California Department of Public Health
Weekly Facility COVID-19 Update Call
March 16, 2021
8:00 am – 9:00 am

AT&T Meeting Recording: 1 (866) 207-1041
Access Code: 1220034
Available after 12 Noon 03/16/2021

I. **Welcome / Introduction** **Heidi Steinecker**

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

- None Provided

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

Quick overview - Variants of concern (VOC), which are those proven to have epidemiologic or clinical significance while other variants I will be discussing have theoretical concerns but have not yet been shown to have epidemiologic and clinical significance. SARS-CoV-19 virus is constantly mutating so we expect to see variants, and most are not significant. For VOI, we do not know clinical or epi significance but are following closely. Most variants do not have impact.

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 likely to higher morbidity/mortality per UK report. This is also the variant that CDC had predicted would become the predominant strain in the US by the end of March. Large number mutations including mutation in RBD of spike protein position 501.

As of March 15, 2021: 4690 cases in 50 states, 343 in CA
For comparison, March 8: 3037 cases in 49 states, 262 in CA/March 1: 2400 cases in 46 states (206 in CA)/Feb 22: 1661 cases in 44 states (195 in CA)/Feb 15: 173 cases in US in 40 states (186 in CA).

Modeling studies suggest that this variant will predominant by end of March. One study suggests that high vaccine coverage will blunt higher transmissibility.

A publication March 5 in International Journal Infectious Disease B117 produces higher viral load than other strains (CT value 15.8 vs 16.9) and its RNA persists longer (16-day vs 14 day).
https://www.ijidonline.com/article/S1201-9712(21)00210-1/fulltext.
Study published in Nature yesterday showed B117 may "pose a 61% higher risk of 28-day mortality
https://www.nature.com/articles/s41586-021-03426-1.

Preliminary data from the UK demonstrate that vaccination with 2 doses of Pfizer vaccine was highly effective (85–86%) against SARS-CoV-2 infection and symptomatic COVID-19 during a period when B.1.1.7 was the predominant circulating strain. High Pfizer-BioNTech vaccine effectiveness (92%) against infection was also seen in Israel in the setting of multiple circulating strains, with the proportion of cases due to the B.1.1.7 variant increasing to 80% towards the end of the study period, Science Brief: Background Rationale and Evidence for Public Health Recommendations for Fully Vaccinated People (cdc.gov)

B.1.351

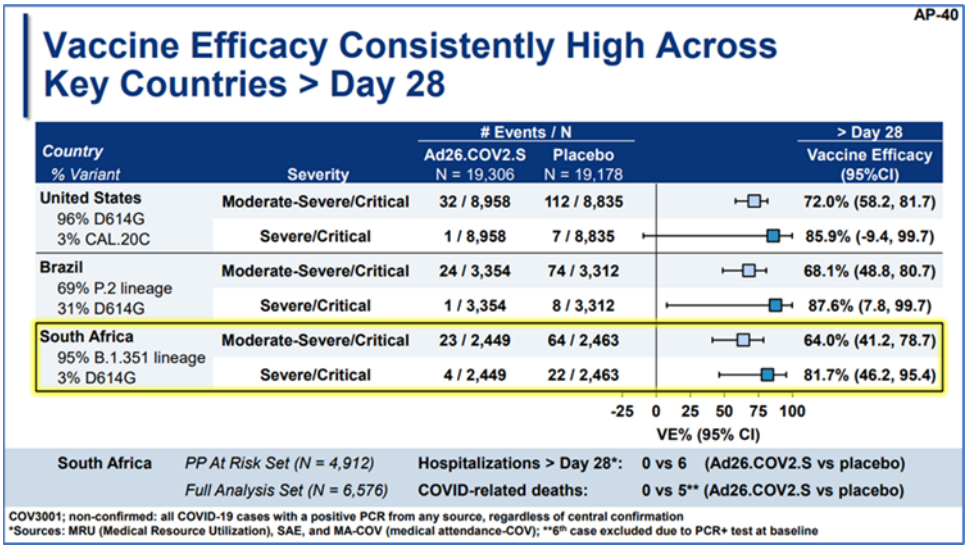
This is the variant that was first identified in South Africa. In addition to concerns about increased infectiousness there are concerns about vaccine effectiveness. No impact on disease severity. (other names 501.V2 20C/ variants). (Key mutations: K417N, **E484K**, N501Y and D614G). Note that the variants with **E484K** are concerning because of vaccine efficacy.

As of March 15, 2021: 143 cases in 25 states

For comparison, March 8: 81 cases in 20 states, 3 in CA (same as before in CA/) March 1, 2021: 53 cases in 16 states/Feb 22-22 cases in 10 states/Feb 15: 17 cases in 8 states

Johnson & Johnson/Janssen Vaccine

Clinical trials for the Johnson & Johnson/Janssen vaccine took place in the US, Brazil, and South Africa. Preliminary data suggest that the Johnson & Johnson vaccine may have reduced efficacy against the B.1.351 variant. In the United States, efficacy was 74% and in Brazil (where ~69% of infections were due to P.2) efficacy was 66%, but in South Africa (~where 95% of infections were due to B.1.351) efficacy was 52%. However, Janssen vaccine efficacy against severe or critical disease was high and similar across all three sites (73–82%). Science Brief: Background Rationale and Evidence for Public Health Recommendations for Fully Vaccinated People (cdc.gov)



https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/02-COVID-Douoguih.pdf

P.1

This is the variant that was first identified in Brazil. Similar to B.1.351 there are concerns about increased infectiousness and vaccine effectiveness. (total of 12 mutations including **E484K**, K417N/T, N501Y, D614G), Note that the variants with **E484K** are concerning because of vaccine efficacy.

As of March 15, 2021: **25 cases in 10 states, "ZERO"* in CA**
For comparison March 8: 15 in 9 states, zero in CA/March 1; 10 in 5 states/Feb 22: 5 cases in 4 states/Feb 15; 3 cases detected in the US

*However, just yesterday, San Bernardino County announced via a press release first P1 in California. Male in his 40s, in self-isolation. No other data available at this time.

Nature article published last week
https://www.nature.com/articles/s41591-021-01294-w.pdf
found moderate to substantial decrease in neutralization of these variants.

Other variants of Interest
B.1.526 variant
Researchers from Columbia in New York reported B.1.526 variant which has emerged there.
https://www.medrxiv.org/content/10.1101/2021.02.23.21252259v1
3 weeks ago. This variant shares some of the concerning mutations VOC particularly as it pertains to vaccine effectiveness. Lineage first detected in late November 2020 and are increasing in detection in NY area and now represent at least one-quarter of their cases. Most cases NY and New Jersey. We have seen a handful of such variants in CA.

B.1. 429 and B.1.427 (Western US variant, **CAL.20C, West Coast variant**)
There are two closely related variants B.1.429 and B.1.427. Both of these variants have a mutation in spike protein and have the potential for increase transmission and immune evasion. Accumulating data showing that B.1.427/B.1.429 are common in California now representing 60% of what is sequenced.

SEQUENCING efforts
The variants underscore the importance of WGS. CDPH continues to expand their whole genome sequencing (WGS) efforts and in past few weeks, additional samples have been sequenced the goal is to test representative samples from diverse populations and wide geographic range over time at least 2% of all positive samples.

Key websites
Science Brief: Background Rationale and Evidence for Public Health Recommendations for Fully Vaccinated People (cdc.gov)

https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/COVID-Variants.aspx

- Variants of concern (VOCs) maps and resources
  - https://pbs.twimg.com/media/EvMTRfDU4AEYbSR?format=jpg&name=large
  - https://cov-lineages.org/index.html
  - https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/genomic-surveillance-dashboard.html

- GSD PCR kit for B117 and B1351 free to PHLs: https://www.gsdx.us/rt-pcr-id
- NS3 data https://nextstrain.org/groups/spheres

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

Last week CDC again updated their work exclusion guidance for higher-risk exposed fully vaccinated healthcare personnel and quarantine for exposed fully vaccinated inpatients and residents of healthcare facilities.

Fully vaccinated HCP (i.e., ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine) with higher-risk exposures who are asymptomatic do not need to be restricted from work for 14 days following their exposure. Work restrictions for fully vaccinated HCP populations with higher-risk exposures should still be considered for HCP who have underlying immunocompromising conditions (e.g., organ transplantation, cancer treatment), which might impact level of protection provided by the COVID-19 vaccine, and for fully vaccinated HCP who have traveled (excluding essential work related travel) when quarantine and work restrictions would apply to any traveler.

Fully vaccinated inpatients and residents in SNFs should continue to quarantine following an exposure to someone with suspected or confirmed COVID-19, however, quarantine is no longer required for residents who are being admitted to a post-acute care facility if they are fully vaccinated and have not had prolonged close contact with someone with SARS-CoV-2 infection in the prior 14 days, although local health departments may continue to recommend quarantine for newly admitted residents from a hospital where there is known SARS-CoV-2 transmission. Also, fully vaccinated SNF residents who leave the facility for non-essential purposes (e.g., to go out to a restaurant or visit family in their home) do not need to quarantine upon return.

AFL 21-08 is being updated to reflect these changes to CDC guidance.

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

Topics for discussion:

- Concerns re: bamlanivimab monotherapy in the setting of SARS-CoV2 variants
- Etesevimab now available for direct ordering without needing to be packaged with bamlanivimab

Monoclonal Antibody Overview

To summarize, three 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 who are at high risk for progression to severe disease. These products are:

1. Bamlanivimab (Eli Lilly, November EUA)
2. Casirivimab + Imdevimab (Regeneron, November EUA)
3. Etesevimab (Eli Lilly, February EUA)

Clinical trial data in outpatients have shown that these products may reduce COVID-19-related hospitalization or emergency room visits in patients who are treated early and who are at high risk for progression to severe disease. The EUAs for these therapies are only to treat symptomatic outpatients. Note that etesevimab is only authorized to be given in combination with bamlanivimab.

Concerns re: bamlanivimab monotherapy in the setting of SARS-CoV2 variants
The federal government recently shared concerns regarding the use of bamlanivimab monotherapy in regions where the SARS-CoV2 mutation L452R found in B.1.429/B.1.427 lineages (a.k.a. 20C/CAL.20C) is circulating in high numbers. Given these concerns that the clinical activity of bamlanivimab monotherapy is impacted by this variant, the Health and Human Services Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR) has stopped the distribution of this product to California.

While HHS/ASPR is working with the Centers for Disease Control and Prevention, the National Institutes of Health, and the FDA on recommendations for bamlanivimab monotherapy moving forward, **the California Department of Public Health at this time recommends facilities and providers stop distributing and administering bamlanivimab monotherapy in California**. We will continue to update our stakeholders with any new recommendations.

Note that this recommendation only applies to the administration of bamlanivimab monotherapy. The other two authorized monoclonal antibody products for treatment of mild to moderate COVID-19, bamlanivimab plus etesevimab and casirivimab plus imdevimab, do not appear to be affected and will continue to be available for direct ordering from the federal government.

Monoclonal Antibody Direct Ordering and Etesevimab
Bamlanivimab plus etesevimab, and casirivimab plus imdevimab, are available for direct ordering from AmeriSource Bergen Corporation (ABC).

The products available for direct ordering include the above combinations as well as etesevimab by itself. **Note that etesevimab is only authorized for use in combination with bamlanivimab but can be ordered by itself to be combined with any bamlanivimab stock a facility already has on-hand.**

All treatment sites can now order these products directly from AmerisourceBergen Corporation (ABC), the drugs' sole distributor. The products remain free of charge to requesting sites. Treatment sites should review the direct ordering process guide and place orders directly with ABC at this site.

Should you have any questions or concerns regarding the direct order process for COVID-19 monoclonal antibodies, you may contact HHS/ASPR at COVID19Therapeutics@hhs.gov or ABC at C19therapies@amerisourcebergen.com.

For facilities and healthcare providers interested in setting up infusions for high-risk patients with COVID-19, ASPR has many resources available. This includes free digital content that your facility can use on social media platforms to help educate providers and patients. HHS has also provided CombatCovid.HHS.gov as a resource for your patients.

In addition to the above direct ordering process, both bamlanivimab and casirivimab/imdevimab are readily available from CDPH. Contact your county's Medical and Health Operational Area Coordinator (MHOAC) to request either of these products from CDPH.

- **Note again that bamlanivimab monotherapy is not recommended by CDPH for treatment of COVID-19 at this time (see above).** However, under its EUA, bamlanivimab can be combined with etesevimab for the treatment of mild-to-moderate COVID-19 in those patients at high risk

for progressing to severe disease. See the Bamlanivimab plus Etesevimab EUA Fact Sheet for Providers for more information.

One final note:
CDPH is in the midst of updating its webpages regarding the monoclonal antibody treatments. These updates will integrate new clinical evidence (previously reviewed on these calls), information on direct ordering, and a new **Monoclonal Info for Providers and Facilities** webpage, which will feature FAQs around these treatments. When these pages are updated, we will alert the participants on this call.

Additional Resources

Bamlanivimab:

- HHS/ASPR Bamlanivimab Update re: SARS-CoV2 Variants of Concern

Bamlanivimab/Etesevimab

- Fact Sheet For Health Care Providers Emergency Use Authorization (EUA) Of Bamlanivimab And Etesevimab 02092021 (fda.gov)
- Bamlanivimab and Etesevimab EUA Letter of Authorization February 9 2021
- Bamlanivimab plus Etesevimab FDA press release
- Bamlanivimab plus Etesevimab FDA FAQs

Casirivimab / Imdevimab:

- Casirivimab and Imdevimab Distribution Fact Sheet
- Casirivimab and Imdevimab EUA Fact Sheet for Healthcare Providers (fda.gov)
- Casirivimab and Imdevimab EUA Fact Sheet for Patients, Parents, and Caregivers (fda.gov)
- Casirivimab and Imdevimab EUA Frequently Asked Questions updated 02102021 (fda.gov)

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/

VI. **Vaccine Update** **Dr.Caterina Lui**

- **Three** COVID-19 vaccines have received FDA emergency use authorization: Pfizer, Moderna, and Janssen
- Blue Shield of California is California's Third Party Administrator to build an enhanced vaccine network, and a transition to the new allocation process will occur over the next few weeks. Providers interested in becoming part of the vaccine network should contact Blue Shield at CovidVaccineNetwork@blueshieldca.com.
- Doses/allocation

- As of 3/15/21, 15,702,230 doses of COVID-19 vaccine have been delivered to LHJs and other provider sites. To date, 12,172,948 have been administered. The CDPH vaccine dashboard has been posted and is updated daily. The link to the dashboard is in the meeting notes: https://covid19.ca.gov/vaccines/#California-vaccines-dashboard.
- As of 3/15/21, 801,175 total long-term care doses have been administered in California. 487,933 individuals have had at least one dose of Pfizer vaccine, and 309,127 have had 2 doses of Pfizer vaccine. Data on doses delivered to the Federal Pharmacy Partnership for LTC Program can be found on the CDC website: https://covid.cdc.gov/covid-data-tracker/#vaccinations-ltc

- Vaccination in long-term care facilities continues with the CDC-Pharmacy Partnership program. Both CVS and Walgreens will give dose #1 at clinic #3. If you are having problems with specific facilities, please contact CVS/Walgreens. If you are still having problems, reach out to your local health department. This program will conclude at the end of March 2021. Plans to continue vaccination in long-term care facilities are under development. This week, four long-term care pharmacies (Innovatix, GeriMed, MHA, and Cardinal) will be receiving doses of Janssen vaccine this week through the CDC Federal Retail Pharmacy Program.
- The CDC Federal Retail Pharmacy Program includes CVS, Rite Aid, Walgreens, and Albertson's. The pharmacies are receiving federal allocations of Moderna, Pfizer, and Janssen vaccine. Eligible persons can make appointments at the pharmacies' individual websites.
- Clinical considerations for vaccines The CDC clinical considerations website is updated with the most recent information about all three vaccines. Please refer to the link in the meeting notes for additional information: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
- Prioritization
  - CDPH's guidance on vaccine prioritization was updated on March 11, and is linked in the meeting notes: https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/VaccineAllocationGuidelines.aspx
  - Individuals eligible for COVID-19 vaccines under the current 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***.
    - Beginning yesterday, March 15, healthcare providers may use their clinical judgement to vaccinate individuals age 16-64 who are deemed to be at the very highest risk for morbidity and mortality from COVID-19 as a direct result of one or more of the severe health conditions included in this provider bulletin
  - The new guidance also includes the following populations:
    - Individuals who reside or work in a high-risk congregate setting, including correctional facilities, homeless shelter, or behavioral health facility
    - Public transit workers
    - Janitors

Additional resources:

- Useful contacts
  - MyTurn: myturninfo@cdph.ca.gov

    - MyTurn onboarding: https://eziz.org/covid/myturn/
- CDC communications toolkit: https://www.cdc.gov/coronavirus/2019-ncov/communication/toolkits/index.html
- 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
- How to report inventory in Vaccine Finder.
- Link to the essential workforce list: https://covid19.ca.gov/essential-workforce/
- CVS / Omnicare https://www.omnicare.com/covid-19-vaccine-resource/
- Walgreens https://www.walgreens.com/topic/findcare/long-term-care-facility-covid-vaccine.jsp
    - CVS: CovidVaccineClinicsLTCF@CVSHealth.com
    - Walgreens: immunizeltc@walgreens.com
    - Local Health Department: https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/Local-Health-Department.aspx

VII. **Questions and Answers**

Q: There is currently a local SNF that has a COVID outbreak with fully vaccinated to non-vaccinated individuals. We were going to use monoclonal to treat them. According to the directive, we cannot use Bamlanivimab alone but try to use the Regeneron as directed. What do you want us to do? And for the second question, for people who are post vaccination, if it's more than two weeks and they have COVID, is it worthwhile to do any type of antibody titer on them or are you guys looking at the entire data yourself?
A: When giving the monoclonal antibody to SNF resident, there is a choice between the Bamlanivimab monotherapy or the Regeneron product, where the practice is to go with the latter, yes that is true. The update today was essentially given the concerns that they federal government shared about this west coast strain and the potential impact it has on Bamlanivimab efficacy, the recommendation at this time, until we have more information, is to stop with any Bamlanivimab therapy. The Bamlanivimab can be combined with Etesevimab for a combination product. That can be ordered directly.

Q: We have the combo product available to use. It doesn't matter what their vaccine status is if they have COVID and they are symptomatic, we should use the product regardless of vaccine status correct?
A: So there's a recommendation about if after you have received the monoclonal treatment with 90 days before getting you next vaccine, but if the person has been vaccinated, if they have received one dose, there is nothing that prevents them from getting the monoclonal treatments.

Q: Ok thank you. And in terms of the antibody titer data in post vaccinated patients who get COVID, should we be collecting titers or serum to save for the state? Are you doing anything about that?
A: The virus lab does have two different assays that basically they are able to discriminate between a vaccine antibody response versus an infection antibody response. We haven't actually put any formal guidelines as to whether you should be sending those but if you are interested in looking at that. If you want to reach out to your Local Health Department (LHD) then reach out to us, we would be happy to work with you on that particular patient or patients.

Q: Our LHD is asking that for all our admitted patients to the hospital, that we submit their samples to the Public Heath, which I assume is for full genome sequencing. Is that being more widely directly to other health departments or other hospitals, to get their admitted COVID swabs sent? Is that part of the push to get more testing done?
A: I don't think that's necessarily a statewide directive. The state is working on guidelines for the LHDs on what to do when you have vaccine breakthrough cases. What jurisdiction do you live in?
Q: Contra Costa
A: I'm sorry I can't answer that question. I'll try to get you an answer and send you a quick email.

Q: We've been seeing breakthrough cases after two doses and 14 days. With these cases, almost all of them, out of seven or eight cases, we have only seen one with any symptoms whatsoever. Some of their cycle threshold (CT) values are at the borderline of 30 that the state was using. If we think this is one of the groups that we are focusing on in the breakthrough cases, can we use a higher level, say 35 or is that a hard cut at 30 and below?
A: The reason there is a cycle threshold cutoff is that the success of actually doing sequencing off samples with that really high CT value is really low. Are these patients not hospitalized?
Q: Yeah, they are all symptomatic except one.
A: Why was testing done?

Q: We are focusing on people who have vaccine breakthroughs. We are looking at specific groups of people. That's one of them. People who've had a second case greater than 90 days from their first one and people who've traveled. We are looking for potentially high-risk people for having variants.
A: I would think they would be less infectious. I think what we're particularly interested in is looking at people with symptoms and particularly interested in people with severe symptoms. I think the science group is working on guidelines for health departments about vaccine breakthrough cases.
A: I'm guessing these people being tested are being tested as part of the screening testing in a healthcare facility. That's what we've been hearing about most of these asymptomatic people, they almost all have high CT values that either reflect RNA fragment from past infection or they could be false positive. The other thing we don't know is if perhaps vaccinated people, if they do become infection, that they never get a low CT value. That would be interesting to know because they probably would never transmit to anybody. There are different things that can cause this. One thing that can be done to sort out these cases is to do another PCR test within 48 hours and if that's negative, in consultation with your LDH, you can decide to consider the first test as a false positive. If the second PCR is positive but still has a high CT value, that would indicate that the first test didn't catch person at the beginning of the infection because if it did, the second test should have a lower CT value. There is a lot of interpretation that goes on here. Some of these people that meet criteria for being a vaccine breakthrough case or they may be. As Carol said, we can't sequence, I think the lab is able to accept up to 33 for sequencing but I think it's 30 for culture but sequencing is what we are most interested in. We are trying to write guidance on this but it's difficult because if these people turn up in a healthcare setting like a nursing home, the next question is "Do they need to be isolated? Do we have to start response testing around them?" and all those questions. I think the HAI program is trying to come up with some guidance about how to manage these. The other thing I should mention is that I anticipate, and CDC has signaled that they're looking at the whole issue of continued screening testing of fully vaccinated people. It may be that CDC will say fully vaccinated people do not need to participate in screening testing program. Of course, that would solve some of this.
A: These are tricky to sort out. I think it's helpful to separate out how we are thinking about potential vaccine breakthrough and the need or ability to further work those up, as far as sequencing etcetera, from how we manage these individuals who are in a healthcare setting such as a healthcare facility where they are being routinely tested. I think the trickiest scenario is the one in which you have

somebody who was previously positive, they are past 90 days from their prior positive, in the mean time they've been fully vaccinated, they get tested and are asymptomatic positive with a high CT value without any know exposure. Right now, it's kind of a nuanced evaluation considering the CT value. It can be really helpful to get a repeat PCR test within 48 hours which would be considered a confirmatory test for the positive. If that is negative, then there's your answer. You could consider that positive a false positive in that situation and I don't think it would be warranted to isolate or carry out any response testing for that. If their CT value is persistently positive albeit high or lower, that's where I think it becomes a bit murkier. Because in part that we don't always get CT values and it can sometimes difficult to obtain CT values even if it's available at the lab, many times we're isolating these individuals. If it's just an isolated case of a single healthcare personnel working in a facility who is known to have been previously positive and asymptomatic, tested routinely, no known exposure, no other positives among healthcare personnel or residents, you know, in those situations, maybe you isolate the individual again but don't necessarily pully the trigger on the full on response testing and all the other things we might do in terms of restricting visitation for the residents of the facilities in the acute setting of an outbreak. So those are complicated scenarios and then of course with residents as well. Usually residents that are asymptomatic are being tested as part of a response to a case, in which case we would consider that as potentially exposed. I think we're likely to err on the side of isolation in these instances, but again, depending on the context, whether there's other evidence of transmission or exposure in the facility, we would based decisions around continued response testing on the basis of what else was going on in the facility. HAI is available and has been fielding a lot of these questions with LHDs and will continue to be and hope for some additional guidance around the interval between a prior positive in particular and when to resume routine screening testing, especially in fully vaccinated individual because these can be so hard to sort out. I would emphasize that it can be helpful in these instances where you get a positive and it can be helpful to obtain a confirmatory test within 48 hours and if it's negative, consider those false positives. That might help alleviate some of these complicated tricky situations.

Q: I have a different perspective on almost everything from what everyone said because I see this as an infection with a vaccine breakthrough, but the manifestation of that infection is attenuated. The vaccine is working and it's creating an asymptomatic or very mild disease. We've seen this with many vaccines. Some kids get a varicella rash very later after they're vaccinated. It's a totally different vaccine, I understand that. So I don't know if a second PCR would help you because, as we're seeing in the CT, there's not much virus there. The vaccine is working but there is a virus, but we don't know how infectious, probably not very, and then you have to decide what to do and that's the hard part. We had one SNF that insisted it was a false positive and it repeated testing. So, we had a positive followed by two negatives, another positive and then a negative. So how do you interpret that?
A: I think those are difficult, and in many instances, kind of uninterpretable. I would clarify that I'm primarily referring to situations where you have an individual who was previously positive. Where we know that individuals can continue to have viral fragments that might show up as positive but with high CT values down the road for prolonged periods of time. In those situations, we have found it to be helpful to get a repeat PCR. I think I would agree that what we have seen, for individuals who aren't known to have been previously positive that meets criteria for vaccine breakthrough and for all we know, it's a new positive acute infection. We would isolate those as you would any individual that an acute infection is suspected or at least can't be ruled out. It's intriguing to see that these individuals tend to have higher CT values and tend to be asymptomatic when they've been vaccinated, and it'll be interesting to see how that pans out if that truly is an indicator of attenuated infection.

Q: Regarding the CDC guidance about fully vaccinated people being around other fully vaccinated people without masks or social distancing or the other option they gave about someone who is fully

vaccinated could be around an unmasked person of low risk. Does CDPH support those guidelines and is there going to be anything official put out in that regard?
A: I just want to clarify that the guidance that came out last week on March 8th is not for healthcare settings. It's for non-healthcare settings. In general, CDPH agrees with that guidance and we are planning to put out a document on that. Hopefully that will be out soon.
A: That guidance is not for healthcare settings. We are still recommending universal source control even for fully vaccinated healthcare personnel and also the continued use of personal protective equipment until we know more.

Q: For new admissions that are admitted to the hospital, do they need to have a private room when coming in since they don't have to quarantine? Can they have a roommate?
A: Just to clarify, the CDC guidance is referring to fully vaccinated new admissions. New admissions who are not fully vaccinated would still be quarantined or admitted in an observation status. Those ideally would be single rooms, but we understand that is not always feasible. So, if a multi-occupancy room is used then we would recommend that the bed space be kept as far away as possible, ideally a minimum of six feet, curtain drawn and the use of PPE. For newly admitted residents who are fully vaccinated with no known exposure in the prior 14 days, they could be admitted as you would with any new admission.

Q: Can they can go to our therapy room to do therapy? They don't have to stay in the room, correct?
A: Yes, that right. They would be managed as any of your presumed unexposed residents. I would also recommend reviewing your plans with your LHD as well. There may still be situations where LPH for example, if there's known transmission occurring in a particular acute care hospital there still might be situations where even the fully vaccinated newly admitted residents might need to be quarantined if there was a known exposure in the setting they came from.

Q: What do we do as far as an employee who has received both of their COVID shots and it's been greater than three months and they encounter a situation where they are being exposed? Is there a plan or action where we're going to say "Hey we're going to start from scratch. You have to quarantine yourself because it's been longer than three months". Are there any plans around that situation?
A: No not at this time. CDC clarified that they are no longer recommending that three-month consideration. Their current recommendation, no longer requiring quarantined work exclusion for fully vaccinated healthcare personnel does not have that three-month caveat at this time. Facilities need to be aware that CDC is going to continue to review and updates these recommendations and that they could be updated as additional information, including the ability of the current vaccines to prevent infections with the novel variants and effectiveness of any additional authorized vaccines and duration of effectiveness. As information becomes available there might be new recommendations that could result in some additional circumstances with work restrictions for fully vaccinated healthcare personnel could be recommended again. But at this time, no there is no three-month consideration.

Q: So basically what you are saying is if it's been like for months since the second dose and there's been an exposure, obviously we always follow the signs and symptoms, but you're saying that there are no guideline that we will have to start from scratch and quarantine particular employee. So then basically we don't have to do that. They can continue working so long as there are no signs or symptoms correct?
A: That is correct as long as they are asymptomatic.

Q: With Bamlanivimab is taken out of California, is there any clinical evidence that it was failing, because we had a very high success rate until this. And the federal government, is it just a guess that it

may not work because the spike protein has changed a little bit, or do you know any information on the clinical decision they made?
A: We've followed up with the federal government to ask this very question essentially, what the supporting evidence may be. They've yet to share anything so I'm not entirely sure what the basis is. I just know that it's a concern that they share pretty widely with Arizona, Nevada and California and they've stopped distribution of that drug to those tree states. We'll follow up and expect some information soon. Unfortunately, we don't have any hard-clinical evidence to share on this call.

Q: Is that a recall? Do we need to send it back?
A: No there is no recall. I think part of that may be that the Bamlanivimab can be combined with the other monoclonal product, Etesevimab, for the combination which has shown good evidence in terms of reducing hospitalizations and deaths. There's a relative risk reduction of 70 percent. So, there's no recall as the product can be combined with Etesevimab and be used effectively. Any stock on hand can remain.

Q: I just wanted to clarify the latest AFL that was released regarding visitation versus the CMS QSO 20-39 updated release which was released two days after California's was released. I just wanted to clarify, in the California release, there was no limitation for indoor visitation however CMS indicated that unvaccinated residents if the facility positivity rate is greater than 10 percent and less than 70 percent, Residents who are fully vaccinated would have to limit indoor visitations. Same thing on the California AFL. It says even on the yellow area, we can go and do visitations, but CMS is saying residents on quarantine whether vaccinated or unvaccinated should limit visitations. I also wanted to clarify if there was going to be an updated release to clarify the information as far as visitation is concerned for indoor visitation where there is an outbreak. CMS indicated that visitation would have to stop where there is an outbreak, but our AFL does not indicate that.
A: Great question. We have received a lot of questions on this since the two do not align. We will be enforcing the CDPH guidelines which are more in line with Title 22 and the federal guidelines for patient rights. So typically, where there are discrepancies between CMS and CDPH, we go with the strictest, meaning strictest closest alignment to the actual reg. In this case, the strictest closest to the actual reg, is actually the least restrictive for visitation which is the CDPH guidelines. We will put that in writing in the notes today, so everyone knows. We even instructed all of our staff yesterday. Told our surveyors that we will be using the CDPH guidelines. We have talked with CMS about that. That is what we will be using as guidelines. We won't be updating that AFL but we are working on a crosswalk document that kind of helps explain the two because in some cases the QSO memo is similar to ours, it's just that they use different language or we use different terminology. We will be providing a crosswalk attachment to our AFL. We'll continue to answer questions on our weekly webinar tomorrow and our Thursday for skilled nursing facilities. But yes, you are correct. CDPH guidelines states that if there is an outbreak, yes there are still safe way to still have forms of visitation in the facility. An outbreak definition for skilled nursing is just one case and we do not want to have to shut down facilities every single time there's the singular case even if it's asymptomatic or especially if it's a breakthrough case. It won't pose danger to other or risk. We also expect that yes, visitations can happen in quarantine or what we call the yellow zone, and we list out the ways that can be done safely as well. The key is that we must be able to keep open and make sure we have a safe way for people to connection, otherwise you have downstream effects that are even worse.

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