San Francisco Village

COVID – 19
Research and Advisory Team:
Report and Recommendations #29
September 27, 2020

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This report contains a summary of the key updates on the status of Covid-19 that are more evident since our last report (June 14), along with our current recommendations for actions for SFV to consider taking. 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.

RECENT FINDINGS

1) The Coronavirus Trials Questions

We may not find out whether the vaccines prevent moderate or severe cases of Covid-19. According to the protocols for their studies, which they released late last week, a vaccine could meet the companies' benchmark for success if it lowered the risk of mild Covid-19, but was never shown to reduce moderate or severe forms of the disease, or the risk of hospitalization, admissions to the intensive care unit or death.

To say a vaccine works should mean that most people no longer run the risk of getting seriously sick. That's not what these trials will determine.

Knowing how a clinical trial defines its primary endpoint — the measure used to determine a vaccine's efficacy — is critical to understanding the knowledge it is built to discover. In the Moderna and Pfizer trials, even a mild case of Covid-19 — for instance, a cough plus a positive lab test — would qualify and muddy the results. AstraZeneca is slightly more stringent but would still count mild symptoms like a cough plus fever as a case. Only moderate or severe cases should be counted.

First, mild Covid-19 is far more common than severe Covid-19, so most of the efficacy data is likely to pertain to mild disease. But there is no guarantee that reducing the risk of mild Covid-19 will also reduce the risk of moderate or severe Covid-19. The reason is that the vaccine may not work equally well in frail and other at-risk populations. Healthy adults, who could form a majority of trial participants, might be less likely to get mild Covid-19, but adults over 65 — particularly those with significant frailty — might still get sick.

Second, Moderna and Pfizer acknowledge their vaccines appear to induce side effects that are similar to the symptoms of mild Covid-19. In Pfizer's early phase trial, more than half of the vaccinated participants experienced headache, muscle pain and chills.

If the vaccines ultimately provide no benefit beyond a reduced risk of mild Covid-19, they could end up causing more discomfort than they prevent.

Third, even if the studies are allowed to run past their interim analyses, stopping a trial of 30,000 or 44,000 people after just 150 or so Covid-19 cases

may make statistical sense, but it defies common sense. Giving a vaccine to hundreds of millions of healthy people based on such limited data requires a real leap of faith.

Declaring a winner without adequate evidence would also undermine the studies of other vaccines, as participants in those studies drop out to receive the newly approved vaccine. There may well be insufficient data to address the aged and underrepresented minorities. There will be no data for children, adolescents and pregnant women since they have been excluded. Vaccines must be thoroughly tested in all populations in which they will be used.

2) Johnson and Johnson vaccine produced strong immune response
Early results from a Phase 1/2a clinical trial show it was well tolerated and even one dose appeared to produce a strong immune response in almost all of the 800 participants. The trial included two age groups: 18- to 55-year-olds and 65 and older, and looked at the safety and side effects of two different doses. Initial findings from the trials suggest the vaccine does provoke an immune response and is safe enough to move into large-scale trials. The study was posted on MedRxiv, but it has not been peer-reviewed or published in a medical journal yet.

The researchers found that 99% of the participants age 18 to 55 in both dose groups had developed antibodies against the virus 29 days after getting vaccinated. The analysis found that most of the side effects, like fever, headache, fatigue, body aches and injection-site pain, were mild and resolved after a couple of days.

UNITED STATES

Total Cases: 7,053,171
Total Deaths: 204,093

1) Massive genetic study shows coronavirus mutating and potentially evolving amid rapid U.S. spread
The first study to analyze the structure of the novel coronavirus from two waves of infection in a major city found that a more contagious strain dominates recent samples, researchers from Houston Methodist Hospital said on Wednesday. They examined more than 5,000 genomes from viruses

recovered in the earliest phase of the pandemic in Houston, an ethnically diverse city of 7 million, and from an ongoing more recent wave of infections.

The study, which has not yet been reviewed by outside experts, found that nearly all strains in the second wave had a mutation, known as D614G, which has been shown to increase the number of “spikes” on the crown-shaped virus. The spikes are what allow the virus to bind to and infect cells, increasing the ability of the mutated virus to infect cells.

The Houston researchers said patients infected with the variant strain had significantly higher amounts of the virus on initial diagnosis.
But they found little evidence that mutations in the virus have made it deadlier, noting that severity of COVID-19, the disease caused by the virus, was more strongly linked to patients' underlying medical conditions and genetics.

2) Updated CDC guidance acknowledges coronavirus can spread through the air

The US Centers for Disease Control and Prevention updated guidance on its website to say coronavirus can commonly spread "through respiratory droplets or small particles, such as those in aerosols," which are produced even when a person breathes. "Airborne viruses, including COVID-19, are among the most contagious and easily spread," the site now says. Previously, the CDC page said that Covid-19 was thought to spread mainly between people in close contact -- about 6 feet -- and "through respiratory droplets produced when an infected person coughs, sneezes or talks."

The page now says, "There is growing evidence that droplets and airborne particles can remain suspended in the air and be breathed in by others, and travel distances beyond 6 feet (for example, during choir practice, in restaurants, or in fitness classes).” "In general, indoor environments without good ventilation increase this risk."

3) Trump claims White House can overrule FDA's attempt to toughen guidelines for coronavirus vaccine

President Donald Trump claimed Wednesday that the White House could override the US Food and Drug Administration if the agency released tougher standards for the authorization of a Covid-19 vaccine, casting such a move as "political." His comments come as the FDA considers new Covid-19 vaccine

guidelines that would likely push an authorization beyond Election Day, according to three sources familiar with the situation. That timeline would dash Trump's hopes of a pre-election authorization, having repeatedly said the vaccine could be ready by November 3.

The President's comments are sure to fuel new unease in a vaccine process that was already being greeted with skepticism by many Americans in polls. A lack of trust in the program is a nightmare scenario, public health experts say, since a vaccine is the best hope of eventually ending the pandemic and restoring normal life.
Earlier Wednesday, the commissioner of the FDA, Dr. Stephen Hahn, made a commitment to America that the "FDA will not authorize or approve a vaccine that we would not feel comfortable giving to our families."

4) NY will evaluate vaccine safety, itself.
New York will assemble a panel of experts to evaluate the safety and effectiveness of coronavirus vaccines independent from the federal government, Gov. Andrew Cuomo announced Thursday. The Clinical Advisory Task Force will be led by the state's department of health and will step in to evaluate the drugs once federal officials have made their assessment.
Although New York officials do not control whether drugs are cleared by the Food and Drug Administration, the state plans to play a major role in distributing a vaccine, and its leaders could potentially hamper access to drugs it deems unsafe. In May, 72% adult respondents had said that they would likely get a vaccine if it were available that day, according to the Pew Research Center. This month, however, that number has dropped to 51%.

5) Young adults are now the largest group of Americans getting COVID-19, CDC says
A new study from the Centers for Disease Control and Prevention reports that the median age of people with COVID-19 in the U.S. has declined over the spring and summer, with Americans in their 20s now accounting for more cases than people in any other age group. The findings suggest that if the U.S. wants to get its coronavirus outbreak under control, it will need more cooperation from young adults.

In May, the median age of U.S. residents with COVID-19 was 46. By July, it had dropped to 37, then rose slightly to 38 in August.

Likewise, in May, people in their 20s made up 15.5% of confirmed COVID-19 cases nationwide. At the time, they trailed people in their 30s (who accounted for 16.9% of total cases) as well as people in their 40s and 50s (both of those age groups accounted for another 16.4% of cases). But by June, 20-somethings had taken over the top spot, making up 20.2% of all cases. That figure rose to 23.2% in July, then dropped back to 21% in August. The proportion of cases among Americans in their 30s also increased in June and July. But by August, it had fallen slightly below the level seen in May. Meanwhile, the share of cases among adults 40 and older decreased steadily through the end of July, according to the study.

Over time, these infections in younger adults appeared to spread to older, more vulnerable adults in certain parts of the country, the researchers wrote. In the Southeastern U.S., an increase in the test positivity rate for people in their 20s and 30s was followed nine days later by an increase in the positivity rate for people in their 40s and 50s. Six days after that, people ages 60 and up had a higher positivity rate as well. In the Southwestern U.S., an increase in the positivity rate for people under 60 was followed about four days later by an increase in the positivity rate for people ages 60 and up. The same pattern was seen in the south-central states, though the lag there was seven days.

6) Experts are warning of a coming surge of Covid-19 cases in US

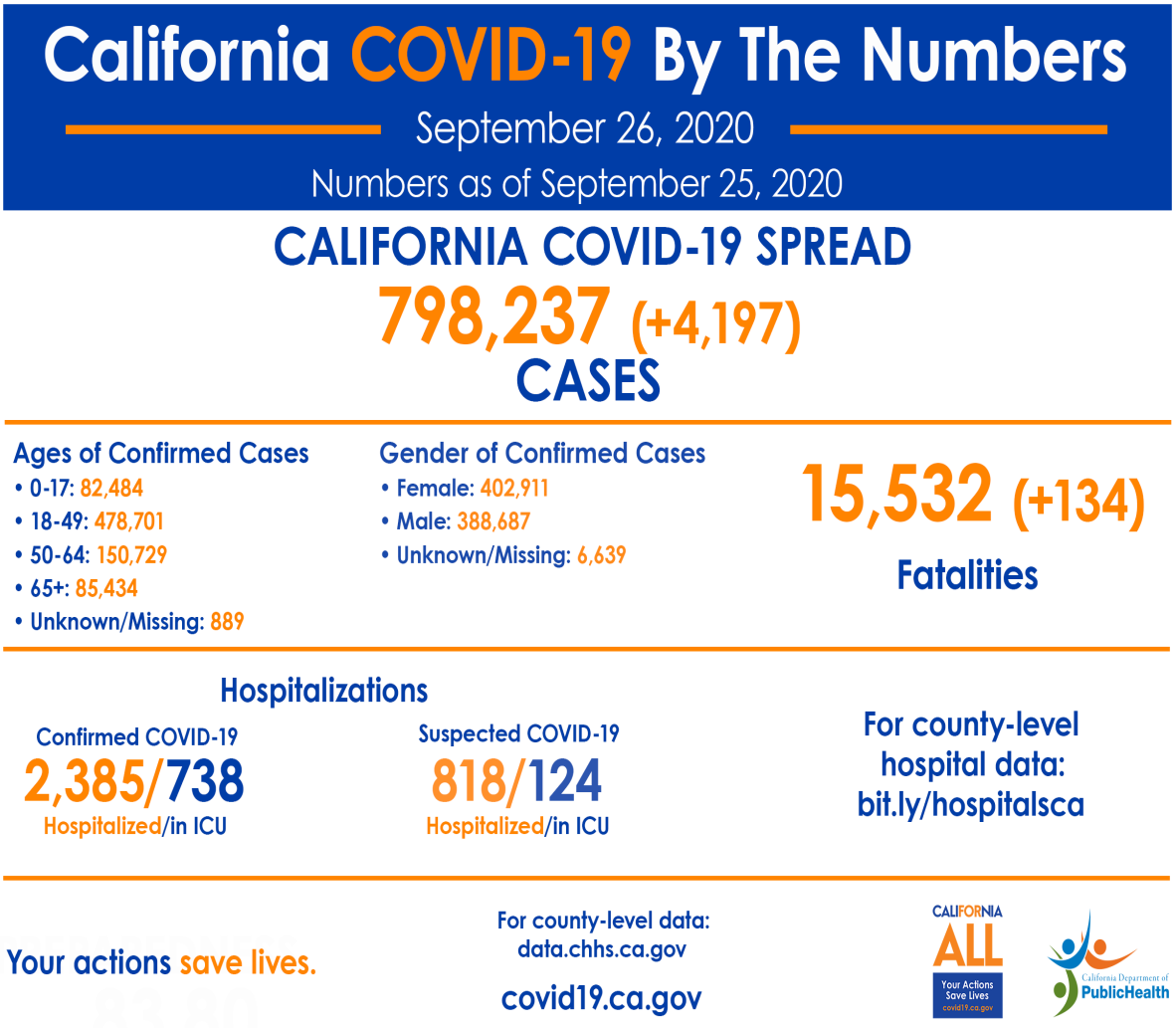
The US could see an explosion of Covid-19 cases as fall and winter set in, one expert says, joining a chorus of health officials who have warned about the challenges of the coming months. Two things will likely help drive that expected winter surge, according to Dr. Chris Murray, director of the University of Washington's Institute for Health Metrics and Evaluation (IHME). "First, as case counts have come down in some states, we tend to see that people become less careful, they tend to have more contact," he said. "But then the most important effect is the seasonality of the virus, that people go indoors, transmission happens more." According to the IHME model, the country is seeing about 765 daily deaths from Covid-19, but that number could jump to 3,000 daily deaths by late December. At least 24 states are now reporting a rise in new cases compared to the previous week, mostly across the US heartland and Midwest, according to data from Johns Hopkins.

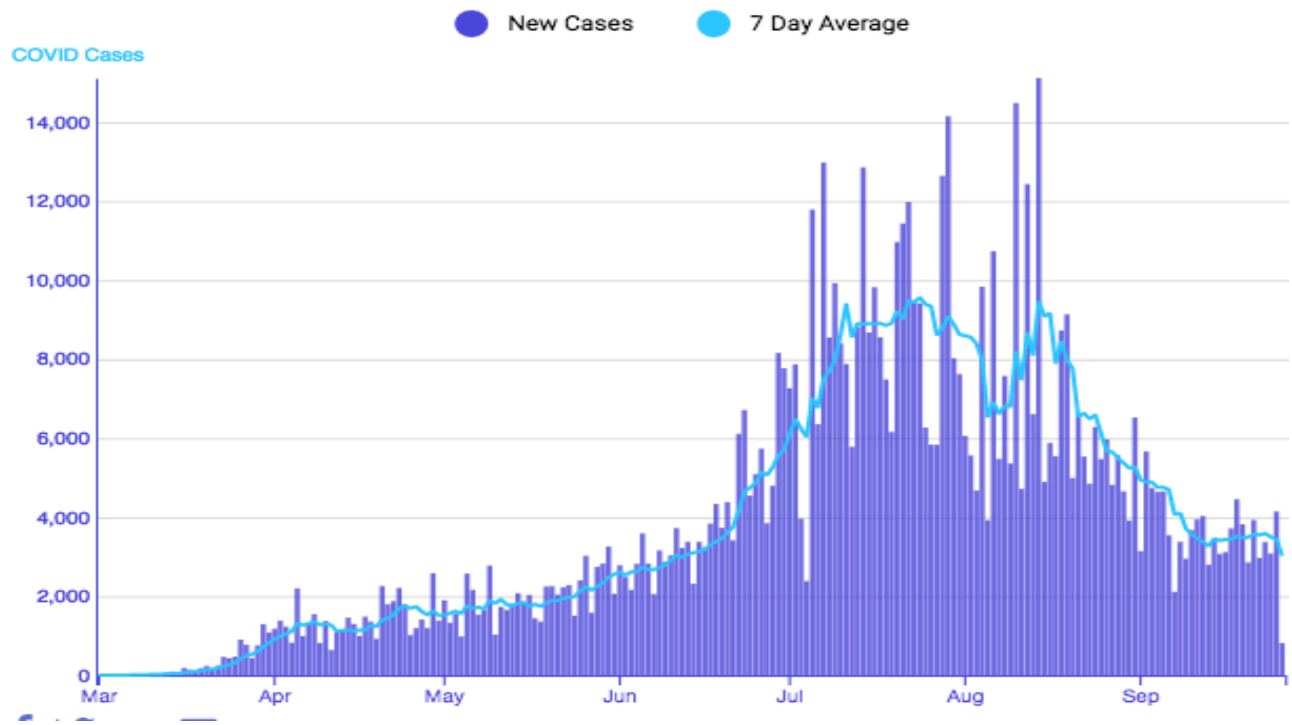
7) Only 10% of US adults may have COVID-19 antibodies.

More than 90% of U.S. adults remain susceptible to COVID-19, according to research published on Friday. Using data from dialysis centers in the United

States, the study, published in The Lancet, estimates that less than 10% of U.S. adults have virus antibodies, meaning everyone else is potentially vulnerable to infection. Those figures roughly match those of a forthcoming Centers of Disease Control and Prevention study, according to CDC Director Dr. Robert Redfield, who spoke at a Senate hearing on Wednesday. The study raises questions over "herd immunity," the idea that when enough a large enough population becomes immune the virus could die off. One big problem, experts have said, is that they don't yet know enough about how immunity to COVID-19 develops to say whether antibodies provide adequate protection from reinfection.

CALIFORNIA



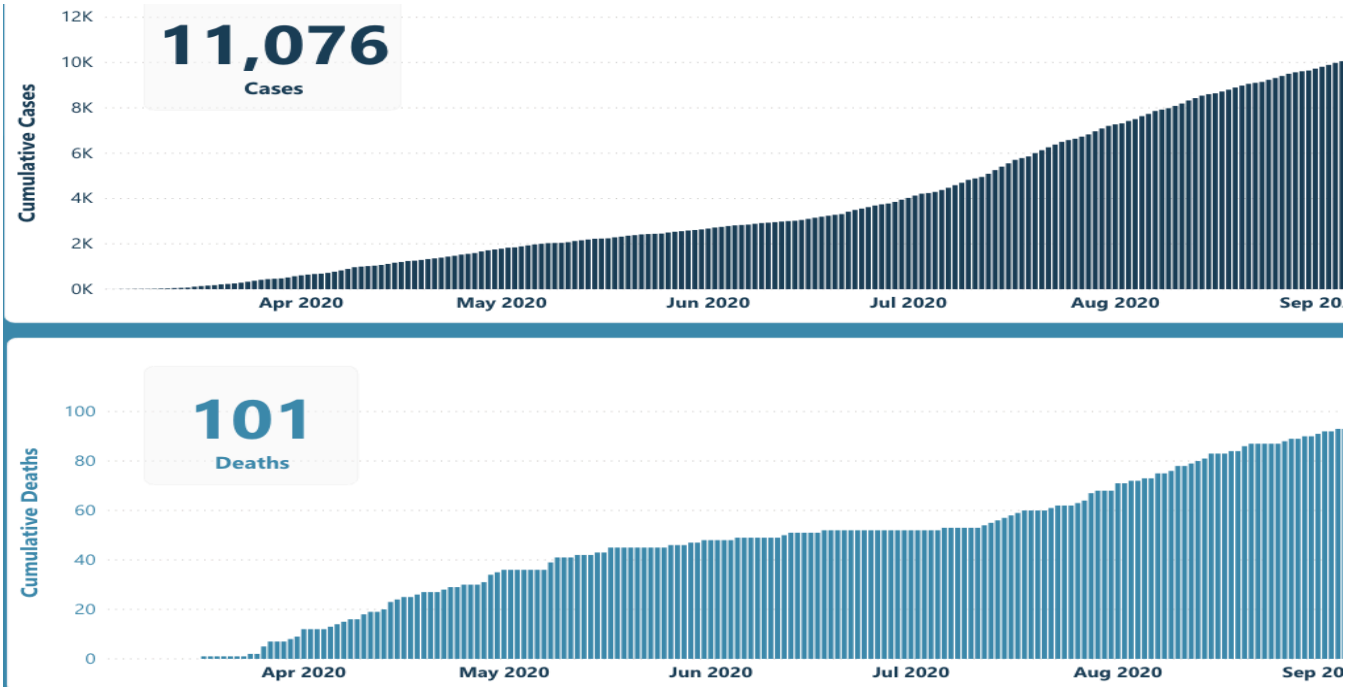


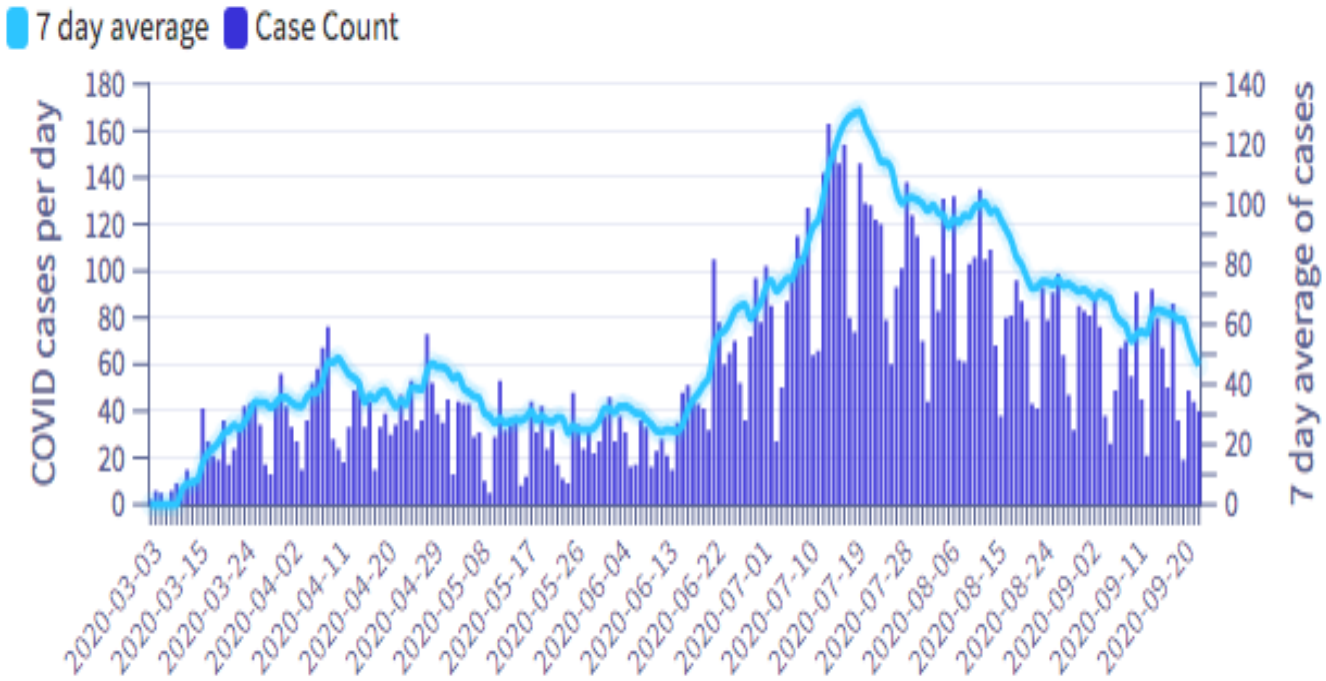
1) California sees virus positivity rate drop below 3% for the first time. Just under 3% of people tested for the coronavirus in California were confirmed positive — the lowest positivity rate the state has seen since it began tracking such metrics in the spring. Health officials are still cautious, as it can take a few weeks for cases to show up in testing or hospitalizations after holiday weekends, such as Labor Day, when people tend to gather in larger groups. The state is still seeing an average of 3,400 confirmed cases of the coronavirus daily. Hospitalizations have dropped by about 23% in the last two weeks.

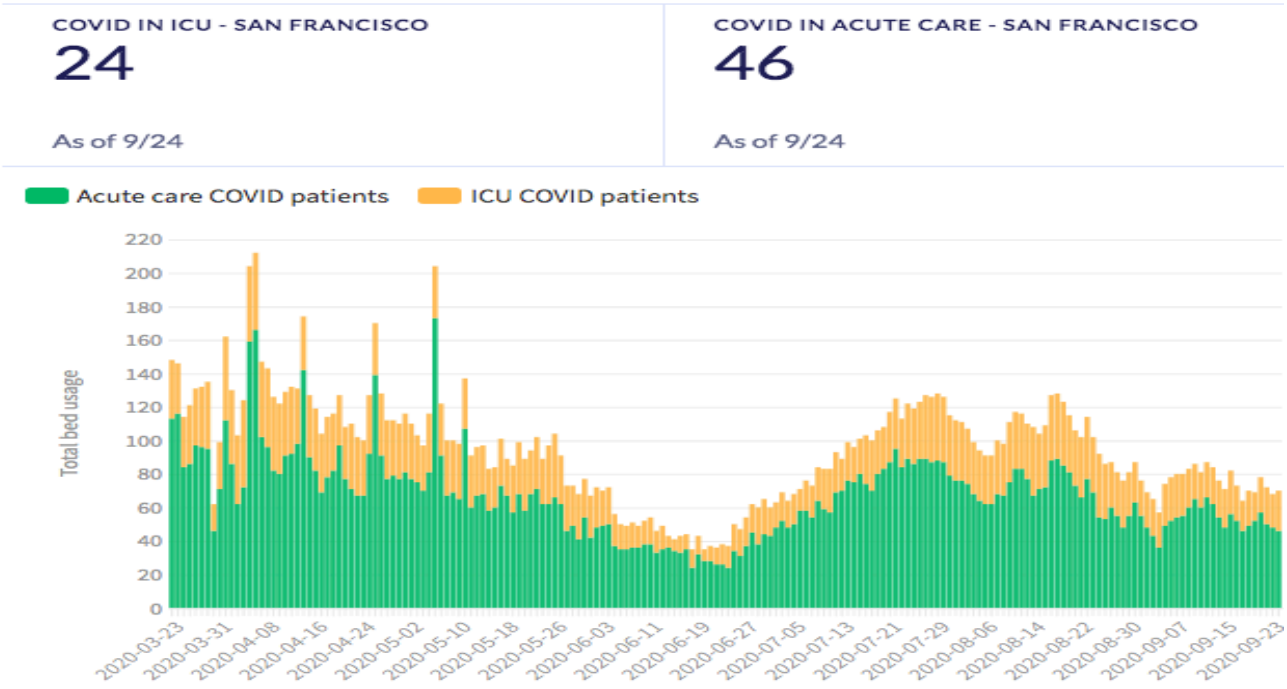
"This disease has not gone away — quite the contrary," Gov. Gavin Newsom warned at a press conference on Monday, urging people to continue wearing face masks and social distancing. It remains to be seen how coronavirus cases will fare in the state moving into the fall, as more schools are set to reopen in person and more businesses are able to have limited indoor service. The governor encouraged people to get their flu shot to avoid overwhelming hospitals with a "twin-demic" of the flu and coronavirus cases.

SAN FRANCISCO

Total Positive Cases: 11,076
Total Deaths: 101





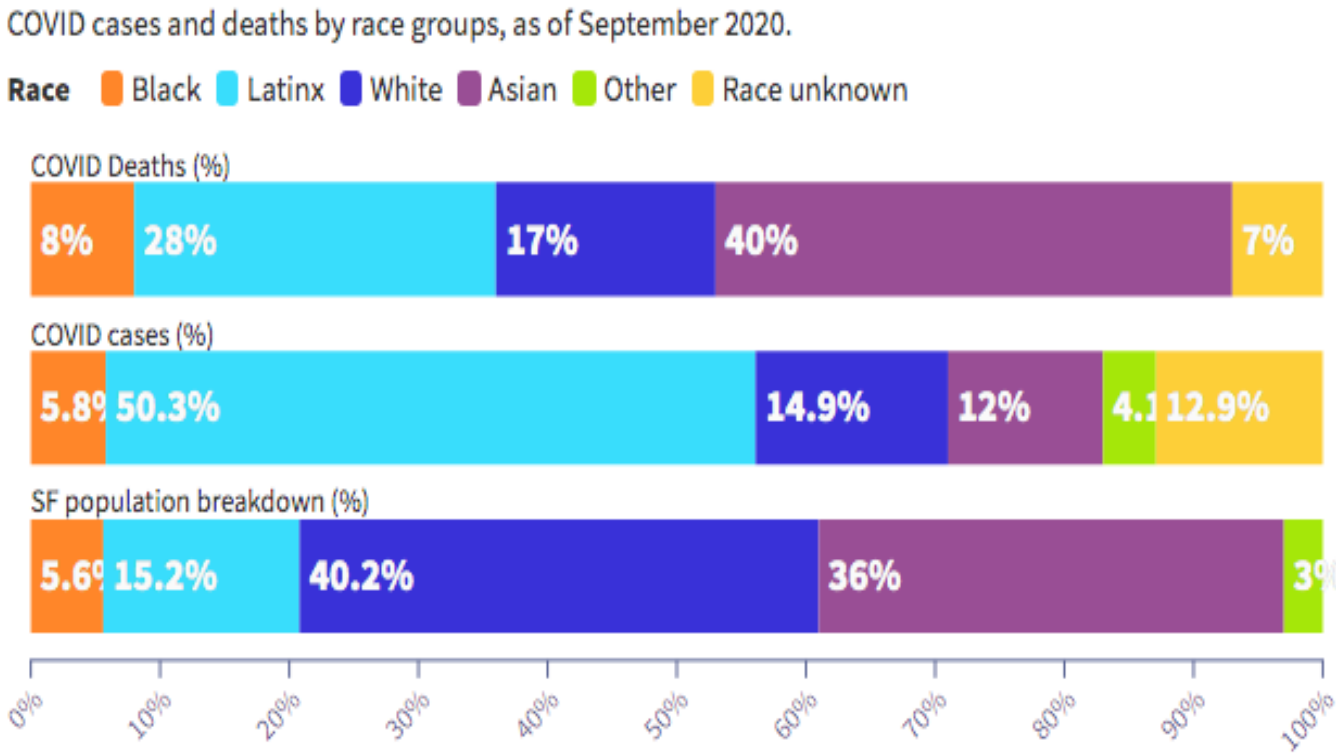


1) Dearth of data and Covid testing in SF Latinx community.
The city's seven-day average case rate for the week of Sept. 7 per was 6.8 per 100,000 residents. That's one of the metrics the state looks at for moving a county through tiers. That rate is high – it would put San Francisco in the state's second-highest risk level. But break that average down by race, and the numbers tell a catastrophic story for some residents of the city.

The city's seven-day average case rate for the same week in September was 2.3 for white residents, 4.71 for Asian Americans, 6.5 for Blacks and 16.4 for Latinx — more than double the city's "substantial" risk rating by state metrics, and well beyond the "widespread" risk category for case rates above 7. In a transmissible virus, researchers said, it's dangerous to allow the impact on segments of the population to be diluted by tossing them in with everyone else. Those harder-to-reach but persistent cases become all the more important to stop the spread of the virus.

San Francisco has had a remarkably low death rate, but here too, the racial disparities are apparent: Of the 99 Covid-19 deaths, Asians comprise 31 percent of the deaths, compared to their 34 percent of the population; Latinx, 27 percent, compared to their 15 percent of the population; Whites, 17 percent, compared to their 40 percent of the population; and Blacks, 8 percent, compared to their 5 percent of the population.

Because the death rate has been so low, the city has been able to focus on cases, but testing has not been aimed at the most impacted populations. Only 9 percent of the city's nearly half million tests have been conducted on Latinx residents. Cases will continue to spread in those groups, the healthcare system will be taxed because many individuals in the most impacted groups don't have access to healthcare, and we will continue to see Covid transmission throughout the city



RECOMMENDATIONS

We have no new recommendations at this time.