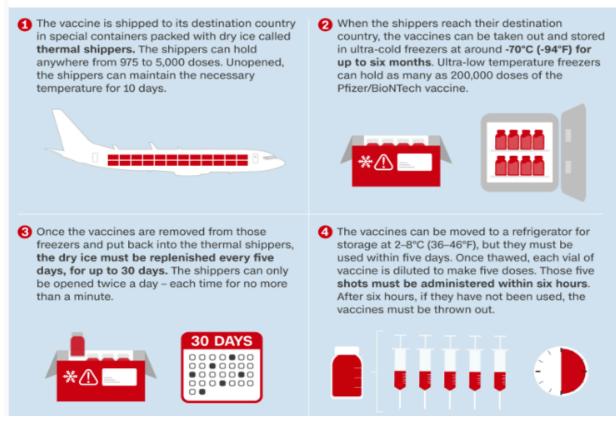
Pfizer and BioNTech's coronavirus vaccine, called BNT162b2, is an mRNA vaccine given as two shots administered 21 days apart. One dose is to prime the body, and then a few weeks later, the second dose is to boost the response. The messenger RNA or mRNA used in the vaccine codes for a structure called the spike glycoprotein of the virus. That's the part of the virus that it uses to attach to cells. The vaccine prompts

the human body to produce copies of that protein, eliciting an immune response that leads to some protection against coronavirus infection. Such mRNA vaccines are the newest approach to vaccine technology.

The data come from more than 43,000 trial participants: 21,720 who were randomly given the vaccine and 21,728 who were randomly given a placebo. The data show that there were only eight Covid-19 cases among people who received the vaccine, compared with 162 cases among those given the placebo. The paper notes that a two-dose regimen of the vaccine has an efficacy of 95% in people ages 16 and older.

Safety over a median of 2 months was similar to that of other viral vaccines. The safety profile of the vaccine is favorable and the most common adverse reactions to the vaccine have been reactions at the injection site, fatigue, headache, muscle pain, chills, joint pain and fever. Severe adverse reactions occurred in less than 4.6% of participants, were more frequent after the second dose and were generally less frequent in older adults as compared to younger participants.

How the Pfizer/BioNTech vaccine will be distributed



5) First Vaccine Doses To Begin Rolling Out Early Sunday To Hundreds Of Sites

The first doses of Pfizer's coronavirus vaccine are currently being packaged at the company's Michigan facility and will begin rolling out for delivery Sunday morning Shipments are expected to reach 145 predesignated sites across all 50 states on Monday. Another 425 sites will receive shipments Tuesday, and 66 more sites will receive shipments Wednesday, for a total of about 2.9 million doses.

The plan to distribute the Pfizer vaccine with military precision was unveiled hours after the Food and Drug Administration officially approved the drug late Friday night. The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices voted Saturday to recommend the Pfizer vaccine for use on people 16 and older. Companies such as Walmart have already announced that their in-store pharmacies will help distribute the vaccines.

RECOMMENDATIONS

We are all suffering from degrees of pandemic fatigue and this, coupled with the holiday season, may strain our appreciation of the need to maintain the necessary precautions to keep us safe.

Given the severity of this recent surge in infections, hospitalizations, and deaths in California and San Francisco, along with the recent approval and release of the first vaccine (with more to come), let's proceed with having a public health expert offer an educational talk on these topics and answer members' questions.

We have been in contact with one public health official who has not yet committed to offering a talk. We may need to reach out to other experts.