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

AT&T Meeting Recording: 1 (866) 207-1041
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I. **Welcome / Introduction** **Heidi Steinecker**

II. **Overview** **Dr. Kathleen Jacobson**

- None Provided

III. **Laboratory Update** **Dr. Carol Glaser**

As mentioned before, genomic surveillance is important because of the implications of variants for therapeutics, vaccines, diagnostics, virus characterization/pathogenesis and the animal-human interface.

On today's call, I will provide updated information on the 3 primary variants of concern (VOCs) - as well as 2 variants of interest (VOIs) that we have been following in CA.

B.1.1.7

This is the variant that was first identified in the UK and has now been detected in 70 countries. It is more infectious and per a recent UK report may have higher morbidity/mortality but there are no concerns about vaccine effectiveness. (other names 20I/501Y.V1 and VOC 202012/01). (Key mutations: 69/70 deletion, 144Y deletion, N501Y, A570D, D614G, P681H)

Two days ago, the group at Scripps in San Diego published a report examining the growth dynamics of the B117 variant (Washington NL, et al. Genomic epidemiology identifies emergence and rapid transmission of SARS-CoV-2 B.1.1.7 in the United States. Available at: https://www.medrxiv.org/content/10.1101/2021.02.06.21251159v1.full.pdf).

They found that detection of B117 variant increased at a logistic rate with a doubling time of just over a week and as observed in UK, an increased transmission rate of 35-45%. They concluded that the U.S. is on a 'similar trajectory' as other countries where this variant became dominant. This agrees with the earlier CDC forecast that this may be the dominant US strain by March.

- As of Feb 7, 690 cases in the US in 33 states (150 in CA and 201 in Florida)
- Most of the California cases have been from S CA.

B.1.351

This is the variant first identified in South Africa. In addition to concerns about increased infectiousness, there are concerns about vaccine effectiveness. (other names 501.V2 20C/ variants). (Key mutations: K417N, E484K, N501Y and D614G).

Now detections in 30 countries including US

- 6 cases US: 3 states (2 South Carolina, 3 in Maryland and 1 Virginia)
- None in California

P.1
This is the variant first identified in Brazil. Similar to B.1.351 there are concerns about increased infectiousness and vaccine effectiveness. (Mutations; E484K, K417N/T, N501Y, D614G)

P.1 has been detected in 4 countries so far.

- 3 cases detected in the US
- It has not been detected in California (*in case asked why a news report mentioned "Brazilian" strain in San Mateo/Stanford lab, this was P.2 not P.1*).

Variant of Interests in CA
Keep in mind that variants are common with this virus and are not necessarily a problem. Two such variants include B.1.429 and B.1.427. Both of these variants have same mutation in spike protein.

B.1. 429 (aka L452R or 20C, Western US variant, CAL.20C)
You may first have heard about the B.1.429 four weeks ago on news. This virus was first detected in California in July but in recent months has increased in prevalence. There are concerns about this variant being more infectious as well as vaccine effectiveness, but data are speculative (in vitro data suggest the L452R mutation spike mutation will lead to immune evasion). Outbreaks with high attack rate.

B.1.427 (aka L452R)
Closely linked to variant I just mentioned (has at least one additional mutation in the ORF gene). Like B.1.429, there are concerns about this variant being more infectious and about vaccine effectiveness, but data are speculative.

Both of these variants increasing in frequency.

SEQUENCING efforts
CDPH continues to expand their whole genome sequencing efforts. The goal is to test representative samples from diverse populations and wide geographic range over time.
Encourage you to maintain high vigilance for outbreaks and work closely with your LHDs if you suspect VOC or VOI.

COVIDNET/Sequencing is an active network of public health labs, academic and commercial labs that have formed a collaboration to track SARS-CoV-2 viruses in California through sequencing. The goal is to sequence ~1% of positive samples. The capacity of COVIDNET is being ramped up.

At CDC there is a similar program called the National SARS-CoV-2 Surveillance System (aka NS3). This program is also ramping up sequencing.

IV. **Healthcare Associated Infections** **Dr. Erin Epson**

The HAI Program has recently consulted on multiple outbreaks in skilled nursing facilities where cases were identified in residents admitted from the hospital during the prior 14 days. We'd like to remind facilities that the purpose of 14 days quarantine and testing for newly admitted residents is to observe and separate these residents from the remainder of facility, since their exposure status prior to admission is unknown, and they could become positive sometime during the 14 days after admission and expose other residents and healthcare personnel. SNF need to understand that these newly admitted residents should be managed with transmission-based precautions for COVID and placed in an observation area or set of rooms that are separate from the rest of the facility, including the green-unexposed or recovered area as well as the yellow-exposed area for residents with known exposures within the facility (if the facility is accepting new admissions during an outbreak with known exposures). SNF that identify a new case in a resident during this 14 day observation period should notify their local health department as well as the infection preventionist for the transferring facility, to prompt an investigation to evaluate for exposures and transmission within that facility.

V. **Monoclonal Antibody Update** **Dr. Sohrab Sidhu**

- Monoclonal antibody allocation updates
- NIH statement on the use of tocilizumab (and other interleukin-6 inhibitors) for the treatment of COIVD-19

Monoclonal Antibody Overview

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. The EUAs for both therapies are only to treat symptomatic outpatients.

General updates

Allocations of the monoclonal products from CDPH are occurring every two weeks.

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.

Medical directors or other authorized prescribers at SNFs and PACE programs who contract with specialty pharmacies receiving state allocations can order monoclonal product . The pharmacy would prepare the product and send to the SNF or PACE program for infusion. There are now 15 specialty pharmacies that have received at least one allocation of bamlanivimab or casirivimab/imdevimab since week 1. The complete list of pharmacies can be found in the meeting notes:

These pharmacies are Pacific West Pharmacy, Skilled Nursing Pharmacy, Consonus Pharmacy Services, AlixaRx, Pharmerica, Citrus Pharmacy, Ron's Pharmacy, OmniCare, AmeriPharm, Owens Pharmacy,

CareKinesis, Premier Pharmacy Services, Rivers Edge Pharmacy, Quality Home Infusion, and Physicians Plaza Pharmacy.

Please also note that for facilities who have received product before, they may now request product directly from the distributor, AmeriSource Bergen, should they require any in between allocations. These requests can be done in parallel and in addition to the previous methods described, namely acquiring the product via specialty pharmacies or requesting the product from their county MHOACs.

This 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 "Treatment Guidance" section and titled "Monoclonal Antibody Allocation").

Bamlanivimab updates
For weeks 13-14, California received an allocation of 10,250 doses of bamlanivimab.

Specialty pharmacies received 300 doses.

The remaining 9,950 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, some was re-allocated to other counties and 2,389 doses were sent to the CDPH warehouse.

Please note again that recent updates have been made to the bamlanivimab EUA. Want to point that the minimum infusion times have changed and are now based on the size of the infusion bag with the minimum infusion time for one vial of bamlanivimab mixed with a 50 mL normal saline bag now 16 minutes. The one-hour post-treatment observation is still mandated. A link to the updated bamlanivimab EUA fact sheet can be found in the meeting notes.

Casirivimab / imdevimab updates
No allocation for casirivimab/imdevimab was made this cycle. The Regeneron product is currently undergoing repackaging. Allocations are expected to resume in the future. The CDPH warehouse currently has a supply of casirivimab/imdevimab. Requests for additional casirivimab/imdevimab can be made through county MHOACs.

NIH COVID-19 Treatment Guidelines Panel's Statement on the Use of Tocilizumab (and Other Interleukin-6 Inhibitors) for the Treatment of COVID-19
On February 3rd, the NIH COVID-19 Treatment Guidelines Panel updated its recommendation regarding the use of tocilizumab and sarilumab for the treatment of COVID-19.

Tocilizumab and sarilumab are IL-6 inhibitors FDA-approved for the treatment of rheumatological conditions. It is hypothesized that modulating levels of pro-inflammatory IL-6 may improve the course of COVID-19. To date, no IL-6 inhibitor is FDA-approved or authorized for the treatment of COVID-19.

Initial studies evaluating the use of IL-6 inhibitors for the treatment of COVID-19 produced conflicting results and were limited by low power, heterogenous study populations with varying degrees of disease severity, and/or low frequency of concomitant use of corticosteroids, which has become the standard of care for patients with severe or critical COVID-19. More recently, preliminary data from the

largest randomized control trial that has investigated the role of IL-6 inhibitors in COVID 19 patients, the REMAP-CAP trial, showed that compared to placebo, the use of either tocilizumab or sarilumab reduced both mortality and time to ICU discharge, and increased the number of organ support-free days.

In response to the available clinical evidence, the recommendation now states that the panel has determined the following:

- "For patients who are within 24 hours of admission to the ICU and who require invasive or noninvasive mechanical ventilation or high-flow oxygen (>0.4 FiO2/30 L/min of oxygen flow), there are insufficient data to recommend either for or against the use of tocilizumab or sarilumab for the treatment of COVID-19.
    - Although many trials of tocilizumab for the treatment of COVID-19 have included patients who meet the above criteria, the collective data available to date preclude a definitive recommendation for or against the use of the drug.
    - In view of the results from the REMAP-CAP trial, some Panel members would administer a single dose of tocilizumab (8 mg/kg of actual body weight, up to 800 mg) in addition to dexamethasone to patients who meet the above criteria and who are also exhibiting rapid progression of respiratory failure.
    - Too few patients in REMAP-CAP received sarilumab for the Panel to assess its efficacy in the treatment of patients who met the above criteria.
- For patients who do not require ICU-level care or who are admitted to the ICU but do not meet the above criteria, the Panel recommends against the use of tocilizumab or sarilumab for the treatment of COVID-19, except in a clinical trial (BIIa)."

Note that this update represents a shift from the NIH panel's previous recommendation on IL-6 inhibitors in which they recommended against the use of these products for the treatment of COVID-19, except in a clinical trial.

"Use of tocilizumab for the treatment of COVID-19 may affect supplies for other indications, such as rheumatic diseases and cytokine release syndrome related to CAR-T therapy. Health systems are encouraged to ensure an adequate supply of tocilizumab for patients who need the drug for the FDA-approved indications"

Read the full statement: Statement on Tocilizumab | COVID-19 Treatment Guidelines (nih.gov)

Additional Resources

Bamlanivimab links for further information:

- Bamlanivimab Distribution Fact Sheet (ca.gov)
- Fact sheet for healthcare providers: https://www.fda.gov/media/143603/download
- Fact sheet for patients, parents, and caregivers: https://www.fda.gov/media/143604/download
- FDA FAQ: https://www.fda.gov/media/143605/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 for further information:

- Casirivimab and Imdevimab Distribution Fact Sheet
- 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
- FDA FAQ: https://www.fda.gov/media/143894/download

Remdesivir:

- Frequently Asked Questions for Veklury (remdesivir) (fda.gov)

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. The FDA meeting to discuss the Johnson & Johnson 1-dose vaccine will be on February 26.
- Enrollment:
  - CalVax has now become myCAvax. General questions about Provider Enrollment can be directed to our COVID Call center at 833-502-1245 or COVIDCallCenter@CDPH.ca.gov
- Doses/allocation
  - As of 2/8/21, 7,119,225 doses of COVID-19 vaccine have been delivered to LHJs and other provider sites, including the LTC facility sites participating in the federal pharmacy partnership program. To date, 4,746,539 doses have been administered. The CDPH vaccine dashboard has been posted and is updated daily at VaccineDoses (ca.gov).
  - On 2/3/21, CDPH released updated guidance for all vaccination providers. Key points of the guidance include the following:
    - Providers should plan to zero out their doses at the end of every week.
    - Do not distinguish between vials designated as first and second doses. Manage the inventory you have to ensure you have the doses required to meet your second dose schedule, and then schedule the balance as first dose appointments.
    - Report administered and inventory daily
    - Please refer to the link for the full guidance.
- Other vaccine delivery:
  - The CDC Federal Retail Pharmacy Program begins this week. CVS and Rite Aid are California's initial partners and are receiving a separate federal allocation of vaccine to their retail locations. Appointments can be made at the pharmacy's individual website.
  - On 2/3/21, Governor Newsom announced a pilot project to open FEMA community vaccination sites, one in Oakland and the other in Los Angeles. Registration for these sites will be available via California's MyTurn website. Full Office of Governor announcement.
- LTCF: Vaccination in long-term care facilities continues with the CDC-Pharmacy Partnership program. CVS and Walgreens are reaching 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. Please review documents, resources, and FAQs directly on pharmacy LTCF webpages:

- CVS / Omnicare https://www.omnicare.com/covid-19-vaccine-resource/
- Walgreens https://www.walgreens.com/topic/findcare/long-term-care-facility-covid-vaccine.jsp
- Communications: The CDC website has been recently updated with new communications toolkits for diverse populations:
    - https://www.cdc.gov/coronavirus/2019-ncov/communication/toolkits/index.html
- Clinical considerations: The CDC website is updated with the most recent information about both the Pfizer and Moderna vaccines
    - Link: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
- Prioritization
    - On 2/4/21, CDPH released updated guidance on vaccine allocation during phase 1b. https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/VaccineAllocationGuidelines.aspx
    - Individuals eligible for COVID-19 vaccines under the new guidance include:
        - Phase 1a, all tiers
        - Phase 1b, tier 1:
            - Persons 65 years of age and older
            - Essential workforce sector populations with risk of exposure: Education and Childcare** , Emergency Services*** , Food and Agriculture***.
    - Please refer to the full guidance for additional details.
    - Link to the essential workforce list: https://covid19.ca.gov/essential-workforce/
    - Decisions about inclusion in Phase 1b, tier 2, and Phase 1c have not been finalized and released.
- **Additional resources:**
    - Link to COVID vaccine resources: https://eziz.org/covid/vaccine-administration/
    - The CDC website is updated with the most recent information about both the Pfizer and Moderna vaccines.
        - Main landing page: https://www.cdc.gov/vaccines/covid-19/hcp/index.html
    - Authorized Vaccinators: https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/Authorized-Licensees.aspx

VII. **Questions and Answers**

Q: Walgreens and CVS are saying that they can only give out the second dose of the vaccine in some facilities. We were told to reach out to our State Departments of Health because they are supposed to be able to give the first vaccines as directed by the federal government. Any thoughts on that and what we should do?

A: The really should be giving their first dose at the second clinic because they can come back for the third clinic. In terms of the third clinic, they will give the first dose but will not come back to vaccinate those for the second dose. It's up to the facility to help their employee or resident find options for the second dose. If there are problems, you can email CVS and Walgreens representatives. They should be able to handle that. You can email your local health department and they can pass that information along for specific facilities that are having issues.

Q: Regarding genotyping for persons who are thought to have reinfection, is that something you have any data on that you can share with us?
A: I don't have that data at this time. I can try to have it on the next call.

Q: Are you concerned about the fact that a single monoclonal might lead to higher incidence of escaped mutants and potential expanded transmission of escaped mutants in the community and do you have any data on that?
A: We don't have any data on how the monoclonal are doing in terms of the emerging variants. On a call with HHS and Eli Lilly and Regeneron and they at least could share that they thought the products were effective against the UK variant, given their testing but they didn't share any data more granular than those statements. I think there's more information to come. I can also tell you that the Bamlanivimab was tested with another monoclonal known as Infleximab and the results, at least according the press release, Eli Lilly's were encouraging with a reduction of hospitalizations and or deaths by 70 percent. I think they are pursuing an EUA for those products as well so Bamlanivimab may transition to a combination product in the future.

Q: If they need to transition to a dual monoclonal like Regeneron, doesn't that suggest that they do have concerns about escaped mutants with their single product and that's why they're doing a dual product? Are we doing a disservice possibly by recommending a monoclonal product? Is that potentially not the best recommendation for society although they work on a patient?
A: I would say that it's important for some shared decision making for the doctor and patient, taking into account the options available for treatment, the risks of progression to severe disease and so on and so forth. I hear you on the lack of clinical data making it hard to fully promote these kinds of treatments and what I would say is, I think it's important for providers to review the data and engage with shared decision making with their patients.
A: We are looking very closely at anything that looks like a vaccine failure. That's part of the reason we are really trying to expand surveillance because we know it's a concern. As we are able to build out even more surveillance, we will be able to detect these situations that much better.

Q: Are you going to try to collect specimens form people who've been treated with a single monoclonal?
A: I don't know if we targeted monoclonal. It's probably something we should think about and have a conversation offline. Anybody with reinfections or anyone who looks like they had a vaccine failure are pretty high priority, but we'll probably target the monoclonal group.

Q: Should we be asking individuals to quarantine for 14 days after returning from the hospital to a skilled nursing facility?
A: I believe that is reasonable especially when there is exposure to transmission withing the hospital. While it's not as strong of a recommendation or requirement as it is for newly admitted residents, I think that facilities can consider doing so with their existing residents who are returning from a hospitalization.

Q: Can you clarify why we are not receiving our requested allocation while other larger facilities are getting their allocations?

A: There has been a lot of changes in terms of the allocation planning and the final plan is still being worked out. There was an announcement about California partnering with Blue Shield and Kaiser to assist in vaccine allocations and that has caused some changes to happen with how allocations are made. I don't have any final information to share besides the fact that we continuing to work on this.

Q: What if we have no vaccines on hand, do we need to continue to report our daily that we have zero or can we wait until we get more vaccines before we start reporting again?
A: All facilities should continue reporting even if it is zero.

Q: Some small counties are doing a lot of antigen test and those aren't being tallied as a understand it, in terms of overall positivity rates in order to move to a lower tier. Some rural hospitals are having a hard time getting enough PCR test or a turnaround time that's reasonable because there are delivery issues such as snow. I was wondering if there is any thought of being able to include negative antigen tests in the overall positivity rate in some special scenarios and how to go about requesting that.
A: I can bring your concerns back to the people that do the reporting. If you need help setting up PCR testing, we can help with that.

Q: There are reports of no ITP associated with the vaccine. I was wondering if you guys were going to put out an advisory statement or wait for the CDC to do so.
A: The safety investigation is done by the CDC. Any cases you are concerned about should be reported to VAERS. We defer to their investigation in terms of vaccine associatedness. If there's any case that you are concerned about that may be related to the vaccine, filing a VAERS report is recommended.

Q: Can you give us any more information on the quality control issues at the Perkins Elmer Lab?
A: A lot of issues are being addressed and they've have been addressed for a while. I think that we are confident that the results coming out now are of good quality and I'm going to leave it at that. I can assure you that the issues have been addressed and they have been for a while.

Q: When will you expect that we will allow increased visitors again? What is the criteria that we are waiting for?
A: We have 2 AFLs that address visitations. It's based on the spread rate of the county. Unfortunately, most of our facilities are still in the purple tier. There are special rules for visitation in the purple tier. If the spread rate is lower, visitations can be expanded. We are also looking at vaccine rates particularly in our congregate settings. If everyone is vaccinated or a different percentage is vaccinated, it helps us increase our chances of being able to open up different parts of the skilled nursing facility, not just the green zone. At this point, we are still assessing that. For now, just keep checking the tier for your county on blueprint for California. That what you can base what your visitation is.
A: The AFL is 20-38.5

Q: Regarding testing, for the BinaxNOW, is the guidance still that they patient must be symptomatic in order to use that test?
A: Yes, that is the current recommendation. The test can be used in congregate setting where the test can is done more frequently, at least two times a week, for screening of asymptomatic individuals. If you are going to use it as a once off, it's recommended to use it symptomatic individuals. If it is used in

asymptomatic individuals and it's negative and there's been a high likelihood of exposure, then we would recommend getting a PCR test. If it's positive, you should consider confirming with a PCR test.

Q: Can out of county visitors get vaccines here if they wanted to, by going to CVS to get a vaccine? I had COVID back in December and every now and then I still get severe headaches and body aches. My other family members are experiencing the same thing. Are we considered still infectious and is this normal?
A: The pharmacies are not requiring proof of residents. So long as you can attest that you meet their priority criteria, they will give you the vaccine and you don't have any contraindications.
A: The criteria for discontinuing isolation and precautions, for most individuals that time is 10 days from the date of symptom onset or a positive test for asymptomatic individuals with at least 24 hours of resolution of fever and improving other symptoms. We acknowledge that there is an emerging understanding about the long COVID experience. It's something that you should consult with your personal physician about strategies for managing those long COVID symptoms. In terms of infectiousness and need to isolate and take precaution, the criteria is the same as I stated.

Q: My skilled nursing facility is in a green zone and our counties positivity rate is 10.6%. What type of masks do you recommend for our staff? Should staff that have not been vaccinated, should they be wearing N95s for their protection?
A: In a green zone, for a facility that does not have any COVID positive cases, staff need to wear a medical procedure mask for source control. For newly admitted patients coming into the facility, staff should be wearing a N95 respirator due to the unknown status of the new patient.
A: Regardless of the health care personnel vaccination status, if they need respiratory protection while caring for positive or exposed residents, they should still wear a respirator even if they have been vaccinated, for personal protective equipment. The recommendation is for universal source control. There wouldn't be a different requirement for their PPE while caring or residents, depending on the resident's status.

Q: About the L452 variant, have you determined infectivity patterns? Is it more or less infective than B117?
A: What we have observed in some of the outbreaks where this particular variant was found, there seems to be a very high attack rate so there's a lot of concern that it might have a higher transmission. We have not yet proven that. It's pretty much speculation at this point and we're continuing to monitor it but there is concerns about a higher infectiousness that some of the other viruses. We will continue to monitor and update as we know but it's all speculative still at this point.

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