# UNIVERSITY OF CALIFORNIA HEALTH

December 4, 2020 Update
COVID-19 AND 'CORONAVIRUS' UPDATES

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#### THE IMPACT ON OUR HEALTH SYSTEM

This is the 26th update for Regents regarding the SARS-CoV-2 virus pandemic and its impact on the University's health and academic enterprise. The past month has included both bad news and hope. The trends in COVID-19 cases and hospitalizations across the nation and in California are extremely concerning and will challenge health system capacity in many states. At the same time, we see great scientific achievement with very encouraging findings reported from several COVID-19 vaccine clinical trials. We expect the first COVID-19

vaccinations to be delivered to health care workers this month.

#### **COVID-19 BY THE NUMBERS**

The United States is averaging more than 200,000 new cases a day, now totaling more than 14 million, with a cumulative death toll of 275,386 people as of December 3, according to data from the Centers for Disease Control and Prevention (**CDC**). Although California is better off than many parts of the country, there are more than 1.29 million cases in the state, with 19,437 deaths, and a 14-day average <u>positivity rate</u> that has risen to 6.9%, according to the California Department of Public Health (**CDPH**).



Virtually all counties are now in the state's 'widespread' or purple tier, resulting in capacity reductions or closures for indoor - and some outdoor - activities. Details by <u>county</u> can be seen here. State government has moved rapidly.

On November 21, Governor Newsom implemented <u>limited stay-at-home requirements</u> that all non-essential work and activities stop between 10PM and 5AM in counties in the purple tier. On November 30, the Governor warned that if behaviors do not change, some ICUs will be at or above capacity by mid-month. On December 3rd, he announced plans to implement a <u>Regional Stay Home Order</u> when a region's available ICU capacity drops to less than 15%. When triggered, the Order will prohibit private gatherings of any size, close sector operations except for critical infrastructure and retail, and require 100% masking and physical distancing in all others.

The <u>five geographic regions</u> are Northern California, Bay Area, Greater Sacramento, San Joaquin Valley and Southern California. Orders will remain in effect for an initial three-week period followed by weekly assessments about the need to extend.

#### TWO VACCINES NEAR APPROVAL - UCH IS READY

A COVID-19 vaccine candidate, BNT162b2, created by Pfizer and BioNTech is 95% effective according to preliminary data, and the companies applied for an Emergency Use Authorization (**EUA**) from the Food and Drug Administration (**FDA**) on November 20.

Ten days later, on November 30, Moderna applied for EUA clearance for its vaccine candidate, mRNA-1273, after clinical trials demonstrated it to be 94% percent effective.

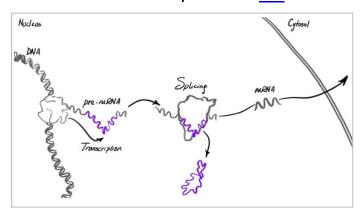


Both vaccines create resistance to the virus through the novel use of messenger RNA (**mRNA**). The mRNA platform is new and these are the first vaccines ever developed using this technology.

Most vaccines contain a weakened version of a virus or its signature proteins to teach the body's immune system to recognize and fight the virus when the body is exposed to it in real life. By contrast, the mRNA technique provides genetic instructions to cells, causing them to produce viral proteins that mimic the spike from SARS-CoV-2. This, in turn, teaches the immune system to recognize the virus and be prepared to fight it. Both the Pfizer and Moderna vaccines require two doses.



Source: Pfizer. Watch the explainer video here.



Source: Moderna. Explaining the use of mRNA video.

All vaccines go through a rigorous scientific review process before they can be deployed.

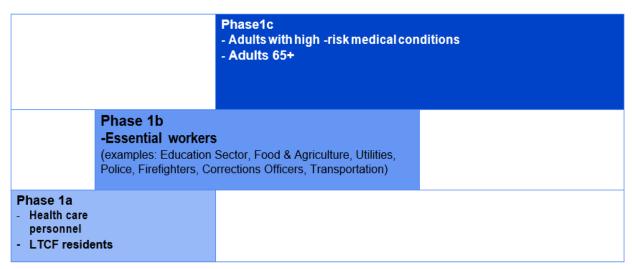
Dr. Stephen Hahn, the Commissioner of the FDA, has assured the public and scientists that this will also be true for the COVID vaccines. When the FDA issues an EUA for one or more of the vaccines, it will be only after extensive vetting of data has been completed. In general, the expectation for all COVID vaccines is that clinical trials must demonstrate vaccine safety, achieve efficacy of more than 50%, and the manufacturer must show that it can be produced reliably. An EUA would allow the vaccines to be used while awaiting more data about the length of time each vaccine provides protection.

A <u>public meeting of the FDA</u> to discuss the Pfizer vaccine safety and efficacy is planned for December 10. A second meeting is planned for December 17 to discuss the Moderna vaccine.

In addition, <u>California's COVID-19 Scientific Safety Review Workgroup</u>, which includes four UC faculty members, will independently assess data from the trials and make a determination about whether to proceed with vaccinations.

Anticipating the likelihood of FDA approval, the CDC's Advisory Committee on Immunization Practices (**ACIP**) voted on December 1 to prioritize health care workers (**HCWs**) and residents of long-term facilities as the highest initial priority, **1a**, while supplies are limited. This framework can be customized by state public health officials. On December 3, Govenor Newsom indicated the state's 1a prioritization would include acute care, psychiatric and correctional facility hospitals, skilled nursing and assisted living facilities, paramedics and EMTs, and dialysis centers.

## **Work Group Proposed Interim Phase 1 Sequence**



Source: ACIP Phase I priority sequence. ACIP Meeting Slides from 12/1

As of this writing, we do not know the precise number of doses UC facilities will receive to administer to its HCWs. California expects 327,000 doses of the Pfizer vaccine to be in-state by mid-December. The state is allocating the early shipment supply on a regional basis. The initial supply will be pre-positioned, potentially even ahead of the FDA approval of the vaccine, in 34 hospitals and public health departments capable of providing the -94°Fahrenheit storage facilities required for Pfizer's vaccine. Four UC health centers are among the pre-positioning sites. Once federal and state approval is given, further distribution and vaccinations begin.

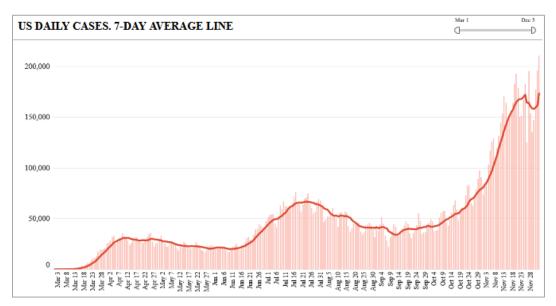
While complex, this multi-step approval and distribution process will unfold very quickly in December. If the Moderna vaccine is also approved, CDPH expects that two million vaccine doses from Pfizer and Moderna will arrive in the state within a matter of weeks.

Although the details of subsequent prioritizations have not been finalized by federal and state entities, **Phase 1b** priorities are likely to include essential workers such as educators, food and agricultural workers, utilities, police, firefighters and transportation workers. The **Phase 1c** priority group is expected to focus on adults with high-risk medical conditions and all adults 65 years of age or older.

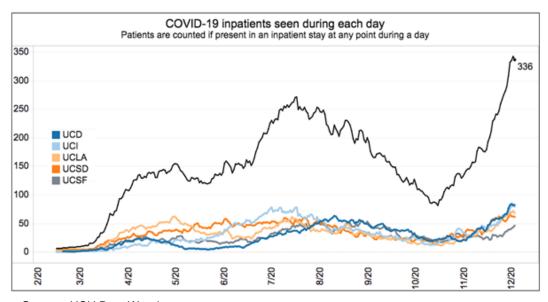
Distribution to people outside of these groups will occur later, possibly beginning in late spring or summer of 2021 depending on availability. This is a herculean task with an estimated 144 million individuals in category 1a, 1b, or 1c for vaccination. Following the immunization of these priority populations, the United States will work to immunize the general population in an effort to achieve at least 70% immunity. At least 230 million people (630K per day) will need to be immunized in 2021 to meet this goal. This means that non-pharmaceutical interventions will remain our best defense for several months to come.

#### COVID-19 CASES SURGING ACROSS THE COUNTRY

The nationwide surge in newly diagnosed cases is expected to lead to a significant increase in COVID-19 inpatient admissions, which have already reached an all-time high at UC academic health centers: **336.** 



Source: The COVID Tracking Project, US Daily Cases, 7-day average line



Source: UCH Data Warehouse

#### UCH JOINS OTHER HEALTH SYSTEMS TO DELIVER A MESSAGE - MASKUP!



The surge in cases and hospitalizations is undeniable.

Unfortunately, the politicization of public health measures has undermined a cohesive response.

University of
California Health and
its medical centers
joined a nationwide
network of health
care organizations to
speak with one voice
- MASKUP!

Masks and physical distancing are the most effective way to reduce the spread of the virus.

The campaign includes print ads in The New York Times and Washington Post, social media through TikTok and YouTube, and TV outreach.

# CLINICAL TRIALS CONTINUE TO ASSESS NEW THERAPEUTICS

UCH is participating in clinical trials for four COVID-19 vaccine candidates: Pfizer, Moderna, AstraZeneca and Janssen. Other trials may be added in the future as more

companies make progress. Simultaneously, we continue to assess existing and new therapies to reduce the severity of illness and length of stay.

Clinical Trials at All Five Medical Centers	Pending, Active, and Closed Clinical Trials at One or More Medical Centers Treating COVID-19
ACTT-1 – Remdesivir (NCT04280705)  ACTT-2 – Remdesivir & Baricitinib (NCT04401579)	Sarilumab – Davis and UCLA (NCT04315298)  DAS181– UCLA and UCSD (NCT03808922)  Tocilizumab – UCLA and UCSD (NCT04320615)  Azythromycin – UCSF (NCT04332107)  Mesenchymal stem cells – UCSF (NCT03818854)  HCQ (prevention) – Davis, UCLA, and UCSF (NCT04332991)  HCQ (treatment) – UCLA (NCT04328961)
Vaccine Trials  Janssen – UCSF (VA) and UCSD:  NCT04505722	Colchicine – UCSF (NCT04322682) Colchicine – UCLA (NCT04355143) Aviptadil – Irvine (NCT0431697) PUL-042 – Irvine (NCT04313023) PUL-042 – Irvine (NCT04312997) Azithromycin/HCQ- UCSF (NCT04358081)
Moderna – UCLA and UCSD: NCT04470427	Leronlimab – UCLA (NCT04347239) Leronlimab – UCLA (NCT04343651) Canakinumab – UCSF (NCT04362813)
AstraZeneca – UCLA, UCSD, UCSF: NCT04516746	Selinexor – Davis and UCLA ( <u>NCT04349098</u> ) Gimsilumab – UCLA ( <u>NCT04351243</u> ) Mavrilimumab – UCLA ( <u>NCT04399980</u> )
BioNTech/ Pfizer – Davis: NCT04368728	Hyperbaric Oxygen – UCSD (NCT04327505)  Oral Vaccine - UCSD (NCT04334980)  Ramipril – UCSD (NCT04366050)  TAK-981– UCSD (NCT03648372)  Convalescent Plasma - UCSF (NCT04421404) and (NCT04355767)  Convalescent Plasma - UCSD, UCLA, Irvine (NCT04323800)  Convalescent Plasma - UCLA, Irvine (NCT04373460)  EA Convalescent Plasma – UCLA, UCSF, Davis, Irvine (NCT04338360)
Some recently launched trials are not yet listed on ClinicalTrials.gov at the time of this publication.	Antiseptic Mouthwash – UCSF (NCT04409873) S1P Agonist Siponimod – UCLA (NCT# Pending) LY3819253 – UCSD (NCT04411628) LY3819253 and LY3832479 – Irvine (NCT04427501) ACTT-3: Interferon Beta-1A & Remdesivir – UCSD, UCLA, Irvine, UCSF (NCT04492475) I-SPY: Remdesivir plus standard of care – UCSF, UCSD (NCT04488081) DISulfiram – UCSF (NCT04485130) Theraputic and Prophylactic Heparin – UCSF (NCT04505774) Zanubrutinib – UCLA (NCT04382586) Intramuscular Injections of PLX-PAD – Davis and Irvine (NCT04389450) Cell therapy to Treat Patients with COVID-19 – Davis and Irvine (NCT04365101)

Allogeneic Adipose Stem Cells – UCSF (NCT04486001)
Outpatient Remdesivir – UCSF (NCT04501952)
Molnupiravir (EIDD-2801) – UCLA (NCT04405739)
Cap-1002 – Davis (NCT04623671)

Anti-coagulation with Anti-platelet Agents – UCSF (NCT04498273)
PET/CT Imaging: 18F-αγβ6 Binding Peptide – Davis (NCT04376593)

REGN-COV2 Monoclonal Atb (ambulatory patients)- Davis (NCT04425629)

REGN-COV2 Monoclonal Atb (inpatients)- Davis (NCT04426695)
REGN-COV2 Monoclonal Atb (asymptomatic)-UCLA, Davis

(NCT04452318)

#### INCREASING TESTING CAPACITY FOR CAMPUSES REMAINS A PRIORITY

Although vaccines may be imminent for priority populations, vaccination of healthy, college-age students remains a number of months away. Thus, we must continue to focus on non-pharmaceutical means of reducing viral spread and increasing testing capacity if we hope to incrementally increase campus density or expand in-person instruction opportunities in the Spring Quarter (March 2021).

A system-wide Testing Capacity Task Force was established within the UCH Coordinating Committee to deliver recommendations in the following key areas:

- Near-term paths by which students, staff, and faculty can safely and reliably return to campus, leveraging the testing modalities available to the UC system
- Determine ideal test quality value(s) and ensure all UC testing sites are meeting threshold(s)
- Leverage existing capacity of UCs, as is practical
- When external vendor(s) must be used, ensure costs are as low as possible

The strategies to cover these costs are being addressed in campus financial plans along with focused advocacy for state, federal and philanthropic support. Campuses with in-house testing programs are projecting lower costs as testing platforms stabilize and volumes increase. Importantly, campuses with excess testing capacity are coordinating with campuses that need capacity, enabling us to expand testing at lower costs than third-party providers.

More information about the expansion of testing capacity for campuses will be shared in a future update.

#### **UC CONTINUES TO DRIVE TESTING IN HARD-HIT COMMUNITIES**



UCSF and Latino Task Force launched pop-up testing sites in four SF neighborhoods in a three-day push that aims to test 6,000 people. The selected San Francisco neighborhoods are the Mission District at the 24th Street BART station, the Excelsior and Bayview neighborhoods, and the Tenderloin. This drive, similar to earlier ones throughout San Francisco County, the East Bay and Marin strives to bring testing to hard-hit communities and connect people

who test positive with resources to recover.

### SOME OF THE HEROES OF THE PANDEMIC

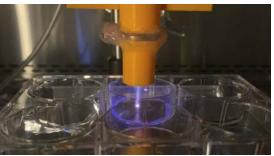






















#### Captions for previous page:

**Top L:** Dr. José Mayorga of UCI's Family Health Center notes that his clinics have seen large increases in positivity rates, especially among Latinx and low-income communities. PODCAST

**Top R:** UCSF physicians <u>Robert Rodriquez, Eric Goosby and David Kessler</u> will help guide President-elect Joe Biden's pandemic strategy as members of his newly-announced Transition COVID-19 Advisory Board.

**2<sup>nd</sup> Row:** The Fresno <u>COVID-19 Equity Project</u> (CEP), with UCSF Fresno's support, was created to stop the spread of COVID-19 among underserved and Limited English communities.

**3rd Row L:** We salute the <u>Executive Committee of the Latino Task Force</u>, which has worked very closely with UCSF to test, study and track the virus in the Latinx community.

**3rd Row R:** UCLA Researchers have found that <u>cold plasma</u> can effectively and quickly disinfect surfaces contaminated with the SARS-CoV-2 virus and can be used on a variety of surfaces including porous ones that cannot be treated with chemicals and UV light.

**4<sup>th</sup> Row L:** Mahmoud Malas, MD, division chief, Vascular and Endovascular Surgery at UC San Diego Health led a meta-analysis study of 8,000 patients to note how COVID-19 produces blood clots that increase mortality.

**4<sup>th</sup> Row R:** UCSF HEAL Initiative co-founder Sriram Shamasunder talks in-depth about the experience of helping the Navajo Nation and supporting community-driven care amid a pandemic.

**5**<sup>th</sup> **Row L and M:** Throughout the pandemic, volunteers like the <u>Youth Ambassadors</u> at UCLA Mattel Children's Hospital continue to give of themselves to make our little patients feel at-ease.

5<sup>th</sup> Row R: Lunch is always appreciated. Thank you <u>Blue Shield</u> for bringing meals and goody bags to UCSF Benioff Children's Hospital Oakland.

#### **IN CLOSING**

We are standing between the darkness of the pandemic and the coming light of new vaccines.

This is a vulnerable time. Knowing that vaccines are nearing approval may cause some to let down their guard prematurely as we approach the highest patient surge thus far. Masks and other public health measures remain our best resource for avoiding the tragedy of overwhelming our health care systems with preventable infections when the potential for community immunity is only a few months away.



**CDPH Thank You video** 

I remain grateful for the unending work of our front-line clinicians, our researchers who are supporting clinical trials and exploring new therapeutics, and to everyone – **despite pandemic fatigue** – who continues to deliver the essential work of UCH. I encourage everyone to honor them and to recognize their sacrifice by wearing a face covering, practicing physical distancing and modeling behavior that encourages others to do the same.

As we enter the winter holiday season, I wish all of you good health and time to rest, relax, and reflect on the many lessons of 2020. I look forward to a brighter 2021.

With hope, Carrie L. Byington, MD Executive Vice President University of California Health