

California Department of Public Health Weekly Facility COVID-19 Update Call January 05, 2021 8:00 am – 9:00 am

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

Access Code: 8999335

Available after 10am 01/05/2021

I. Welcome / Introduction

Heidi Steinecker

II. Overview Dr. Kathleen Jacobson

None Provided

III. Laboratory Update

Dr. Deb Wadford

Brief update on UK SARS-CoV-2 variant virus

The SARS-CoV-2 variant virus known as lineage B.1.1.7 (https://cov-

<u>lineages.org/global report B.1.1.7.html</u> first detected in the UK in September 2020 that has now become the predominant variant in the UK. This (B.1.1.7) lineage has now also been reported in 26 other countries, including 4 states in the US (CO, FL, NY and CA; CA has at least 30 cases, most reported from the San Diego area).

Two noteworthy mutations associated with the B.1.1.7 variant are located within the spike (S) protein and have potential biological effects:

- 1. <u>Mutation N501Y</u> is within the receptor-binding domain (RBD) of the Spike protein and has been identified as increasing binding affinity to human cell receptor, ACE2.
- This same N501Y mutation is seen in a different lineage B.1.351 (https://cov-lineages.org/global report B.1.351.html) that has emerged in South Africa.
- 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 ThermoFisher TaqPath Combo assay. This double deletion has occurred spontaneously and independently many times and may be involved with immune escape. Currently there is no evidence to suggest that the B117 variant has any impact on the severity of disease or vaccine efficacy.

Surveillance for Lineage B117 in California

If there is a suspicion of the B117 variant, please contact your local health jurisdiction or local public health laboratory to determine where to send the SARS-CoV-2 positive respiratory specimen for whole genome sequencing to rule-in/out the B117 variant. WGS is the only way, at this time, to confirm the B117 variant. Routine respiratory specimens are appropriate, such as a nasopharyngeal swab, nasal swab, etc., in viral or molecular transport medium.

Lineage B117 may be indicated by ThermoFisher Taqpath Combo RT-qPCR assay results that show an "S dropout" (e.g., ORF1ab target Ct=27, N target Ct=26, and S target Not Detected). Samples showing the S dropout should be referred for WGS, but these may be another variant and not necessarily B117.

Important to note that non-pharmaceutical interventions (NPI) should be maintained, especially with the current surge in cases, including staying home/away from crowds, masking, physical distancing, hand washing, and avoiding poorly ventilated spaces. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html

See also:

Brief article on the lineage B.1.1.7 variant:

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

CDC summary of SARS-CoV-2 variant viruses:

https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/scientific-brief-emerging-variants.html

Spike gene 69/70 deletion:

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

IV. Healthcare-Associated Infections

Dr. Erin Epson

- 1. CDC recently posted guidance on ventilation in buildings https://www.cdc.gov/coronavirus/2019-ncov/community/ventilation.html#Ventilation-FAQs, as part of a layered approach to reduce exposures to SARS-CoV-2, which also includes efforts to improve social distancing, wearing face masks, and hand hygiene. The ventilation guidance provides a range of ventilation interventions that can help reduce the concentration of SARS-CoV-2 virus particles in the air, ranging from simple no/low-cost interventions such as opening windows and opening outdoor air dampers to reduce HVAC air recirculation, to use of portable high-efficiency particulate air (HEPA) fan/filtration systems, and upper room ultraviolet germicidal irradiation (UVGI).
- 2. Reminder: Upcoming webinar "Respiratory Protection Programs for Long-Term Care Facilities During the COVID-19 Pandemic" sponsored by CDPH on Thursday, January 7th from 1:00-2:00pm Pacific Daylight Time. 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 – bamlanivimab and casirivimab/imdevimab – received an emergency use authorization (EUA) in November for the treatment of mild-to-moderate COVID-19 in non-hospitalized adult and pediatric patients. 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 are 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) are now allocating the monoclonal products to the states from once every two weeks. Thus, allocations of the monoclonal products from CDPH will occur every two weeks. Allocation determinations for Weeks 9-10 are currently underway.

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. Contact information for each MHOAC program can be found here. 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. During the last allocation, 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. This allocation stream will continue in Weeks 9-10. 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.

Since California is in the midst of receiving a new allocation from the federal government this week, there are no new allocation numbers to report. Last week's allocation numbers can be found in the meeting notes for this call. This information is also updated every other week and posted publicly in greater detail here (under the "Other" section and titled "California Monoclonal Antibody Allocation").

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 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.

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 <u>EUA fact sheet</u> for bamlanivimab 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 bamlanivimiab. 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 casirivimib/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.

(Please note the <u>EUA fact sheet</u> has been officially updated to reflect the elimination of the step to first withdraw 20 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.)

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

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

MHOAC County Contact Information:

https://emsa.ca.gov/medical-health-operational-area-coordinator/

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 Dr.Caterina Lui

- To summarize, two COVID-19 vaccines have received FDA emergency use authorization, one from Pfizer, and the other from Moderna.
- 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
- Doses/allocation
 - As of 1/4/21, 772,200 doses of Pfizer vaccine and 1,136,300 doses of Moderna vaccine have been allocated to CA to be administered on a local level to Phase 1A populations. 317,850 doses of Pfizer vaccine have been allocated as part of the federal pharmacy partnership with CVS and Walgreens. 459,564 doses have been reported in immunization registries as administered. The first booster (or second Pfizer doses) started arriving in California yesterday and today and second dose allotments are mimicking first dose allotments. CA is now receiving new allocation numbers from CDC each Tuesday morning and will continue to send new allocation numbers to counties each Tuesday afternoon.
- Vaccination in long-term care facilities continues with the CDC-Pharmacy Partnership program. CVS and Walgreens will reach out to facilities directly to schedule vaccination clinics. Please provide your facility's best contact information and accurate numbers of staff and residents to be vaccinated. Staff already vaccinated through local health departments should plan to receive their 2nd dose from the LHD. Staff who have not received COVID-19 vaccine yet can be vaccinated by CVS and Walgreens. Eligible staff refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and staff can be employees, contractors, students, trainees and volunteers.

- Clinical considerations
 - The CDC website is updated with the most recent information about both the Pfizer and Moderna vaccines, and updated the clinical considerations page on 12/30/20. A list of changes is noted on the CDC Clinical Considerations page.
 - Notably, CDC updated its "Contraindications and Precautions" section with greater detail, and included a guide to distinguishing immediate allergic reactions, vasovagal reactions, and vaccine side effects. Contraindications to vaccination include:
 - "Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
 - Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])*
 - Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)*
 - * These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available)."
- Prioritization: CDPH will release guidance on sub-prioritization during Phase 1b in the coming weeks.
- Additional resources:
 - Link to COVID vaccine resources: https://eziz.org/covid/vaccine-administration/
 - https://covid19.ca.gov/vaccines/#When-can-I-get-vaccinated
 - 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
 - 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=mm695152e 2 w

VII. Additional Resources

As part of the COVID response, Medi-Cal established a new COVID-19 Uninsured Group program.

The COVID-19 Uninsured Group program provides access to no cost diagnostic testing, testing-related services, and treatment services, including all medically necessary care, which includes associated office, clinic, or emergency room visits related to COVID19, for up to 12 months or the end of the public health emergency, whichever comes first. This program is available to uninsured and underinsured individuals determined eligible by a Qualified Provider (QP) based on preliminary applicant information.

To qualify for the COVID-19 Uninsured Group, individuals must:

- Have no health insurance, or
- Have private health insurance that does not cover at no cost all diagnostic testing, testing- related services, and treatment services, including all medically necessary care for COVID-19, or
- Not have Medicare, or
- Are not eligible under any of the other Medi-Cal programs (with the exception of individuals who have not met their Medi-Cal Share of Cost obligation), and
- Be a California resident

More information can be found here.

VIII. Questions and Answers

Q: In the yellow zone when we are doing the biweekly testing, can we use the POC testing for one of the two testing periods?

A: In the All Facilities Letter 20-53.3 there is language around the use of POC tests as part of testing in skilled nursing facilities. There is a link from that AFL to a set of flow diagrams which show the necessary confirmatory testing that would be done depending on the scenario and the result of the POC antigen test. So, for response testing, POC antigen test can be used and in general for symptomatic individuals who are tested with a POC test, if the POC test is negative an in a symptomatic individual that does need to be confirmed with a PCR immediately. For asymptomatic individuals tested with a POC test, we would recommend consideration that a PCR for those individuals who are known to be exposed as part of an outbreak.

Q: Regarding vaccinations, I heard a lot about immediate family members of nurses, CNAs, those who work in health care setting, being on the priority list for vaccination. I haven't heard anything about that for a month at least. Do you have any information on when we can expect our family member to receive vaccinations?

A: Some of them may be included in Phase 1b but the final prioritization guidance is pending but the guidance will occupations, age and also comorbidity considerations. We anticipate that some of the family members will be included in Phase 1b.

Q: There has been some delays in getting the QC swabs. I just wanted to let you know that. For the 117 variant, what type of active surveillance are we doing?

A: CDPH has established a partnership with the Chan Zuckerberg Bio Hub as well as many other laboratories throughout the state to put efforts in whole genome sequencing. We call it COVID-NET because it's a network of laboratories and it's private, public and philanthropic interest here all contributing to try to understand what strains are here in California. We have done some more enhanced surveillance bases on the assay results that I mentioned in my notes about those S dropouts. That kind of gives us a clue that you might have the 117 variants in hand but mind you, all RNA viruses mutate. So, it's important for us to not only to focus on looking of that one particular variant but just to know for situational awareness what's happening on in the state. It is ongoing.

Q: I have a nurse that had a history of Bell's Palsy as a child. After the first Pfizer vaccine, she had some numbness on the same side of her face that her prior Bell's Palsy. It went away but no motor findings. She wonders if the second vaccine should be ok for her. I think there is no contraindication for history of Bell's Palsy for giving the vaccine. I told her it should be ok. Are there any advice?

A: I agree with you that that is not a contraindication that's listed on the CDC website. The main contraindications are severe allergic or immediate allergic reaction so that would not be included.

Q: The CALvax website is live and is allowing patients to go in and enter a request for vaccination. It's causing some confusion amongst my colleagues. I had a physician call yesterday telling me that some patients were able to get the vaccine by going some distance. I'm curious as to how this is going to be incorporated, how you are going to publicize this website and how it interfaces with the prioritization guidance for vaccination.

A: I will talk to my team about the call back system. COVID REDIE software, which is for registration and enrollment will be phased out in the next week or so and be preplaced by a website called CALvax. It should not be a patient facing website. I'm going to talk to my team about these concerns that individual public members are accessing vaccines. The intent of the website is to replace COVID REDIE to provide a more streamlined experience, but the final announcement has not been made.

Q: I work in a psychiatric health facility and have a max capacity of 15 patients. As a requirement for admission, the patient must be COVID negative. I don't see us going into a COVID surge crisis at our facility. Are we still required to propose a crisis care plan?

A: The crisis care plan was for general acute hospitals only.

Q: Is CDPH looking at working with Medi-Cal to expand emergency Medi-Cal coverage for homecare after care services or oxygen for an uninsured population in all honesty is blocking beds that other patients could be taking?

A: That's an interesting and unique point that hasn't come up. I will take that back for us to look about with DHCS. We have been planning with the Department of Managed Care for making sure there is coverage across systems and insurances from that standpoint.

Q: Do you have any further guidance regarding the crisis care plan?

A: There are two actions in the AFL. Make sure you post your crisis care plan by January 6th. The goal is that we want to transparency with the public of what our plans and procedures are particularly when there is so much fear around if you had a loved one in the hospital. The second piece is to notify us the moment you are entering crisis care. Those are really the two actions to take from that AFL.

Q: Are there any thought about moving patients to Northern California hospitals to help with other hospitals that are overwhelmed?

A: We are working with EMSA on transfers, but we are starting first with counties. We are trying to level load between counties. There could be a point in the next couple of weeks that even within an entire county, every hospital could be at its tipping point. At that point, yes, we will be expanding regionally. We do have to be mindful of transfer trauma. Sometime even families themselves are refusing transfers that are too far away. Those are the things that we will work out when we come to that but for right now, we are able to at least level load at the county level. We are preparing for perhaps having to go more to a regional model as the next couple of weeks go on.

Q: We went through our first vaccination clinic this week and it was disaster. We were only able to do 7 vaccinations in an hour. We had two individuals that did the injection and 10 members doing the intake and paperwork. When we spoke with the pharmacy about it, they blamed it on the state of

California and the federal government related to what paperwork needs to be done before they can administer the vaccination. I think that needs to be looked at and refined.

A: We are in regular communications with CVS and Walgreens. We will bring your concerns to the pharmacies when we meet with them.

Follow up answer from DHCS: Regarding patients who are uninsured, we do have a group uninsured program so that people who do not have insurance can get Medi-Cal for COVID related testing and treatment including hospitalization and all medically necessary care. You can google COVID uninsured group program DHCS or you can find it on our website.

Q: Regarding the 21-day interval period of the Pfizer vaccine, there is a grace period of four days from 17 to 21 days and we have been using that. In some of the latest information it talks about the grace period with a strong preference towards 21 days. There is some description around that anything earlier should be seen as an exception. Has that always been there? Is there any data around 17 vs 21 days short of the Phase 3 studies?

A: The CDC guidance says that the grace period is within 4 days and doses administered earlier do not need to be repeated. They do include language that says the second dose should be administered as close to the recommended interval as possible however, there's no maximum interval between the first and second dose for wither vaccines.

Q: Is there data around that? Is that a change?

A: That grace period is the same since they first released the guidance. I'm not certain what the evidence that they've used behind it but is what they have used from the start.

Q: What should we look for if we were to call the county to get genomic sequencing done on specimen? Is there anything unique to look for with these possibly mutated strands?

A: There are some levels of suspicion. Some criteria that you might consider is if the patient has recently traveled to the United Kingdom, although many more countries are reporting this variant and that may not be as relevant anymore. And then also the S dropout if you are using TagPath combo

assay. Otherwise just general suspicion overall.

Wednesday Webinar: 3–4 p.m., Attendee Information:

Register at: https://www.hsag.com/cdph-ip-webinars
Call-In Number: 415.655.0003 Access Code: 133 788 3426