



California Department of Public Health

Weekly Facility COVID-19 Update Call

December 29, 2020

8:00 am – 9:00 am

AT&T Meeting Recording: 1 (866) 207-1041

Access Code: 9457770

Available after 5pm 12/29/2020

I. **Welcome / Introduction** Heidi Steinecker

II. **Overview** Dr. Kathleen Jacobson

- None Provided

III. **Laboratory Update** Dr. Jill Hacker

Brief update on UK SARS-CoV-2 variant virus

Recently a rapidly spreading SARS-CoV-2 variant virus (called lineage B.1.1.7) was detected in the UK, as early as September 2020. This (B.1.1.7) lineage accounts for an increasing proportion of cases in parts of England, and it seems to be out-competing other variants in the UK. Over the past week, additional countries have reported detecting this variant, including countries in Western Europe, Israel, Hong Kong, Singapore, Japan, Australia, and Canada.

Several aspects of this variant are noteworthy. With 17 mutations, this B.1.1.7 has an unusually large number of genetic changes, 8 of which are located in the spike (S) protein. Three of these S gene mutations have potential biological effects:

1. Mutation N501Y is within the receptor-binding domain (RBD) of the viral Spike protein and has been identified as increasing binding affinity to human cell receptor, ACE2. In a mouse model, N501Y has been associated with increased infectivity and virulence (Gu et al. 2020), but the impact on human disease remains to be elucidated.
 - This same N501Y mutation is seen in a different lineage (B.1.351) in South Africa and is postulated to be associated with rapid spread in that country (anecdotal).
2. A deletion of 2 amino acids (69/70 deletion) has been associated with diagnostic failure in some assays that target the S gene, including the three-target TaqPath Combo assay and the two-target BioFire assay. This double deletion has occurred spontaneously many times and likely affects the shape of the spike protein. There may be other FDA-approved assays that target the S gene that also are affected.
3. Mutation P681H occurs at the furin cleavage site, known for biological significance in membrane fusion promoting entry into respiratory epithelial cells and transmission in animal models (Hoffmann, Kleine-Weber, and Pöhlmann 2020; Peacock et al. 2020; Zhu et al. 2020).

Both N501Y and P681H have been observed independently but not in combination before now.

To put things in context, mutations in the spike protein are not anomalous or new. The spike (S) protein is a heavily glycosylated trimeric protein that mediates entry into host cells via fusion with ACE2. Since the spike protein projects from the surface of the mature virion, it is subjected to immune response pressures from the host, and therefore some degree of mutation is expected. Also, when mutations result in a conformational change to a structural protein, there can be additional mutations elsewhere in the genome to ensure that structural stability is maintained. This was demonstrated early in the pandemic when the D614 G mutation was in the news: One study identified 9 missense mutations (including D614G) in the spike protein that were thought to be relatively conservative and thus unlikely to affect protein function. Another study of 68 whole genome sequences identified 42 missense mutations, 8 of which occurred in the S gene. However, some scientists are concerned that variant B.1.1.7 has accumulated its 17 mutations at a rate much higher than the typical 1-2 changes per month.

From ECDC Threat Assessment

(<https://www.ecdc.europa.eu/en/publications-data/threat-assessment-brief-rapid-increase-sars-cov-2-variant-united-kingdom>):

ECDC reports that a preliminary analysis suggests that this variant is significantly more transmissible than previously recognized circulating variants, with an estimated potential to increase the reproductive number (R) by 0.4 or greater with an estimated increased transmissibility of up to 70%. There is no indication at this point of increased infection severity associated with the new variant.

From the CDC: Persons infected with this strain have a 3-4 times greater viral load, even though they don't appear to have more severe illness.

US/California and the UK Strain?

Currently, this variant virus has not been identified in California or elsewhere in the US. However, monitoring the genomic makeup of the virus is essential for tracking this disease and ensuring compatibility of available diagnostic tests and vaccines. CDPH requests that health care providers help monitor for this and other variant viruses.

If you see a patient in whom there is a suspicion of the UK variant, a SARS-CoV-2 respiratory specimen (nasopharyngeal swab, nasal swab, etc., in viral or molecular transport medium) should be sent to your usual diagnostic testing laboratory to determine if the person is positive for SARS-CoV-2. If positive, that specimen should be sent to a laboratory that performs whole genome sequencing. If you performed an antigen test, you will need to submit a new sample to a sequencing laboratory. Please collect and submit specimens for sequencing from individuals with COVID-19 with the following characteristics:

- Recent travel to the areas with known cases of lineage B.1.1.7
- Exposure to persons with recent travel to the United Kingdom or Europe
- Marked differences in real-time RT-PCR viral target(s) Ct values (e.g., ORF1ab target Ct=27, N target Ct=26, and S target **Not Detected**)

Please work with your local public health jurisdiction to determine where to send your positive samples for SARS-CoV-2 whole genome sequencing. The CDPH/VRDL is accepting suspect UK variant specimens for WGS, and through COVIDNet we and other public health labs in CA have partnered with

UCSF, the CZ Biohub, and Invitae to do high volume WGS of suspect cases. To better understand the new variant, indicate vaccination history, real-time RT-PCR viral target(s) Ct values if available, and travel and exposure information.

See also:

<https://virological.org/t/preliminary-genomic-characterisation-of-an-emergent-sars-cov-2-lineage-in-the-uk-defined-by-a-novel-set-of-spoke-mutations/563>

<https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-emerging-variant.html>

<https://www.biorxiv.org/content/10.1101/2020.12.14.422555v2.full.pdf>

<https://khub.net/documents/135939561/338928724/SARS-CoV-2+variant+under+investigation%2C+meeting+minutes.pdf/962e866b-161f-2fd5-1030-32b6ab467896?t=1608470511452>

<https://pubmed.ncbi.nlm.nih.gov/32075877/>

<https://pubmed.ncbi.nlm.nih.gov/32092483/>

IV. Healthcare-Associated Infections

Dr. Erin Epson

1. CDC's guidance on vaccinating people who have been exposed

(<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>)

“For persons residing in congregate healthcare settings (e.g., long-term care facilities) where exposure and transmission of SARS-CoV-2 can occur repeatedly for long periods of time, residents with a known COVID-19 exposure may be vaccinated. In these settings, healthcare personnel are already in close contact with residents (e.g., entering patient rooms for evaluation and treatment) and should employ appropriate infection prevention and control procedures, so administering COVID-19 vaccine should not result in additional exposures. ... However, where feasible, precautions should be taken to limit mixing exposed individuals with other residents or staff (except those essential for the provision of vaccination services, who should employ appropriate infection and control procedures). Persons residing in congregate settings (healthcare and non-healthcare) with an exposure who are awaiting results of SARS-CoV-2 testing may be vaccinated if COVID-19 is not strongly suspected. For example, when facility-wide testing is conducted because exposures have occurred in the facility, and this testing coincides with a period when a vaccination event is planned, those persons in whom COVID-19 is not strongly suspected may be vaccinated.”

CDC's guidance on vaccinating in the setting of COVID-19:

“Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation. This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose. While there is otherwise no recommended minimum interval between infection and vaccination, current evidence suggests that reinfection is uncommon in

the 90 days after initial infection. Thus, persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired.”

2. Upcoming webinar sponsored by CDPH on Thursday, January 7th from 1:00-2:00pm Pacific Daylight Time: “Respiratory Protection Programs for Long-Term Care Facilities During the COVID-19 Pandemic”. During this webinar, participants will become familiar with the required elements of a respiratory protection program. They will also be provided with resources to assist them in implementing a respiratory protection program in their long-term care facility. An emphasis will be put on fit testing, which is essential to ensure that all staff are being effectively protected by their respirators. The webinar will include a question and answer period with representatives from CDPH and Cal/OSHA.

Event address for attendees: <https://cdph-conf.webex.com/cdph-conf/onstage/g.php?MTID=e487d85bdbf5d402f545d3328651823bc>

V. **Monoclonal Antibody Updates**

Dr. Sohrab Sidhu

To summarize, two investigational monoclonal antibody products have received an emergency use authorization (EUA) for the treatment of mild-to-moderate COVID-19 in non-hospitalized adult and pediatric patients. Bamlanivimab received an EUA on November 9th and is a single monoclonal antibody. Casirivimab/imdevimab received an EUA on November 21st and is a cocktail of two monoclonal antibodies. Clinical trial data in outpatients have shown that both bamlanivimab and casirivimab/imdevimab may reduce COVID-19-related hospitalization or emergency room visits in patients who are treated early and who are at high risk for severe disease. Clinical trial data in hospitalized patients, however, have not shown a benefit with either bamlanivimab or casirivimab/imdevimab use in hospitalized patients and as such the EUAs for both therapies is only to treat symptomatic outpatients. Given the limitations to using existing acute care hospital infrastructure during the ongoing surge, CDPH is allocating and encourages the distribution of both products to non-hospital outpatient settings.

General updates

The Health and Human Services Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR) have changed the frequency of the federal allocation of the monoclonal products to the states from weekly to once every two weeks. Thus, allocations of the monoclonal products from CDPH will occur every two weeks moving forward. The next allocation from CDPH will be occur the week of January 6th.

HHS/ASPR is also strongly encouraging states/territories to use the monoclonal products and to not stockpile or hesitate to use based upon perceived scarcity. Currently California has a sufficient supply of monoclonal antibodies for all providers who request them.

Should any facilities in California need more monoclonal product, they should contact as soon as possible their county's Medical and Health Operational Area Coordinators (MHOACs) according to local policies and procedures. If the MHOAC programs do not have any product, the MHOACs should make a request at the regional level, to the Regional Disaster Medical Health Coordinators (RDMHS). The RDMHS can check with other MHOAC programs and if the RDMHS is unable to obtain the necessary quantities, the resource request will move to the state. If the state has product in stock, the state will fill the request.

Previously, CDPH allocated product directly to Skilled Nursing Facilities (SNFs) prior to allocating to the counties. Starting in week 7, in addition to SNFs and because there is currently a sufficient supply of

monoclonal antibodies for all providers who request them, CDPH began allocating directly to state prisons prior to allocating to counties. Like SNFs, state prisons have been identified as ideal non-hospital settings for treatment with these products; they serve a population with a high prevalence of high-risk medical conditions; testing occurs frequently resulting in early diagnoses; and they can infuse these products onsite or have locations near their facilities that are able to do so.

California Department of Public Health (CDPH) will continue to monitor demand for these products from all sites and counties and adjust the allocation scheme accordingly so that the process remains data-driven, equity-informed and transparent.

Bamlanivimab updates

For weeks 7-8, California received an allocation of 14,020 doses.

Specialty pharmacies serving SNFs did not request additional product from the state this past week though some counties did allocate to a few pharmacies directly. Medical directors or other authorized prescribers at SNFs and PACE programs who contract with these pharmacies can order bamlanivimab if they have a patient that qualifies for treatment. The pharmacy would prepare the product for infusion and send to the SNF or PACE program for infusion. The 10 pharmacies that have received at least one weekly allocation of bamlanivimab since week 1 are Pacific West Pharmacy, Skilled Nursing Pharmacy, Consonus Pharmacy Services, AlixaRx, Pharmerica, Citrus Pharmacy, Ron's Pharmacy, OmniCare, AmeriPharm and Owens Pharmacy.

4,000 doses of bamlanivimab were proportionately allocated directly to 22 state prisons based on their 7-day new COVID-19 diagnoses.

The remaining 10,020 doses of bamlanivimab were proportionally allocated to the counties' MHOACs based on their 7-day average of new COVID-19 hospitalization and 7-day average of overall new COVID-19 diagnoses.

Of the product that was declined by various counties, much was re-allocated to other counties and 1,242 vials were sent to the CDPH warehouse.

This information is updated weekly and posted publicly in greater detail [here](#) (under the "Other" section and titled "California Monoclonal Antibody Allocation").

CDPH continues to encourage counties to consider allocating bamlanivimab to more outpatient settings including federally qualified health centers (FQHCs), state hospitals, jails, and other congregate setting that may have clinical capacity to use.

(Please note the [EUA fact sheet](#) has been officially updated to reflect the elimination of the step to first withdraw 70 mL from the saline bag, thus simplifying the preparation of the drug. Please refer to the EUA fact sheet included in the resources list for more information.)

Eli Lilly also recently released a short video detailing the preparation and administration of bamlanivimab. Link to the video can be found in the meeting notes.

Casirivimab / imdevimab updates

In weeks 7-8, California received an allocation of 4,080 doses of casirivimab / imdevimab this week.

Specialty pharmacies and state prisons did not request any casirivimab/imdevimab this week.

The entire 4,080 doses were therefore proportionately allocated to the counties' MHOACs using the same allocation formula as is used for the bamlanivimab product. The MHOACs then allocate casirivimab / imdevimab within their county.

Of the product that was declined by various counties, much was re-allocated to other counties while 636 treatment courses of casirivimab/imdevimab were sent to the CDPH warehouse.

While casirivimab/imdevimab was previously only allocated to acute care hospitals and their affiliated settings, the federal government recently expanded the eligible locations casirivimab/imdevimab can be distributed to. Now, CDPH is encouraging the allocation of casirivimab/imdevimab to appropriate non-hospital outpatient settings just like bamlanivimab.

Finally, casirivimab / imdevimab continues to only be shipped in increments of 6, per the distributor Amerisource Bergen. Counties will need to consider these new shipping rules and alter their distribution plan accordingly for this week and all future weeks.

Additional Resources

Bamlanivimab links for further information:

<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Bamlanivimab-Fact-Sheet.aspx>

Fact sheet for healthcare providers:

<https://www.fda.gov/media/143603/download>

(NEW) Eli Lilly video for bamlanivimab preparation/administration:

https://www.kaltura.com/index.php/extwidget/preview/partner_id/1759891/uiconf_id/30232671/entry_id/1_i3nkvs7k/embed/dynamic?

- Complete video transcript and more info:

<https://www.covid19.lilly.com/bamlanivimab/hcp/dosing-administration#dosing-and-administration>

Casirivimab / Imdevimab links to the EUA including information for healthcare providers and patients is included in the meeting notes.

FAQ: <https://www.fda.gov/media/143894/download>

Fact sheet for health care providers: <https://www.fda.gov/media/143892/download>

Fact sheet for patients, parents, and caregivers: <https://www.fda.gov/media/143893/download>

NIH COVID-19 Treatment Guidelines:

<https://www.covid19treatmentguidelines.nih.gov/whats-new/>

IDSA COVID-19 Treatment Guidelines:

<https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/#toc-10>

VI. Vaccine Update

- Enrollment:

- General questions about Provider Enrollment into COVIDReadi can be directed to our COVID Call center at 833-502-1245 or COVIDCallCenter@CDPH.ca.gov

Dr.Caterina Lui

- Doses/allocation
 - As of 12/28/20, 766,350 doses of Pfizer vaccine and 904,900 doses of Moderna vaccine have been allocated to CA and 269,183 doses have already been administered. The allocation numbers granted to California today, 12/29, will also include CA's first deliveries of second doses. Second dose allotments are mimicking first dose allotments. Counties will receive information later on today about their latest Pfizer and Moderna allocations as well as their second dose allocations. Orders placed by COB on Thursday will arrive on Monday, January 4.
- Vaccination in long-term care facilities update
 - CDC Pharmacy Long-Term Care program update
 - The first skilled nursing facility clinics by CVS and Walgreens are starting this week (week of 12/28/20)
 - California has activated the CDC Pharmacy Long-Term Care partnership with CVS and Walgreens to provide COVID-19 vaccination for residents and staff of long-term care facilities: <https://www.ca.gov/2020/12/28/governor-newsom-announces-partnership-with-cvs-and-walgreens-to-provide-pfizer-vaccines-to-residents-and-staff-in-long-term-care-facilities/>
 - CDC [Long Term Care Facility \(LTCF\) Toolkit](#) is now live, and includes materials for staff and residents.
- Clinical considerations
 - The CDC website is updated with the most recent information about both the Pfizer and Modern vaccines.
 - Main landing page: <https://www.cdc.gov/vaccines/covid-19/hcp/index.html>
 - Clinical Considerations for Pfizer and Moderna vaccine:
<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>
- Prioritization
 - The ACIP's recommendations for prioritization of vaccine during phase 1b and 1c are now online:
https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm?s_cid=mm695152e2_w
- Additional resources:
 - Link to COVID vaccine resources: <https://eziz.org/covid/vaccine-administration/>
 - Tuesday, 12/29 Provider Office Hours from 9-10 am
 - Here is the link: <https://cdph-conf.webex.com/cdph-conf/onstage/g.php?MTID=e5afe8269a2ec10ce2e784bfd4a906474>
 - Guidance on incorporating additional inventory from the extra doses into CAIR:
<https://eziz.org/assets/docs/COVID19/2020Dec23AccountForAdditionalDosesCOVIDVaccine.pdf>
 - <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>
 - Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and [criteria](#) have been met for them to discontinue isolation. This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose. While there is otherwise no recommended

minimum interval between infection and vaccination, [current evidence](#) suggests that reinfection is uncommon in the 90 days after initial infection. Thus, persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired.

VII. Questions and Answers

Q: Our Skilled Nursing Center is being vaccinated this week but when can the rest of our Continuing Care Retirement Community (CCRC) be vaccinated.

A: Our current understanding is that the second part of the program has been activated but will not start until mid-January.

Q: Can you talk about showering residents in the yellow and red zone? I am finding conflicting information regarding efficacy and transmissibility.

A: About showering in common shower areas, we generally recommend that your red zone residents have their own shower area from those in the yellow or green. If that is not feasible, we recommend for those in the red zone to have bed baths. Any way that you're avoiding any mixing or exposure between residents in those status groups.

Q: Is there any extended use for N95s other than the same day?

A: Extended use refers to wearing the same respirator throughout the course of a given single shift. I think per Cal OSHA, that shift length can be up to 16 hours for a double shift. Their stipulation is that the respirator not be doffed and readonned more than 5 times over the course of that given shift. However, reuse, which would involve using that same respirator on a subsequent shift, is currently not permitted per Cal OSHA.

Q: You cannot bag them for 5 days and reuse them correct? There is no reuse after the single shift correct?

A: Current that Cal OSHA's requirement. You could, as a conservation strategy, save those respirators for disinfection and potential reuse at a later date. But as of right now, I am not aware of any updates to Cal OSHA's August guideline that did not permit reuse of respirators at this time.

Q: Regarding the what was released yesterday about travelers having to quarantine for 10 days after returning from LA County, does this apply to any and all healthcare workers?

A: I know from the state perspective, they were trying to have an exception for healthcare workers. I think the new travel guidance will be out soon and that will be addressed. You might want to check with LA to see if healthcare workers are exempt.

Q: If an employee is vaccinated and develops COVID illness before the second dose, do you finish the second dose once they have recovered or do you start over the two-dose series after they have recovered, greater than 90 days?

A: We would agree with your plan to wait the 90 days. There is no need to repeat the series. Even if some missed the second dose and a long period has passed, there is no recommendation to repeat the series.

Q: Regarding the previous question, I want to confirm that we will not complete the series and wait until the 90 days even if they are also asymptomatic correct?

A: That is my understanding. The CDC does not distinguish between symptomatic or asymptomatic infection in their recommendation for waiting for the discontinuation of isolation as the earliest timepoint.

Q: With anaphylaxis response to the first dose, we do not give the second dose correct?

A: That is the current CDC guidance. At this point the CDC does not have any guidance about alternative strategies in the setting in anaphylaxis.

Q: We are a stand along acute psychiatric facility and I was wondering if the state had a specific framework for how we can partner with an acute hospital nearby to immunize our employees? Are they able to redistribute a portion of their vaccine to us directly or are we able to provide some of our licensed staff to them for vaccination support?

A: I would have to get back to you on that. Do you have an email?

Q: At what point can we partner with a facility to get our staff vaccinated for our outpatient surgical facility? Our staff is wondering at what point are they going to get the vaccinated. Are we going to be sent vaccines to vaccinate our staff or do we have to partner with a local hospital or local clinical providers office that may be getting the vaccine?

A: In terms of prioritization guidance, outpatient providers are in tier two and as of right now, there has only been a limited number that have been invited to enroll in COVID Ready. One strategy is to reach out the local health department about your plans and concerns. In terms of specific partnerships with other clinics or hospitals, I will have to get back with everyone about our specific framework but our understanding is that most of those conversations are happening at the local level.

Q: We were invited to enroll in COVID Ready for our facility but my understanding is that if you were to enroll, you would have to be ready to accept a minimum of 1000 doses and also be willing to distribute it or vaccinate our patient population which we typically do not offer any vaccinations as an outpatient facility to any of our patients. That is why we were hesitant to enroll because I don't want to take away from somebody that will be able immunize many people while we were just looking to do it for our staff. Is there a different guidance for that?

A: My understanding is that was for the Pfizer vaccine. The Moderna vaccine can actually be received in smaller quantities. Let me get your email address and I will follow up with you.

**Wednesday 12/30 Webinar 3–4 pm & Thursday 12/31 SNF IP 12noon Call
are CANCELLED this week!!!**