California Department of Public Health
Weekly Facility COVID-19 Update Call
April 20, 2021
8:00 am – 9:00 am

AT&T Meeting Recording: 1 (866) 207-1041
Access Code: 6094940
Available after 12 Noon 04/20/2021

I. **Welcome / Introduction** — **Cassie Dunham**

- None Provided

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

- None Provided

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

Variants of high consequence

Currently, there are NO SARS-CoV-2 variants that rise to this level.

Variants of concern (VOC)

The list of VOCs have remained the same for past several weeks; B.117 (first identified in UK), B.351 (first identified in South Africa), P.1 (first identified in Brazil) and B.1.427 and B.1.429 (first identified in CA, sometimes referred to as West Coast or California variants) are currently on CDC's classification as variants of concern..

Nationally: B.117 is the most common VOC in the US and represents > 40% of variants sequenced while the proportions of B1.427/1.429 decreasing.
The numbers of P.1 and B.351 remain relatively low (1-2% of all sequenced)

In California: In California the proportion of B.117 is not as high as many other states but in the past several weeks we are seeing an increasing in proportion of cases. For example, the percent of B.117 was ~1-2% in January, ~4-5% in February and increased to ~20% of sequenced samples in March). B.1.427/B.1.429 proportions are decreasing (~60% in February, ~50-55% in March).

In March, almost 200 individuals were identified in CA with P1-this is a large jump in number of cases but overall represents small proportion of overall cases.

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

Variant of Interest (VOI)

B.1.526 (first detected New York), B.1.525 (first detected in Nigeria) and P2 (originally identified in Brazil). These variants have potential for immune evasion (reduction in neutralization by antibody as well as potential decrease neutralization monoclonal antibody). California has some of these variants but fairly low numbers. (B.1.526-78, B.1.525 –5 and P.2-33).
(B.1.617 (India) aka "double mutant'/not yet added to CDC list of VOI)

Sequencing efforts

The identification of these variants continues to underscore the importance of WGS. Through COVIDNet, WGS capacity has increased substantially in the last month. Currently ~10% of all positive samples are sequenced (this is ~ same level of UK).
Not only has capacity increased, VRDL and some local PHLs have WGS instruments (Clearview) that can expedite WGS with results within 24-36 hours for high priority and urgent samples.

We encourage physicians to submit samples for WGS. In particular, we are interested in samples from patients who are critically ill patients and any patient hospitalized with what appears to be a vaccine failure.

Information to be included

1) Fully vaccinated – Yes/No (Yes = 14 days post final vaccine)
2) Acute symptoms that could be explained by COVID-19 infection? – Yes/No
3) Hospitalized at time of report – Yes/No
4) If hospitalized, requiring ICU level of care at any time during hospital stay – Yes/No
5) If hospitalized, requiring mechanical ventilation at any time during hospital stay – Yes/No
6) Patient died of illness – Yes/No

Aware that several local public health departments have already reached out to their local hospitals and encouraged submission of samples. For those submitting samples, request that basic clinical information (as above). (I was on call yesterday with several local public labs who report that they are received lots of samples but no clinical data so don't know if hospitalized vs. non hospitalized, vaccinated vs not vaccinated)
We will send out guidance with specific guidance on submission of 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 - GRINCH report
    - 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 CDPH updated AFL 20-22.7 – Guidance for Limiting the Transmission of COVID-19 in Long-Term Care Facilities with additional visitation consideration for pediatric long-term care facility residents.

In addition to adhering to the general visitation guidelines outlined in this AFL, pediatric long-term care facilities should additionally:

- Involve Child Life workers, parents, legal guardians, or authorized representatives in planning the facility visitation program and the most developmentally appropriate visitation program for each resident, including residents who may not have family who can visit. The visitation program shall provide routine and ongoing visitation to meet each resident's developmental and medical needs.
- Visitors may include parents, legal guardians, or authorized representatives of the pediatric resident and family, regardless of age. Child visitors must be able to observe the required infection control practices, (e.g., source control, hand hygiene, physical distancing) and should be accompanied by an adult visitor.
- Visitors may also include educational instructors, special education aides, and physical, speech or other therapists and service providers who are referenced in a resident's Individualized Education Plan, Section 504 Plan, Individualized Program Plan, or Community Placement Plan.
- Extended periods of physical contact may be allowed between the pediatric resident and fully vaccinated visitors.
- Encourage COVID-19 vaccination of staff, visitors, and residents who are 16 years or older for Pfizer-Biotech, 18 years or older for Moderna and Johnson & Johnson's Janssen vaccine.

On the subject of visitation, we'd like to remind facilities of the importance of safe visitation practices and monitoring to ensure these practices are followed. Visitors must wear a face covering upon entry and at all times within the facility. Visitors should maintain 6-ft physical distancing from other visitors not from the same household as well as from other residents and the facility HCP at all times. All indoor visitors must go directly to and from the resident's room or designated space for visitation and stay in the resident's room or other designated space throughout the visit, i.e., they should not walk around in hallways or other common areas of the facility. Facilities should incorporate a process for monitoring these safe visitation practices in their visitation plans, and consider sharing a copy of your safe visitation plan and procedures with visitors to help them understand and facilitate compliance.

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

- FDA revokes EUA for bamlanivimab monotherapy

To summarize, two investigational monoclonal antibody products are currently recommended for use in California:

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

These products have received an emergency use authorization (EUA) for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients who are at high risk for progression to severe disease. Clinical trial data in outpatients have shown that these products may reduce COVID-19-related hospitalization or emergency room visits in symptomatic patients who are treated early.

All treatment sites can now order these products directly from AmerisourceBergen Corporation (ABC). 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.

Please note that the FDA recently released revised fact sheets for health care providers, which now include additional information on susceptibility of SARS-CoV2 variants to each of the monoclonal antibody therapies. The revised FDA fact sheets, which include this data, can be found in the meeting notes.

Given the sustained increase in variants resistant to bamlanivimab alone, and availability of alternative authorized monoclonal antibodies, the U.S. government has stopped the distribution of bamlanivimab alone. In March 2021, CDPH stopped recommending bamlanivimab monotherapy. And on April 16, 2021, the FDA revoked the EUA for bamlanivimab monotherapy.

In addition to these combination therapies, etesevimab alone is also available for direct ordering. **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.**

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 (see above).** However, under its EUA, bamlanivimab can be combined with etesevimab. See the Bamlanivimab plus Etesevimab EUA Fact Sheet for Providers for more information.

FDA Revokes EUA for Bamlanivimab

On April 16th, the FDA revoked the emergency use authorization that allowed for the investigational monoclonal antibody therapy bamlanivimab, when administered alone, to be used for the treatment of mild-to-moderate COVID-19 in adults and certain pediatric patients. Based on its ongoing analysis of emerging scientific data, specifically the sustained increase of SARS-CoV-2 viral variants that are resistant to bamlanivimab alone resulting in the increased risk for treatment failure, the FDA has determined that the known and potential benefits of bamlanivimab, when administered alone, no longer outweigh the known and potential risks for its authorized use. Therefore, the agency determined that the criteria for issuance of an authorization are no longer met and has revoked the EUA.

Please see the full FDA statement here.

Casirivimab plus imdevimab as well as bamlanivimab and etesevimab (administered together) continue to be available under EUA. There is no shortage of monoclonal antibody product. Sites that are administering monoclonal antibodies can order bamlanivimab and etesevimab, etesevimab to pair with the current supply of bamlanivimab that the site has available, or casirivimab/imdevimab from the authorized distributer using the direct ordering process.

Additional Resources
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.

Bamlanivimab – ***Bamlanivimab alone without etesevimab is not recommended for use in California:***
HHS/ASPR Bamlanivimab Update re: SARS-CoV2 Variants of Concern
Fact Sheet For Health Care Providers Emergency Use Authorization (EUA) Of Bamlanivimab (fda.gov)

Bamlanivimab/Etesevimab
Fact Sheet For Health Care Providers Emergency Use Authorization (EUA) Of Bamlanivimab And Etesevimab (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
Fact Sheet For Health Care Providers Emergency Use Authorization (EUA) Of Regen Covtm (Casirivimab With Imdevimab) (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)

HHS/ASPR Call Center for Questions and Information Related to Monoclonal Antibodies:
Please share broadly with your networks of patients and providers.
English: 1-877-332-6585
Spanish:1-877-366-0310

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
- On 4/13/21, CDC and FDA recommended a pause on the use of Janssen vaccine following reports of a rare and severe type of blood clot occurring in a small number of vaccine recipients. The pause continues. Providers should not refuse any vaccine shipments, and follow the CDPH operational guidance linked in the meeting notes.
    - People who have received the J&J vaccine who develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination should contact their health care provider.
    - Health care providers are asked to report adverse events to the Vaccine Adverse Event Reporting System at https://vaers.hhs.gov/reportevent.html.
    - The American Society of Hematology released clinical guidance regarding the diagnosis and management of Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT), which is linked in the meeting notes.
    - CDC and the American Society of Hematology are holding a webinar today 4/20/21 at 10am. The call information is in the meeting notes, or can be found on the American Society of Hematology Vaccine-Induced Immune Thrombotic Thrombocytopenia page
        - Please click the link below to join the webinar:
            - https://www.zoomgov.com/j/1600672158?pwd=YUF2Q29ORmxCMnBDbi84Y2xLdkRYUT09
            - Passcode: 810423
            - Or One tap mobile:
            - US: +16692545252,,1600672158#,,,,*810423# or +16468287666,,1600672158#,,,,*810423#
            - Or Telephone:
            - US: +1 669 254 5252 or +1 646 828 7666 or +1 551 285 1373 or +1 669 216 1590
            - Webinar ID: 160 067 2158
            - Passcode: 810423
            - International numbers available: https://www.zoomgov.com/u/achNm2sQkg
    - The ACIP is meeting on Friday 4/23/21, and further guidance is expected following the ACIP meeting. A link to the Friday webcast is in the meeting notes: https://www.cdc.gov/vaccines/acip/index.html
- Blue Shield is California's Third Party Administrator to build an enhanced vaccine network. Many local health jurisdictions have been added to the Blue Shield Network. Providers who have not signed agreements with the TPA will likely not be able to receive any more first dose allocations after mid-April. Second dose requests will be honored until all previously-started series are complete. Providers interested in becoming part of the vaccine network should contact Blue Shield at CovidVaccineNetwork@blueshieldca.com.

Doses/allocation:

- As of 4/19/21, 31,625,990 doses of COVID-19 vaccine have been delivered to LHJs and other provider sites. To date, 25,790,401 have been administered. 10,269,507 people have been fully vaccinated. The CDPH vaccine dashboard has been posted and is linked in the meeting notes: https://covid19.ca.gov/vaccination-progress-data/
- As of 4/19/21, 836,754 vaccine doses have been administered to long term care facility patients and HCWs in California via the CDC-LTC Pharmacy program with CVS and Walgreens. 496,297 individuals have had at least one dose of Pfizer vaccine, and 333,515 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. This program officially concluded on March 31st, although both CVS and Walgreens have a small number of clinics remaining through the end of April.

The following pharmacy partners are receiving doses via the CDC Federal Retail Pharmacy Program:

- Long-term care pharmacies: Innovatix, GeriMed, MHA, and select Cardinal member pharmacies. A link to the pharmacies included under each of these pharmacy groups can be found on the CDC website: https://www.cdc.gov/vaccines/covid-19/downloads/participating-ltc-pharmacy-list.pdf.
- Retail pharmacies: CVS, Rite Aid, Walgreens, Albertson's, Cardinal, Walmart, Topco, Kroger, CPESN, HealthMart, and GoodNeighbor. The pharmacies are receiving federal allocations of Moderna, Pfizer, and Janssen vaccine. Eligible persons can make appointments at the pharmacies' individual websites. Link with pharmacy scheduling links.

Clinical considerations for vaccines The CDC clinical considerations website is updated with the most recent information about all three vaccines. The most recent update to the page includes additional information regarding the Janssen vaccine pause. There are a number of useful job aids linked on the website. 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

- All Californians 16 and older are eligible for COVID-19 vaccines as of April 15, 2021.
    - https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/VaccineAllocationGuidelines.aspx

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/**
- **Authorized Vaccinators: https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/Authorized-Licensees.aspx**
- **How to report inventory in Vaccine Finder.**

VII. **Questions and Answers**

Q: What is the recommendation for screening employees after the 90-day post vaccination after exposure?

A: That no longer exists. Anyone who is exposed to COVID-19 after 90 days no longer has to quarantine as long as they remain asymptomatic.

Q: When was that announced and where can I find that in writing?
A: It came out after the initial guidance on fully vaccinated individuals. We can include the link to the CDC guidance in the notes.

Q: Is there going to be anything officially released on that?
A: Those studies are still ongoing. I'm not aware of any definitive updates as of yet. I think we can anticipate some of the interim or preliminary results of those studies of the duration of immunity hopefully soon.

Q: Is there any specific guidance on how long employees need to be out that have been vaccinated and show COVID related symptoms but no known COVID exposure?
A: Any employee who shows symptoms should be tested regardless of their vaccination status. The results of those tests should guide their management. If it's positive, they should isolate for the symptom-based duration which is generally 10 days with resolution of fever and improvement of symptoms. We know that the vaccines are highly effective in preventing both symptomatic as well as emerging evidence on preventing asymptomatic infection but of course, vaccine breakthrough cases do occur.

Q: So as long as they are testing negative then they can return upon resolution of symptoms without a specified duration?
A: That is correct with the caveat that a symptomatic individual who tests negative using the POC antigen test needs to have that confirmed with a PCR test because it's a less sensitive test. If the PCR test is negative in the context of their symptoms, then in general, we could consider that negative and their return to work would be based on your usual.

Q: Is there any guidance from CDPH for testing patients utilizing antigen testing as opposed to PCR testing for screening our patients prior to surgery?
A: There's been CDC guidance for quite some time for the use of testing universally prior to surgery with the caveat that the test only tells you the individual's status at the time of collection. If it's positive then you can act accordingly but if it's negative, there is the potential for some false reassurance because the individual could become positive if they had an exposure leading up to that time period when the test was obtained but they weren't positive yet. They could become positive later. Provider still need to keep in mind that they still need to use PPE. There is no recommendation against use of those test but every provider needs to understand the limitations of the testing.

Q: Is there any update on prevalence of the California variants and the South Africa variants and any concerns about the reduced susceptibility to Bamlanivimab and Etesevimab?
A: The west coast prevalence is much less common in many areas of the U.S. In California and the West Coast, these are more common. They've been around 50-60% of prevalence. In March, we did see a slight drop off. In February they were about 61% of our samples that were sequenced and that decreased to a little bit less than 50%. So they remain very prevalent in California but potentially decreasing with the idea that we think maybe the B117 has the advantage. We are seeing an increase in the B117 and a slight decrease in the West Coast variants although it's still very common. For the South African variant, thankfully we have not seen very many of those. We saw less than 30 of those statewide in March and only making up 0.3% of all sequence, so less than 1%.

A: To the B117 variant, there was no reduction in susceptibility so at least per the pseudo virus neutralization data. That seems like the activity would be preserved for the West Coast strain, the B1427 and B1429. There was some reduction in susceptibility that was noted not to the extent where the factsheet declared that the combination therapy would likely not be effective, but this is where we don't know how well the pseudo virus neutralization data will correlate with clinical outcomes so it's a little tough to say. Given that it wasn't a complete reduction in susceptibility, there does seem to be some maintained activity at least invitro. At this point, it's reasonable to continue treating with that combination therapy.

Q: One of the ambulatory surgical center companies in our area has made the decision to discontinue preoperative testing for COVID-19 in patients who are more than two weeks and less than 90 days post vaccination. I'm not aware of any specific data that would justify that and curious as to CDPH's position on that, for elective surgical patients who are not going to undergo aerosol generating procedures to be specific.
A: I don't believe that CDPH or CDC has made a new recommendation on prescreening testing relative to the individuals vaccination status. It could be reasonable to not test those individuals so long as they are asymptomatic, perhaps one could consider testing them if they've had a known exposure or recently traveled or something like that. I would add, going back to the first question, the whole 90-day limit on full vaccination where you would consider the individually fully vaccinated for the purpose of limiting quarantine etcetera is no longer a limit. And so the same recommendations would apply indefinitely after full vaccination until we hear from CDC otherwise.

Q: Understood and I get where they extrapolate the data from but from the standpoint of hospital based ambulatory surgery, is it not still the expectation that all hospitals will test all preoperative patients?
A: You're correct that they recommendations for hospitals have not changed at this point for testing individuals at time of admission. I think many have extrapolated that to individuals who might be undergoing ambulatory surgery to necessarily get admitted. There's ongoing discussion and rereview of guidance and upcoming literature around testing recommendations related to individual's vaccination status so stay tuned but those haven't changed at this point.

Q: I'm asking about Intermediate Care Facilities Developmentally Disabled Habilitative (ICF/DD-H) and Intermediate Care Facilities Developmentally Disabled Nursing (ICF/DD-N) as far as getting some updated guidance and including perhaps consideration for being included in the revised AFL 20-22 and the new AFL 21-08 or perhaps looks a something else coming out for guidance for our families for visitation and outings?
A: I can share that we are currently drafting guidance specifically for ICF DDs. That information will hopefully come out later this week or at the latest, early next week but yes, that information is being drafted as we speak.

Q: Are they adjusting the testing cadence for fully vaccinated employees working at SNFs? My concern is that we are still doing weekly testing and we have a lot of data entry from the antigen tests, etcetera. I know that state has said that they no longer need us to put in the negative test, but our county has requested that we continue that.
A: The guidance is also in review and I think we anticipate updates forthcoming. At this time that hasn't changed so the recommendation is currently still a minimum of weekly testing. I would caveat with regards to the use of point of care antigen testing, that should be done more frequently in asymptomatic individuals that are being testing as part of a screening testing program. I believe the guidance is a minimum of twice weekly because of the lower sensitivity of the antigen test.

A: If you are testing through the state antigen testing program, the state also provides access to a reporting system through Primary, which is an application service that will help ease the burden of reporting and make it easier to use antigen testing. If you are interested in learning more, you can go to Testing.COVID19.ca.gov to read more about that. It's been used in other areas across the state including schools and people really liked it.

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