San Francisco Village

COVID – 19
Research and Advisory Team:
Report and Recommendations #23
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SFV Members:
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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) What doctors know works against the virus

Early in the year, there were few known treatments for people who showed severe COVID-19 symptoms apart from sustaining them on ventilators. Now, several months later, there are a handful of treatments, including drugs, that give doctors far better tools to heal patients, particularly very ill ones.

The approach to therapy differs depending on the stage of the illness.
It is therefore important to not only diagnose COVID-19 but to define whether the infection is asymptomatic or pre-symptomatic. Also, how sick a person is – whether it's a mild, moderate, severe or critical case – changes how a patient is treated.

Asymptomatic or pre-symptomatic infection is defined as having a positive diagnostic test for COVID-19 (a PCR or antigen detection test) without symptoms of infection. There is currently no known effective treatment for this stage. Someone with asymptomatic or pre-symptomatic infection should isolate themselves at home for 10 days so as not to expose others.

Symptoms of mild COVID-19 infection can include fever, cough, loss of taste or smell, muscle aches, headache, nausea, vomiting, diarrhea, congestion and runny nose. Someone with mild COVID-19 does not have shortness of breath, chest pain or evidence of pneumonia during a chest X-ray. The exception to this is children with mild disease who may still have an abnormal X-ray. There are no treatments that have been demonstrated to benefit those with mild disease. However, such patients should be well versed on the symptoms of moderate illness, so that they and others recognize if they progress to moderate illness. This is important because progression to more severe disease can be rapid – typically five to 10 days after initial symptoms.

Moderate illness is defined as shortness of breath, chest pain, or on a chest X-ray, evidence of pneumonia but without hypoxia (low blood oxygen levels). There currently is no known effective therapy for moderate illness.

Severe illness is identified by a rapid breathing rate (greater than 30 breaths per minute) or low oxygen levels in the blood, which is called hypoxia. Also,

evidence of pneumonia affecting more than half of the lungs, as diagnosed on a chest X-ray, is a sign of a severe case. Controlled clinical trials have demonstrated that the antiviral drug remdesivir hastens recovery for patients with severe but not critical illness. In addition the anti-inflammatory steroid medicine dexamethasone (a prednisone-like drug) decreases mortality.

Critical illness occurs when the patient becomes so sick that vital organs begin to fail and they require medicines or other therapies to support these vital functions. If failure of the lungs is severe enough, physicians may put the patient on a mechanical ventilator or high quantities of oxygen. There is no evidence that remdesivir treatment is beneficial during this critical phase. Dexamethasone is still recommended for treatment because it has been shown to decrease mortality.

Some treatments that have been shown to be ineffective include chloroquine and hydroxychloroquine. Other potential treatments are still in the middle of clinical trials to test whether they are effective. These include human convalescent plasma, which contains antibodies that should bind to the virus and prevent it from entering cells. There are also drugs to modulate the immune response, such as interferons and inhibitors of IL-6, which in some cases may prevent a harmful overreaction of the immune system, commonly referred to as cytokine storm.

Right now there is no approved treatment for outpatients with asymptomatic or mild to moderate COVID-19. But this appears to be changing, with Eli Lilly's and Regeneron's release of clinical trial data on the use of laboratory-manufactured antibodies against the spike glycoprotein of the new coronavirus. In this approach, as with convalescent plasma, the antibodies work by binding to the virus and blocking it from entering cells and multiplying. This could be particularly effective early on in infection before illness becomes severe.
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2) **Coronavirus can survive on skin for 9 hours**
The new coronavirus can linger on human skin much longer than flu viruses can, according to a new study from researchers in Japan.
SARS-CoV-2, the virus that causes COVID-19, remained viable on samples of human skin for about 9 hours, according to the study. In contrast, a strain of

the influenza A virus (IAV) remained viable on human skin for about 2 hours. Fortunately, both viruses on skin were rapidly inactivated with hand sanitizer. The findings underscore the importance of washing your hands or using sanitizer to prevent the spread of COVID-19.

UNITED STATES

Cases: 7,745951
Deaths 214,641

1) New cases on the increase across country and CDC ensemble forecast foresees death toll from Covid-19 climbing to 233,000 by end of month.

Covid-19 cases are trending upward across the US, with only two states reporting a decline of cases compared to last week. And hospitalizations across the country have also begun to rise, according to data from the COVID Tracking Project. At least half of US states, scattered across the Midwest and Northeast, are reporting more new cases than the previous week, according to Johns Hopkins. Alabama and Hawaii are the two states with a decline in cases. Montana, Nebraska, North Dakota, Oklahoma, South Dakota and Wyoming have all seen record-high hospitalization numbers in the past days.

The uptick in Covid-19 patients comes as the US approaches winter with a daily Covid-19 base line that experts say is far too high. For the first time since August, the nation is averaging more than 44,000 new Covid-19 cases daily, according to data from Johns Hopkins University -- an average that won't help as the country enters what health officials say will be a challenging season. More cases will mean more community spread, more hospitalizations and ultimately, more deaths, Dr. Anthony Fauci has said.

2) Neurologic Symptoms Are Very Common Among U.S. Coronavirus Patients

A paper published Oct. 5 in the *Annals of Clinical and Translational Neurology* is thought to be the first to examine the prevalence of neurologic symptoms in U.S. COVID-19 patients. Out of 509 people admitted to Chicago hospitals for coronavirus care this spring, 82% had a neurologic symptom at some point, according to the paper.

The most common neurologic symptoms were muscle aches and headaches, which were experienced by about 45% and 38% of patients, respectively. Almost a third of the patients developed encephalopathy, an umbrella term that refers to alterations in brain structure or function. "The hallmark of encephalopathy is an altered mental state," according to the National Institute of Neurological Disorders and Stroke; it can come with confusion, lethargy, memory loss and decreased cognitive ability. About 30% of patients experienced dizziness, while 16% lost their sense of taste and 11% lost their sense of smell. Very few patients experienced serious complications, like strokes or seizures.

The new study did find that older patients were more likely than younger ones to develop encephalopathy, which is associated with severe disease. Aside from encephalopathy, however, younger patients were generally more likely to be diagnosed with neurologic symptoms.

For a disease like COVID-19, it can be difficult to untangle whether the virus or its treatment is causing neurologic issues. For example, dexamethasone, a steroid now used to treat some hospitalized coronavirus patients, can produce side effects such mood changes, insomnia and dizziness.

3) Why Trump's Rapid-Testing Plan Worries Scientists

The federal government has purchased 150 million new coronavirus tests from the company Abbott Laboratories. Each Abbott test cost only $5, one-20th the price of the most widely used test type. Instead of taking hours to deliver a result, the Abbott tests—which detect viral proteins—could provide an answer within 15 minutes.

Since the spring, a group of experts led by Michael Mina, an epidemiology professor at Harvard, has called for the government to freely distribute tens of millions of 15-minute coronavirus tests a day. Mina wants to test nearly every American every day, whether or not any given person shows symptoms of COVID-19. That's impossible to do with the gold-standard reverse-transcription polymerase chain reaction, or PCR, tests—they are too expensive and take too long to return results. Frequent, cheaper testing, Mina claims, could defeat the pandemic within weeks, as infectious people are identified and quarantined.

Other experts are doubtful and have warned that cheap, rapid tests will not work as promised. If distributed en masse and used to screen asymptomatic people, these antigen tests will deliver hundreds of thousands—if not millions—of false results, they say. False negatives could lead to reckless behavior by people who don't know they're sick. False positives can also put people at risk: If a virus-free nursing-home resident with a false positive is placed in a COVID-19 ward, that person could become infected.

The stakes of this dispute are not only how Abbott tests are used, but whether they should be used at all. It could shape federal policy next year and determine whether more money is spent on fixes to address the virus aside from a vaccine. Mina, generally an advocate of rapid testing, warned that if the Abbott tests were not deployed the right way, with the proper safeguards and solid public education, they could further erode trust in the nation's public-health systems.

These tests have the potential to create two problems. One is commonly cited by critics and very easy to understand: False negatives will give people too much confidence that they are virus-free. Given a negative test result, many people chose to eschew the simple precautions that have helped slow the spread of the virus. The other problem is that these tests will generate many false *positives*, especially if deployed in asymptomatic populations where relatively few people are sick. It could very well be that, as in Nevada, the majority of positive test results are false. Besides the risks of grouping healthy people with those who are actually sick, false positives will keep well people home from work unnecessarily and prompt people to seek "confirmatory" PCR tests, potentially overwhelming an already fragile system.

The early signs are not encouraging. The new Abbott test, the Binax NOW, received an emergency use authorization (EUA) based on results from just 102 samples. The next day, the government spent $760 million to buy the entire supply of tests. Notably, the FDA *did not* support the use of the test for screening asymptomatic people—which the most ambitious version of Mina's plan depends on. The emergency use authorization only covered testing for people within the first seven days of developing symptoms, when viral loads remain high.

In asymptomatic people, the tests will likely perform worse. The levels of virus are likely to be lower in any individual infected person, which would increase the false-negative rate. And in the general, symptom-free population, the expected levels of infection are actually quite low, so the false-positive rate could be very high. If we add tests that generate imperfect information, that will that embolden people to abandon commonsense safety precautions

4) What 'compassionate use' of a Covid-19 drug means — and doesn't mean

For decades, the Food and Drug Administration's expanded access program has provided a pathway for some patients to access investigational, or experimental, medical products — drugs, devices, and vaccines — before they've been approved by the FDA.

To qualify for expanded access:

- The patient must have a serious or life-threatening disease or condition for which there is no other FDA-approved treatment option
- The potential benefit of using the product must outweigh the potential risks.
- The patient is unable to enroll in a clinical trial.
- And providing the product will not threaten its clinical development.

There are three types of expanded access: individual expanded access, for just one patient; multiple-patient expanded access, the number is not capped by regulation; and widespread treatment cohort expanded access, which can include thousands, even tens of thousands of patients.

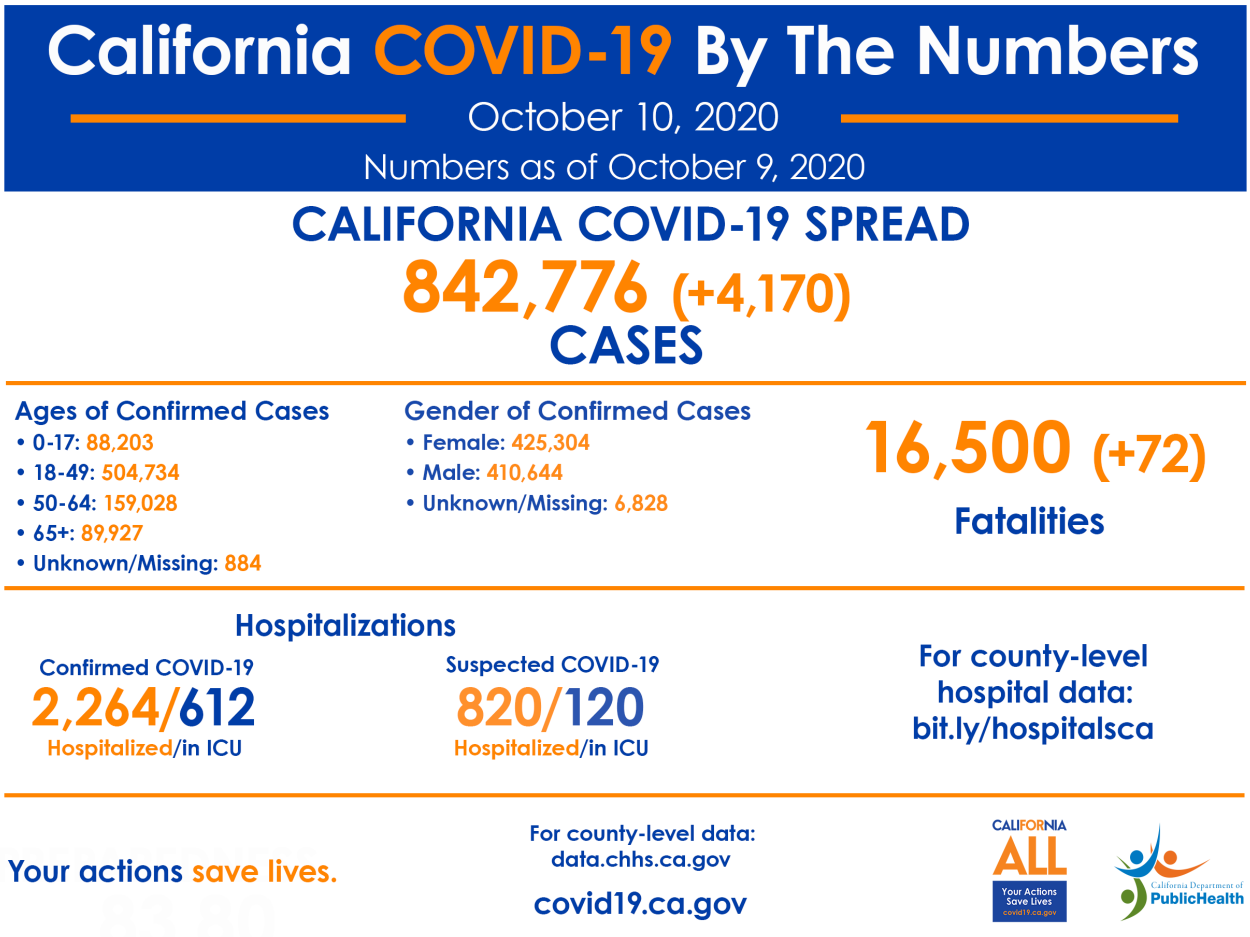
The first of these, individual patient expanded access, is commonly referred to as compassionate use, because companies have no legal obligation to offer access and thus are labeled "compassionate" for doing so.

The compassionate use process goes like this: The patient's physician identifies a potentially beneficial drug in development and requests it from the entity developing it. If that company, also known as the sponsor, agrees to provide the drug — and there is nothing in any regulation requiring any sponsor to provide compassionate use — then the request goes to the FDA for review. If the FDA allows the request to proceed, an institutional review board, a body charged with the protection of human research participants, must sign off on the protocol proposed for delivering the intervention and the

informed consent form the patient would need to complete before beginning it.

The FDA can authorize emergency requests immediately, and the institutional review board must be notified within five business days.
As mentioned earlier, companies are the gatekeepers to access; it is up to them whether to institute policies and practices that might ensure more just access to potentially beneficial investigational drugs. This is something that they might want to give serious consideration to now, with experts predicting a flood of compassionate use requests in the aftermath of Trump's treatment

CALIFORNIA



1) Average deaths in California drop to lowest point in months

As virus spreads unevenly around the state, average deaths have dropped off

California's daily average death count has dropped to its lowest point in more than three months, signaling that the mid-summer's wave of infections is finally over — even as coronavirus infections spread unevenly yet again across the state.
As of Friday, California's seven-day daily death average hit 61, putting the state back on par with trends it experienced throughout the spring and marking the fewest deaths since July 5. Deaths hit an all-time high a month later on Aug. 6, with a weekly average of 145, and have steadily decreased since then.

Within that overall decline, average deaths have dropped off particularly steeply since the start of the month, declining by about 20% since this time last week and about 28% since two weeks ago. Part of that is thanks to progress in Southern California, particularly Los Angeles, which alone accounts for about 40% of the state's 16,504 total deaths. The county's average deaths have petered out throughout early October, reporting one-third fewer average daily deaths as of Saturday than two weeks ago.

In the Bay Area, meanwhile, deaths have increased recently, hitting a seven-day daily death average of 14 this week — just trailing Los Angeles. However, some of that increase could be due to lags in reporting. On Friday, the region's health officials reported 12 new deaths, including six in San Francisco County and three in Santa Clara County; no other county reported more than one death. The region accounted for about 15% of the state's 77 total reported deaths Friday.

2) California's COVID-19 rates plateauing, but a few counties regress
Data continue to reflect positive progress in California's fight to limit spread of the coronavirus, but as some parts of the state fare better than others, health officials continue to warn people not to let their guard down.

California's hospitalization figures remain in relatively good shape, with the state health department as of Thursday reporting a little over 2,300 lab-confirmed COVID-19 cases in hospital beds and about 650 in the ICU. Each are less than a third of peak totals recorded over the summer. After almost two months of consistent and steady decline starting in late July, though, both hospitalization figures have been trending for about the past two weeks on more of a "plateau," as Gov. Gavin Newsom phrased it Monday in a news briefing.

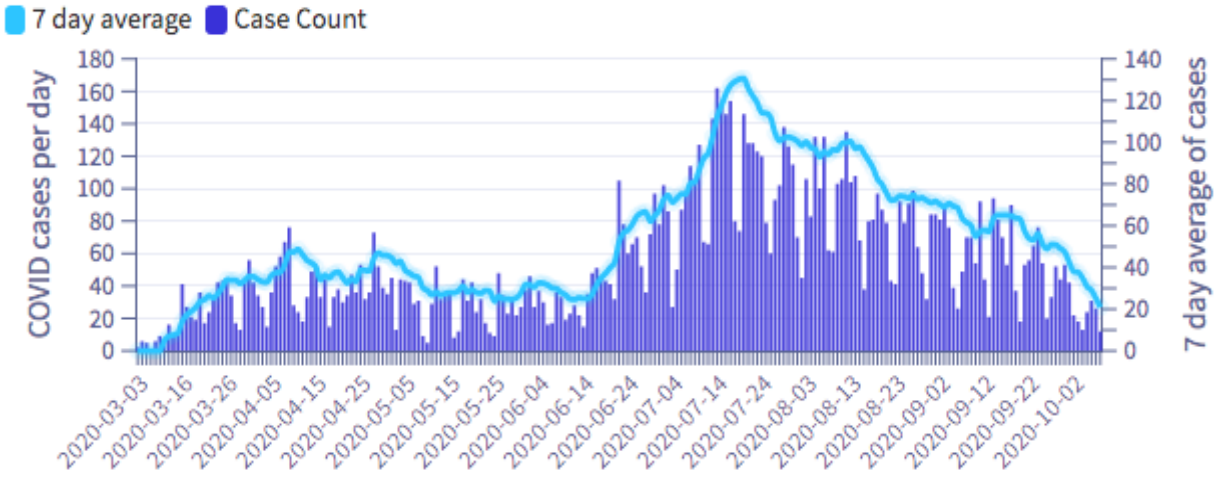
Another key metric, test positivity rate, also appears to be plateauing, but it's doing so at the lowest rate recorded since state health officials began keeping track. The California Department of Public Health said Thursday that only 2.6% of diagnostic COVID-19 tests performed in the last two weeks have returned positive. When that metric drops, it suggests true spread of the virus may be decreasing significantly.

The World Health Organization recommends a positivity rate below 5% before reopening. California uses 8% positivity as one of its thresholds for counties to improve from its most restrictive purple tier into the red tier within its current reopening framework. A rate below 5% is a requirement for the orange tier, and the least restrictive yellow tier is only available for counties with fewer than 2% of tests coming back positive. Eight counties were allowed to loosen business and indoor activity restrictions this week. Health officials continue to emphasize remaining diligent and continuing to avoid social gatherings — which they've blamed as a key factor in the summer surge in infections, spreading the highly infectious respiratory disease between friends and loved ones — as the state's progress will be tested by gradual economic reopening, the continuing academic year, flu season and colder weather that'll keep people indoors for longer time periods.

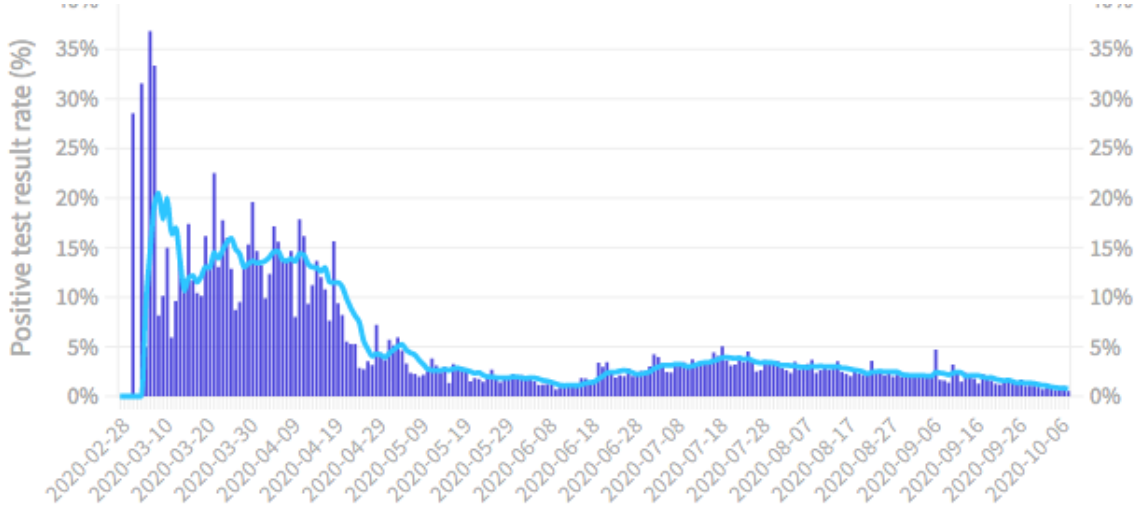
SAN FRANCISCO

Confirmed cases: 11,637 — up by 28 (0.2%) since Saturday
Hospitalized: 38 — down by 3 as of 10/9, with 13 in ICU beds
Deaths: 123 — up by 0 since Saturday

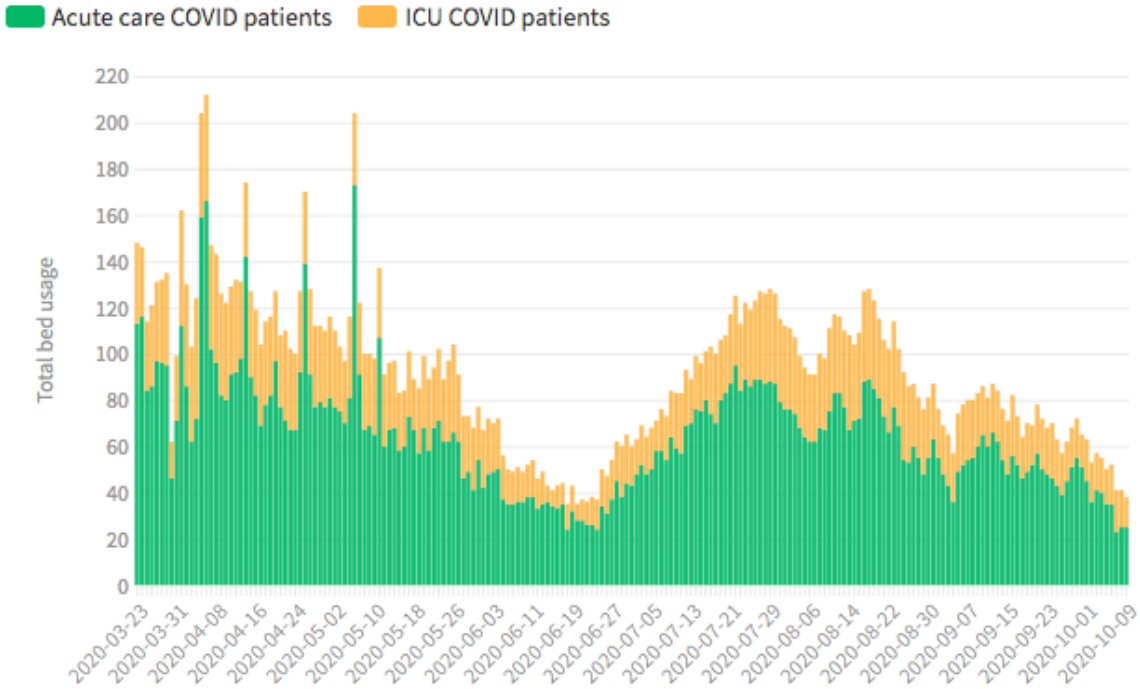
7-Day Average



Positive Tests



SF Hospitalizations



1) San Francisco rates improving

San Francisco added just 27 new cases on Friday and 16 the day before — two of the lowest one-day totals since the early days of the pandemic. San Francisco's R-0 or R-effective (R-e) rate has been steadily declining, and as of Friday it had hit 0.77 — this means that for every positive case in the city, only 0.77 new cases are spawned, creating an eventual decline to zero.

Hospitalizations have been steadily declining across the Bay Area, and San Francisco's COVID patient count (both confirmed and suspected cases) dropped to 41 on Wednesday, its lowest level since June 26.

Across the country, R-e rates are rising, with only 13 states (including California) now holding a rate below 1.0, and most of those closer to 0.99 — California's is now the third best in the nation at 0.89.

RECOMMENDATIONS

1) Given the complexity, confusion, and politicization around treatments, vaccines, vaccine efficacy and safety, vaccine trials, vaccine authorization, production, and distribution, and more – SFV might want to consider inviting an expert to offer a program and discussion for members.

NOTE: Barbara arranged for expert researchers (who were recruiting older adults who live in Berkeley/Oakland) to offer such a talk for Ashby Village. Barbara is in touch with experts in SF who may be available to offer a talk for SFV members.