California Department of Public Health
Weekly Facility COVID-19 Update Call
May 18, 2021
8:00 am – 9:00 am

AT&T Meeting Recording: 1 (866) 207-1041
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I. **Welcome / Introduction** — **Cassie Dunham**

- None Provided

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

- None Provided

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

Variants of high consequence
There are NO SARS-CoV-2 variants that rise to this level.

Variants of concern (VOC)
CDC's list of five VOCs have remained the same for past several weeks; B.1.1.7 (first identified in UK), B.1.351 (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.

Variants of interest
CDC's list of VOI include B.1.526 (first identified in New York) and B.1.516.1 (first identified in NY) , B.1.525 (first identified in Nigeria), P.2 (first identified in Brazil) . The B.1.617 lineages (first identified in India) were recently added to VOI list and include
B.1.617, B.1.617.1, ***B.1.617.2*** *and B.1.617.3.*

International News
Last week, mentioned that the UK had added B.1.617 as VOC. Due to a sharp increase in B.1.167.2, suggestions that this variant more transmissible > B.1.1.7. Also saw a mild increase in B.1.617.1 case mostly related to travel to India. The variant being detected throughout Europe.

WHO has also added B.1.617 as VOC pointing out that B.1617.2 appears to have a **higher transmissibility**, less response to at least one monoclonal and has mild reduction neutralizing antibodies?

About B.1.617

The four lineages all have the L452R mutation and three have the E484Q so concerns about decrease effective of monoclonal antibody and increase transmissibility. Of very limited data, slight decrease in neutralization (two-fold which is less important than P1 and B351). Included in transcript table from CDC:

Name (Pango lineage)	Spike Protein Substitutions	Name (Nextstrain)	First Detected	Attributes
B.1.617	**L452R, E484Q**, D614G	20A	India February 2021	• Potential reduction in neutralization by some EUA monoclonal antibody treatments • Slightly reduced neutralization by post-vaccination sera
B.1.617.1	(T95I), G142D, E154K, **L452R, E484Q**, D614G, P681R, Q1071H	20A/S:154K	India December 2020	• Potential reduction in neutralization by some EUA monoclonal antibody treatments • Potential reduction in neutralization by post-vaccination sera
B.1.617.2	T19R, (G142D), **Δ156, Δ157,** R158G, **L452R,** T478K, D614G, P681R, D950N	20A/S:478K	India December 2020	• Potential reduction in neutralization by some EUA monoclonal antibody treatments • Potential reduction in neutralization by post-vaccination sera
B.1.617.3	T19R, G142D, **L452R, E484Q,** D614G, P681R, D950N	20A	India October 2020	• Potential reduction in neutralization by some EUA monoclonal antibody treatments • Potential reduction in neutralization by post-vaccination sera

India

India now accounts for 50% of world's cases. However, for the first time since April 21, 2021 <300,000 cases/day. Very little WGS data from India but anecdotal reports that the B.1.617 is one of the factors responsible for surge in cases. *According to Oubreak.info—13,289 samples sequenced;* 19% of samples sequenced are B1.617.1 (prevalence last 60 days; 27% last 60 days)*, 11% of samples sequenced are 617.2* (prevalence last 60 days; 32%).

Nationally

From CDC website (updated every Tuesday evenings)

B.1.1.7 continues to increase and ~now represents 60-70% of variants sequenced. Additionally, **P.1 is increasing** in most regions of the US (5% of sequenced samples). Other variants mostly decreasing.

California

The proportion of B.1.1.7 among samples continues to increase and is now ~60+% of samples sequenced (compares with ~1-2% in January, ~4-5% in February, and ~20% in March). Last week mentioned an increase of **P.1**. This trend continues and P.1 now makes up **16%.** B.1.617.2 makes up ~1% sequenced.

Antigen Testing & Variants

As you may remember for prior reports, there have been molecular assays impacted by variants (in particular the Thermo TaqPath assay, N terminal domain deletion in spike protein, part of the B.1.1.7 lineage) (total of four molecular assays have been affected by evolution of virus).

Most antigen tests target the nucleocapsid protein. This protein is fairly stable within the RNA of the virus and is present in high copy numbers. Most evolutionary analysis of SARS-Co-V-2 have focused on the spike protein since it is important both for receptor binding and entry (and therefore target

neutralizing antibody). Last week, a preprint published about uncommon nucleocapsid variant that DOES affect the performance of one of the antigen tests, the Quidel Sofia SARS antigen FIA test (https://www.medrxiv.org/content/10.1101/2021.05.05.21256527v1.) In this study, done at University of Washington in Seattle, Sofia antigen was negative in a specimen with high viral load. Whole genome sequencing revealed 2 coding mutations in the nucleocapsid protein; T2051 and D399N. The lab was then able to identify 6 additional specimens with same 2 nucleocapsid mutations and tested them with antigen tests. The Quidel Sofia assay was negative in these 6 samples. The Abbott BinaxNOW Covid-19 antigen test detected 5 of the 6 the one sample that tested negative Abbott antigen had theoretical Ct of 37.6 which exceeds the Ct 29-30). On a CDC call yesterday, representation from FDA said they are tracking this closely. (In GISAID, only 222 sequences with these mutations, global prevalence of 0.019% (exceedingly rare)).

A related publication, https://www.medrxiv.org/content/10.1101/2021.04.24.21256045v1. Study conducted by Abbott found that antigen assays detected B.1.1.7, B.1.351 and P.1 variants. (did not test other VOI/VOCs).

Vaccine & Variants

On prior calls asked about data vaccine effectiveness and variants. Not a lot of data yet. table below with some of the studies and other information on the topic (this is not a complete list.) Based on limited data, vaccines remain effective against most VOC/VOI but in some cases at a reduced level.

Country study conducted, first author, journal & title	Type study/settings	Vaccine studied	Results	Conclusions/ Other comments
Israel, Kustin T, medRxiv April 2021 *"Evidence for increased breakthrough rates of SARS-CoV-2 variants of concerns in BNT162b2 mRNA vaccinated individuals"*	-case control (vax vs unvax) -B117 predominant strain during study -B.1.351 rare	Pfizer	800 + samples :-250 became infected after 1st dose -150 after 2nd dose ---------- Higher rates of B1117 in partially vax vs controls,	**-i**ndividuals remain susceptible B117 single dose -protection vs B351 less > B117 and wild type (Ho-if vax less effective vs VOC ; proportion of VOC should be higher in vax > non-vax)
South Africa, NEJM, Shinde V, Efficacy of NVX-CoV2373 Covid-19 Vaccine against the B.1.351 Variant May 5, 2021	Phase 2a-b clinical trial, 16 sites in South Africa Aug-Nov 2020	Novavax vs. placebo	2,648 initially infected-15 infections vax vs. 29 infections/un vax. Of those Sequenced; 93% B.1.351	Novavax was "efficacious induced notable cross-protection vs. B.1.351"
Qatar, NEJM Abu-Raddad jj, *Effectiveness of the BNT162b2 Covid-19 Vaccine against the B.1.1.7 and B.1.351 Variants* May 5, 2021	Cohort study Analyze B.1.351 & B117 March 2021	Pfizer	385,853 had 1 dose 265,410 had 2 doses VE=87% for B.117 VE=72% for B.1.351	-efficacy vs. B.1.351 was ~20% < prior report (done in Dec) "*the reduced protection vs. infection with B.1.351 did not seem to translate into poor protection vs. the most severe forms of infection (hospitalization or death), which was robust, at greater than 90%*."
Israel, Lancet	Observational study May 2021	Pfizer (this is primary vax used in Israel)	232,268 cases: 7,694 hospitalizations with -mild/mod disease with severe and 1113 deaths. VE (at least 7 day after 2nd dose) = 95.3%	
UK, Science April 2021 Reynolds CJ *Prior SARS-CoV-2 infection rescues B and T cell responses to variants after first vaccine dose.*	Health care workers Purpose: determine if single dose vaccine, w, and w/o prior infection, provides protect vs. variant	Pfizer	Following 1 dose, those with prior infection showed enhance T-cell immunity, B cell response to spike and neut antibodies vs. B117 and B.351	Single dose vax in setting of prior infectious with different variant enhance neut. ab vs variants
Press release http://www.modernatx.com Background:6-8 months after primary vax, wild type remains high but titers vs B351 and P! lower	On-going phase 2 study, 3 strategies for boosting neut titers in previously vax. 1) mRNA-1275.351 2) mRNA-1273.211 3) mRNA-1273.351	Moderna	Preliminary data ongoing single dose , given as booster to those with two-dose regimen 2 weeks after vax, neut titers increased	Authors concluded' '*the strong and rapid boost in titers to levels above primary vaccination also clearly demonstrates the ability of mRNA-1273 (original Moderna vaccine) to induce immune memory*."

New York, US, Hacisuleyman E, NEJM April 2021 *"Vaccine Breakthrough Infections with SARS-CoV-2 Variants"*	Case report, 2 cases	Pfizer	Patient 1: ~ 3 weeks after 2nd vax, mutations- E4844K and D614G Patient 2: ~4 weeks after 2nd vax, mutations: D614 G and S477N Both w/high neutralizing ab	"potential risk of illness after successful vaccination and subsequent infection with variant virus" Both outpatient & recovered fully at home

Sequencing efforts

Identification of variants continues to underscore the need for WGS.

We continue to encourage physicians to submit samples for WGS. In particular, as you have heard me mention for the last few weeks, we are doing a 'call for cases' to obtain samples on individuals who are hospitalized.

- We are aware that several local public health departments have already reached out to their local hospitals and encouraged submission of samples. This request for specimens' supplements and does not replace calls for samples by local health departments. For those submitting samples, we request basic clinical information – acuity of illness (e.g., ward vs. ICU, intubated or not, and prior receipt of vaccine).
- We also request that serum be submitted along with respiratory samples. Serology at VRDL includes *BioRad ELISA for Ab to nucleoprotein and UBI ELISA for IgG to nucleoprotein and spike. Antibody to nucleoprotein is consistent with infection while antibody to spike protein is consistent with natural infection or vaccine response. Unlike WGS, these results can be reported back to clinicians and to the patient.*

Links:

- https://outbreak.info/
- https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/COVID-Variants.aspx
- 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 CDC updated their **Interim Public Health Recommendations for Fully Vaccinated People,** to indicate that "fully vaccinated people no longer need to wear a mask or physically distance in any setting, including indoors, except where required by federal, state, local, tribal, or territorial laws, rules, and regulations, including local business and workplace guidance." **However, yesterday it was announced that California will keep its existing guidance around masks in place until June 15 when California aims to fully reopen the economy.** As of May 3, 2021, face coverings are no longer required outdoors except at crowded events, and for unvaccinated people, when physical distancing cannot be

maintained. In indoor settings outside of one's home, including public transportation and schools, face coverings continue to be required regardless of vaccination status. After June 15, California plans to implement the CDC's guidelines around masking to allow fully vaccinated Californians to go without a mask in most indoor settings. This four-week period is intended to give Californians time to prepare for this change while continuing to focus on delivering vaccines, particularly in underserved communities.

Participants on this call especially need to understand that CDC's **Interim Public Health Recommendations for Fully Vaccinated People do not apply to healthcare settings.** ***This means that staff, patients, residents and visitors should continue to wear masks as recommended in all healthcare facilities*****.** CDC recommends healthcare facilities continue to refer to the Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination for recommendations regarding source control and physical distancing in healthcare settings. In this guidance, CDC defines circumstances when, if **all** participants are fully vaccinated, visitation or communal activities and dining could occur without use of source control or physical distancing. This includes options for fully vaccinated HCP to eat or have in-person meetings with other fully vaccinated HCP without use of source control or physical distancing. **However, if any unvaccinated persons are present during any of these activities, then all participants in the activity should wear source control (when not eating/drinking) and unvaccinated individuals should physically distance from others**. ***When it is not possible to ensure all persons participating in an activity are fully vaccinated (e.g., in break rooms and other common areas where staff or residents may come and go), then all participants should follow all recommended infection prevention and control practices including physical distancing and wearing source control***. As such, activities where participants do not use source control and physical distancing should be carefully planned in advance and monitored so that vaccination status of all participants can be verified and ensured throughout the activity. CDPH is in the process of updating pertinent AFLs to address these recommendations and provide guidance for safe implementation, so facilities should wait for those AFLs before finalizing any changes to their practices.

Regarding the question of whether an employer (such as a healthcare facility) can ask an employee about their COVID vaccination status:

Generally asking employees for vaccination proof is not considered a HIPAA violation. Asking whether employees are vaccinated and to show proof is permissible, but asking why they were not vaccinated will tread into risky territory as to whether disability or religious beliefs are implicated. See: https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.

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

Topics: Updates to EUA fact sheets for monoclonal antibody treatments.

Monoclonal Antibody Overview

To summarize, two investigational monoclonal antibody combinations 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. The NIH has strongly recommended (AIIa) these treatments for use in non-hospitalized COVID-19 patients.

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.

On April 16, the FDA revoked the EUA for bamlanivimab monotherapy due to the sustained increase in variants resistant to bamlanivimab alone. The product is no longer available for direct ordering and no longer recommended for use.

Sites that have bamlanivimab and are administering monoclonal antibodies, should either:

- **Order etesevimab to pair with the current supply of bamlanivimab, or**
- **Order and use the casirivimab + imdevimab monoclonal antibody cocktail**

In addition to the above direct ordering process, both bamlanivimab (for use in combination with etesevimab obtained via direct ordering) 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.

Updates to EUA Fact Sheets for Monoclonal Antibody Treatments

On Friday, May 14, 2021, the FDA issued major updates to the EUAs for bamlanivimab and etesevimab administered together and casirivimab plus imdevimab (REGEN-COV), both authorized for the treatment of mild to moderate COVID-19 in eligible patients.

Updates include:

- Expanded definition of medical conditions and other factors that signify a high risk for disease progression.
    - Now states "older age (for example age >65 years of age)" rather than making age of at least 65 a requirement.
    - Hypertension, cardiovascular disease, chronic respiratory disease still included but no longer with age >55 co-requirement.
    - Sickle-cell disease, congenital heart disease, and neurodevelopmental disorders still included but no longer with age 12-17 co-requirement
    - Also added the following paragraph:
        - "Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of [these monoclonal antibody treatments] under the EUA [are] not limited to the medical conditions or factors listed above. For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/need-

extra-precautions/people-with-medical-conditions.html. Healthcare providers should consider the benefit-risk for an individual patient."

- Additional information integrating clinical trial safety analyses focused on adverse reactions and most common treatment-emergent adverse events
- Additional Phase 3 clinical trial results and supporting data for EUA

The Fact Sheets for both treatments can be accessed at the links above.

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/Etesevimab

- Bamlanivimab plus Etesevimab Distribution Fact Sheet
- 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 Cov (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)

Bamlanivimab – *The EUA for bamlanivimab alone has been revoked by the FDA:*

- Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Monoclonal Antibody Bamlanivimab | FDA
- HHS/ASPR Bamlanivimab Update re: SARS-CoV2 Variants of Concern
- Fact Sheet For Health Care Providers Emergency Use Authorization (EUA) Of Bamlanivimab (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**

As a reminder, three COVID-19 vaccines have received FDA emergency use authorization: Pfizer, Moderna, and Janssen.

Doses/allocation

- As of 5/17/21, 43,145,000 doses of COVID-19 vaccine have been delivered to LHJs and other provider sites. To date, 34,536,581 have been administered. 15,595,784 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/

Pharmacies continue to receive doses via the CDC Federal Retail Pharmacy Program:

- Eligible persons can make appointments at the pharmacies' individual websites. Please refer to MyTurn.ca.gov or Vaccines.gov to find doses at available pharmacies.

FDA extended the Emergency Use Authorization for Pfizer-BioNTech's COVID-19 Vaccine to ages 12 and older on 5/10/21, and CDC's independent Advisory Committee on Immunization Practices met on Wednesday, May 12 to review data on the safety, immunogenicity, and efficacy of Pfizer-BioNTech COVID-19 vaccine in adolescents 12-15y/o. The committee voted to recommend the use of Pfizer-BioNTech vaccine in 12-15y/o under the EUA. Link to ACIP meeting slides: ACIP Meetings Information | CDC

- CDC hosted a COCA Call for Clinicians on 5/14/21. The presentation and slides can be found here.
- The updated fact sheets for providers and recipient and caregivers are linked on the FDA website here.

CDC updated the Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC webpage on 5/14/21. There are a number of useful job aids linked on the website. Key updates from last week include:

- Updated information about authorized age groups
- Update on coadministration: Previously, CDC recommended a 14 day interval between COVID-19 vaccine and other vaccines out of an abundance of caution. The most recent guidance allows for COVID-19 vaccines and other vaccines to be administered without regard to timing.
    - This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days.
    - When deciding whether to coadminister another vaccine(s) with COVID-19 vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and the reactogenicity profile of the vaccines.

- **If multiple vaccines are administered at a single visit, administer each injection in a different injection site.** For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection.
- **CDC's** Best practices for multiple injections include:
  - Label each syringe with the name and the dosage (amount) of the vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
  - Separate injection sites by 1 inch or more, if possible.
  - **Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.**
- Additional information regarding COVID-19 vaccination and people with a history of **multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)**
  - Currently, there are no data on the safety and efficacy of COVID-19 vaccines in people with a history of multisystem inflammatory syndrome in children (MIS-C) or in adults (MIS-A).
  - People with a history of MIS-C or MIS-A may choose to be vaccinated.
- CDC recommends that persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as HIT, should be offered another FDA-authorized COVID-19 vaccine (i.e., mRNA vaccine) if it has been ≤90 days since their illness resolved.
- An update on people who are vaccinated who subsequently develop COVID-19
  - Cases of vaccine breakthrough that result in hospitalization or death should be reported to VAERS

Additional resources:

- Providers interested in becoming part of the vaccine network should contact Blue Shield at CovidVaccineNetwork@blueshieldca.com.
- 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.
- 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

VII. **Questions and Answers**

Q: Will you be providing specific verbiage in the AFL regarding vaccinated and unvaccinated healthcare workers so we know how to identify these people in our facilities? For example, during influenza season, we've provided stickers or a lock to healthcare workers that have been vaccinated. Is that something that will be provided in the AFL?

A: I believe that facilities need to be tracking the vaccination status of their staff. For skilled nursing facilities, there is a forthcoming requirement to report COVID vaccination number and percentages in

aggregate via the National Healthcare Safety Network or NHSN. How facilities track the vaccination status, at this point, is up to the facilities to decide. I think that many are actively discussing.

Q: Will you be updating AFL 20-88 regarding the testing of presurgical patients? For patients that have received the vaccine, will there be an update in regards to potentially removing these patients that have been previously vaccinated?

A: We anticipate an update to that guidance and in the AFL, although these have not been finalized and approved yet, I will say that the CDC has updated their guidance and included some considerations around modifying testing protocols for patients whose vaccination status is known prior to or upon admission. There are some case by case considerations depending on the level of risk involved in a given procedure. Per the CDC guidance, it's left to the facility to make their own assessment and determination. I will emphasize that unvaccinated patients as well as patients whose vaccination status is unknown or cannot be verified readily, may continue to be tested as has been the guidance and routine practice up until now.

Q: With regard to the AFL coming out to changes to masking guidance in the healthcare setting, specifically in the general acute care hospital setting, is there an ETA on that?

A: We should have that guidance out before June 15th. I would mention that the guidance will not necessarily change the masking requirements in healthcare settings.

A: The June 15th change is for the general masking guidance which is what the CDC changed. The CDC has made it clear in the guidance that they continue to recommend masks and physical distancing in healthcare settings for staff, patients, residents and visitors in most circumstances except in exceptional circumstances where it is possible to verify and ensure that all individuals participating in a specified activity or meeting are fully vaccinated. Again, this is not going to change on June 15th for healthcare settings.

Q: Ok so then if I understand in the foreseeable future, without verification of all parties involved, say a meeting or some sort of gathering within the healthcare setting, if it's not verifiable that all attendees are vaccinated then there is not going to be any changes to masking guidance within the healthcare facility.

A: Correct.

Q: I'm concerned because unlike most news reports, headlines and articles I've seen about the new CDC masks guidelines, the CDC says that if you have a condition or are taking medications that weaken your immune system, you may not be fully protected and talk to your healthcare provider. I was wondering what CDPH's advice is on this as a healthcare provider. I'm wondering what conditions or medications would make the fully vaccinated person, not fully protected? Also is there going to be any public discussion or will CDPH be putting out anything about this, I think, important exception?

A: If you go to the CDC's updated healthcare infection prevention and control recommendations in response to COVID-19 vaccination webpage, which I included the link in my transcript, you'll see a paragraph in the introduction where they provide some information about conditions that might affect response to the COVID vaccine. Although I am acknowledging that there are limited data on vaccine protection in these individuals but the do include some examples. Providers can discus with their individual patients as far as their decisions around continuing to wear masks themselves. It is recommended that healthcare facilities, when caring for these individuals, should continue to follow infection prevention and control recommendations similar to unvaccinated individuals as far as the need to quarantine or test when caring for these individuals who might have been vaccinated but were uncertain and concerned about the degree that they are actually protected.

Q: I'm on the website now and don't see the link that you are referring to. If you can point them out in the transcripts that would be appreciated?

A: This is the updated infection prevention recommendations in response to COVID-19 vaccination. The link is in my transcript and you'll find this section in a gray box under the introduction.

Q: What about some public relations about this. I just think that it's been left out of all the news reports that I've read or heard or seen in the lay press.

A: That's a good point. I'm not sure that we have the right folks on the line but that's something we can bring back for them to discuss.

Q: I work at a long-term skilled nursing facility and I was wondering, in regards to the screening tests for employee, how many personnel do we have to do each week if we are still in the red tier in our county?

A: The recommendation has been for some time that 100 percent of the skilled nursing facility healthcare personnel need to be tested at a minimum of weekly.

Q: Even though they are fully vaccinated? Will you be updating that guidance?

A: Updates to that guidance with regards to the need to test at that cadence for fully vaccinated individuals are in process. The updated CDC guidance has been that fully vaccinated individuals do not need to be routinely screened in that manner as long as they're asymptomatic and haven't had a known high-risk exposure. Updates to the AFLs that provide testing guidance are in process but again I'll emphasize that it has been for some time, the recommendation or requirement that 100 percent of staff be tested when screening testing is being performed at a given cadence. In California, we've indicated a minimum of a weekly cadence. I anticipate that for any staff that are unvaccinated, that they will continue to need to be tested at a minimum of a once weekly cadence regardless of the county positivity or tier, which again, the blueprint is going to be retiring, we anticipate, at the end of June.

Q: When is the vaccination requirement according to NHSN going to take effect?

A: I believe that's in mid-June correct?

A: That's correct.

Q: Going back to the prior question about the advocacy around vaccinated/unvaccinated masking guidance, what I'm hearing, we've heard for a couple of weeks that the AFLs will be updated and all helpful but what I'm hearing from you now is that probably you're not anticipating, even when that comes out, making a change for healthcare facilities. We've been talking about overall thinking safety first and we're in a land where we'll really be coexisting with COVID and so maybe the right question is would we ever go back to the way it was before or will social distancing and source control be a wave of the future? The one thing I want to add is the frontline staff are confused about what happened last week so we are doing our best to tell them that we were waiting on guidance. I think now we're hearing that's probably not going to change so that gives us a better message to speak. Also patients and visitors are getting angry that we are still requiring in healthcare. It's causing quite a concern out here in the field, that people are confused by the public version of what CDC has done and what is still required in hospitals. Lastly, I'll say is that because there has been a lot of local backlash on the idea of vaccine passports or records, if you actually look at the vaccine records, they are very easy to falsify. How do you really prove, without going to VERS, that people are actually vaccinated? I'm just curious on your thinking, maybe that's a question for Chelsea for the policy world about how we're going to message all of this to people in California over time.

A: We have been discussing how to update our messaging to the public. We typically have guidance that is issued to the public in general that we post to our website. I believe the plan is to implement that update to align with the June 15th date when we retire the blueprint. We will be including in our visitation AFL, when they're published, what the expectation is with regard to masking and distancing in healthcare setting. Hopefully that guidance will be coming out in the next week. That will provide the framework for you to communicate that to visitors going forward. I would just add that what happened last week with the updated CDC guidance does not apply to healthcare settings. You can inform visitors of that fact that the CDC guidance was not intended for healthcare settings. In general, California is going to defer to until the 15th. CDC already provided, a few weeks ago, some updated guidance that is more applicable to healthcare settings. It outlines somewhat specific scenarios where as long as vaccination status is known and can be verified, that there are some circumstances where individuals can participate in an activity without wearing masks or distancing, but those are really the exceptions. In general, everything is the same in terms of the need to wear a mask and physically distance when walking into a facility that applies to both healthcare personnel and visitors. Again, it's only the exceptional circumstances where they would be permitted to not mask and not distance. Hopefully the forthcoming AFLs will add some clarity to what those circumstances can be. The default should still be masking and distancing in healthcare settings.

Q: When we get to the point where we will be making the changes to masking, are we using the honor system similar to what the CDC has been discussing. I'm not sure if there's a way to be able to know who has or who hasn't been vaccinated both in and outside of the healthcare setting.

A: I think the honor system is problematic in particular in healthcare settings. CDC over the weekend clarified that the risk of not wearing mask is really born that that unvaccinated individual who's been

putting themselves at risk. I think that is generally true but in healthcare settings, I think we still need to consider the risk that places to the facility and the patients and residents in particular, other healthcare personnel in addition to those individual risks of unmasking where it's not possible to reliable verify and ensure that only the fully vaccinated individuals are not wearing masks. I think that everyone anticipates that a fair number of unvaccinated individuals who will just wear a mask and if that happens in most settings, again that probably just a risk to that unvaccinated individual, but in healthcare settings, if unvaccinated individuals are unmasking, they can put other at risk and especially patients and residents of other congregate residential facilities that cannot be vaccinated, and that includes children, who might have underlying conditions or treatments that decrease their response to vaccination and who themselves may not be able to mask while they're acutely ill in the hospital. These are all the reason why the default in healthcare settings is to wear mask and physically distance unless in controlled circumstances where the facility has been able to verify and is monitoring the vaccination status where it is indeed only fully vaccinated individuals who are not wearing masks and not distancing during a given activity. So not the honor system, basically.

Q: I have two questions. Some people say that it's a violation if HIPPA for an employer to ask about vaccine status. I don't think that's true but I would be interested to hear your response. The second question is to repeat what was said about the PCR testing for some of the variants being compromised.

A: About it being a HIPPA violation, I think that's something that we need to take back and talk with our medial information specialist to make a determination regarding that.

A: Healthcare facilities have an occupational health programs that are able to track and verify an employee's vaccination status for other pathogens like measles for example so there is some precedence of that.

A: About the molecular testing compromised by the variants, that's kind of old news, I was just reminding folks that in the Thermo TaqMan TaqPath assay there has been a S drop out. The nice thing about molecular assay is that they are going to target a couple of different regions so there's not going to be just one target. So people have noticed something has dropped off but the other two targets were positive. So somebody knew something was wrong. It wasn't that it was entirely negative, it was just an odd result. So that was what was seen in the B1.1.7 a few months ago and in fact it was a way that labs could quickly identify or screen for B1.1.7. The reason I brought that up today is that while those molecular assays had been kind of well known for a while, we hadn't really seen the antigen test being affected by variants. There is this new report and that citation will be in my transcript notes. Where the Sofia Quidel test is affected, by a very unusual mutation by the way, so its's not common but it's just important to know the Abbott test seems to continue to perform very well. Again all of this does underscore we need to keep an eye on these variants and we need to make sure that our antigen tests aren't being affected. There was somebody on the phone call yesterday from FDA on the CDC call, they're tracking this quite closely. I'll continue to report out if they find any additional compromise of the antigen test but so far Abbott's performing very well. Sofia is also performing well, it's just with this very unusual mutation, it did not perform well.

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