



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

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- I. **Welcome / Introduction** **Heidi Steinecker**
- II. **Overview** **Dr. Kathleen Jacobson**
- None Provided
- III. **Laboratory Update** **Dr. Carol Glaser**
- For the past two weeks on the laboratory portion of this call, we have been discussing SARS-CoV-2 variants. I will continue that discussion today.

As mentioned last week, RNA viruses such as SARS-CoV-2 mutate on a regular basis. A mutation is a genetic change. A variant is a virus with a specific set of mutations so we should not be surprised when we hear about new variants. Some of these variants emerge by chance and some emerge because they are a “more fit virus”, or in other words, they have a competitive advantage over other strains of the virus.

When SARS-CoV-2 variants are discussed, the WHO strongly encourages that we use nomenclature such as B.1.1.7 or B1.351 rather than terms such as the UK, South African or Brazilian variants. However, on a call such as this one, I will use these terms since it will be easier for most of you to follow.

On last week’s call, I highlighted 3 different variants-the UK, the South American/Brazilian and the South African variant. Today, I will update the status of those 3 variants as well as discuss a variant that has been detected in CA that has been in the local news in last 48 hours. This variant is currently being referred to as L452R variant.

To better understand some of these variants and what they might mean, it is particularly important to note that the SARS-CoV-2 virus genome encodes 4 structural proteins including the spike (S) protein, small protein (E), matrix (M), and nucleocapsid (N) proteins. These proteins are made up of building blocks called amino acids. (In some cases variants references are made to amino acid changes)

The Spike protein (or also called the S protein) is particularly relevant to our discussion. This protein is what allows the SARS-CoV-2 virus to unlock and enter human cells. The spike protein is used as a target

for some diagnostic assays and is what our monoclonal antibodies target and perhaps most importantly what some of our vaccines target.

UK variant, aka B.1.1.720I/501Y.V1 and VOC 202012/01, (and Brazilian P.1, 20J/501Y.V3) & **S African** 501Y.V2) (B.1.351 or 20C/ variants)

Last week, the UK, Brazilian and South African variant mutations were reviewed. Of these, only the UK variant has been detected in California. To date, ~ 122 cases (~20 states) have been identified in the US with ~75 cases of those in California (mostly in San Diego and two in San Bernardino and one LA). Although there has been a lot of information about the UK variant in the news its prevalence in the US is estimated to be less than 0.5% at this time.

There have been no Brazilian or South African variants detected in the United States.

L452R variant

Information about the L452R variant was first reported in the news on Sunday this past weekend.

This variant is called L452R because of the mutation is in the 452 region of the spike protein (the R and L are references to the amino acid changes that have taken place; L stands for leucine and the R for Arginine substitution). This mutation is near the receptor binding domain (possibly affecting the affinity of virus to the human receptor).

Viruses with this set of mutation (L452R) in the spike protein were seen in Michigan in March but the virus we are seeing in CA has not only the 3 spike mutation but also other mutations and is a different virus (ORF1a: I4205V, ORF1b: D1183Y, S: S13I, S: W152C AND S: L452R)
It was likely first identified in California in July and seen in sporadically in several other states.

This variant which was only rarely detected in California (until about 2 months ago) is now being detected with increasing frequency. It accounts for ~25% of recently sequenced specimens in several jurisdictions in CA. It has also been associated with a number of outbreaks in Santa Clara County. (Exact # of not available, ~ 300-400 hundred in CA detected thus far).

In addition to Santa Clara County, the L452R variant has been detected in Humboldt, Lake, Los Angeles, Mono, Monterey, Orange, Riverside, San Francisco, San Bernardino, San Diego, and San Luis Obispo counties. It's important to keep in mind that the places where it has been found may reflect good surveillance rather than more of the variant.

Because genomic sequencing is not done equally across the state or country, it is too soon to know how prevalent the L452R variant is statewide, nationally or globally.

Implications

So, what does this all mean?

While we still don't have complete information, we know that the UK variant has been detected in ~75 cases in California and we know that this variant is more infectious than many other strains of the virus. It has the potential to become a predominant strain in the US as it did in the UK (but currently only rarely detected) We know less about the S African and Brazilian variants.

With regard to the L452R variant, it is unknown at this time whether it is more infectious or whether vaccine effectiveness will be affected

It's important to remember that the FDA-approved vaccines are "polyclonal" and thus induce antibodies that target several parts of the spike protein (rather than just one region). This means that even if overall effectiveness is less, the vaccines should still be protective.

What hospitals should do?

In California, we have an active program for sequencing the SARS-CoV-2 virus via COVIDNet. This is an active network of public health labs, academic and commercial lab who have formed collaboration to track these virus through sequencing.

Please consult with your local health department if you would like to pursue sequencing for any suspicious specimens or if you have concerns about one of these new variants. We will continue to keep you updated on any new information on these, and other, variants that arise.

- If you see what appears to be high attack rate in a given outbreak or more cases > expected, we would want representative samples of sequencing.

If at the time you submit sample and are suspicious be sure to notify lab to hold onto the specimen so not tossed

IV. Healthcare Associated Infections

Dr. Erin Epton

Vaccinating Persons with Prior History of COVID-19

The CDC recommends that persons be offered vaccinations regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. In addition, viral or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision-making. Since current evidence suggests that reinfection is uncommon between the initial infection date and 90 days after the initial infection date, vaccination may be deferred for people who had a documented acute infection that began within the prior 90 days. CDC recommends that vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation. This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose.

As I presented on last week's call, SNF residents exposed to SARS-CoV-2 during the prior 14 days (for example, during a facility outbreak) may be vaccinated, and appropriate transmission-based precautions for "yellow-exposed" status residents should be used when the vaccination is administered. The HAI program developed a set of infection control considerations for facilities planning for vaccinating their exposed residents, which we're sharing with facilities and local health departments. In addition, SNF HCP presumed to be potentially exposed in the facility during an outbreak who are asymptomatic and working can also be vaccinated at the facility along with

residents. For SNF HCP with a recent exposure (including community or household exposures) who are seeking COVID-19 vaccination in community or outpatient settings, the CDC recommends deferring vaccination until the quarantine period has ended to avoid exposing HCP or other persons during their vaccination visit.

V. **Monoclonal Antibody Update**

Dr. Sohrab Sidhu

Monoclonal antibody allocation updates

NIH COVID-19 Treatment Guidelines Panel's statement on the use of ivermectin for the treatment of COVID-19

Monoclonal Antibody Overview

To summarize, two investigational monoclonal antibody products – bamlanivimab and casirivimab/imdevimab – received an emergency use authorization (EUA) in November for the treatment of mild-to-moderate COVID-19 in non-hospitalized adult and pediatric patients. Clinical trial data in outpatients have shown that both bamlanivimab and casirivimab/imdevimab may reduce COVID-19-related hospitalization or emergency room visits in patients who are treated early and who are at high risk for severe disease. Clinical trial data in hospitalized patients, however, have not shown a benefit with either bamlanivimab or casirivimab/imdevimab use in hospitalized patients and as such, the EUAs for both therapies are only to treat symptomatic outpatients. Given the limitations to using existing acute care hospital infrastructure during the ongoing surge, CDPH is allocating and encourages the distribution of both products to non-hospital outpatient settings.

General updates

The Health and Human Services Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR) are allocating the monoclonal products to the states once every two weeks. Thus, allocations of the monoclonal products from CDPH are occurring every two weeks.

HHS/ASPR is also strongly encouraging states/territories to use the monoclonal products and to not stockpile or hesitate to use based upon perceived scarcity. Currently California has a sufficient supply of monoclonal antibodies for all providers who request them.

Should any facilities in California need more monoclonal product, they should contact as soon as possible their county's Medical and Health Operational Area Coordinators (MHOACs) according to local policies and procedures. Contact information for each MHOAC program can be found [here](#). If the MHOAC programs do not have any product, the MHOACs should make a request at the regional level, to the Regional Disaster Medical Health Coordinators (RDMHS). The RDMHS can check with other MHOAC programs and if the RDMHS is unable to obtain the necessary quantities, the resource request will move to the state. If the state has product in stock, the state will fill the request.

Medical directors or other authorized prescribers at SNFs and PACE programs who contract with specialty pharmacies receiving state allocations can order bamlanivimab or casirivimab/imdevimab if they have a patient that qualifies for treatment. The pharmacy would prepare the product and send to the SNF or PACE program for infusion. The 12 pharmacies that have received at least one allocation of bamlanivimab or casirivimab/imdevimab since week 1 are Pacific West Pharmacy, Skilled Nursing Pharmacy, Consonus Pharmacy Services, AlixaRx, Pharmerica, Citrus Pharmacy, Ron's Pharmacy, OmniCare, AmeriPharm, Owens Pharmacy, CareKinesis, and Premier Pharmacy Services

Please also note that for facilities who have received product before, they may now request product directly from the distributor, AmeriSource Bergen, should they require any in between allocations.

These requests can be done in parallel and in addition to the previous methods described, namely acquiring the product via specialty pharmacies or requesting the product from their county MHOACs. Facilities who have received product before should have received an email from AmeriSource detailing the method for requesting additional product directly from HHS/ASPR. Since California is in the midst of receiving a new allocation from the federal government this week, there are no new allocation numbers to report. Last week's allocation numbers can be found in the meeting notes for this call. This information is also updated every other week and posted publicly in greater detail [here](#) (under the "Other" section and titled "California Monoclonal Antibody Allocation").

Bamlanivimab updates

For weeks 9-10, California received an allocation of 14,420 doses.

Specialty pharmacies received 287 doses.

2,350 doses were proportionately allocated directly to 21 state prisons. Fourteen new prison locations were added to receive the product this cycle.

The remaining 11,783 doses of bamlanivimab were proportionally allocated to the counties' MHOACs based on their 7-day average of new COVID-19 hospitalization and 7-day average of overall new COVID-19 diagnoses.

Of the product that was declined by various counties, much was re-allocated to other counties and 1,491 vials were sent to the CDPH warehouse.

CDPH continues to encourage counties to consider allocating bamlanivimab to more outpatient settings including federally qualified health centers (FQHCs), state hospitals, jails, and other congregate setting that may have clinical capacity to use.

(Please note the [EUA Fact Sheet](#) for bamlanivimab for bamlanivimab has been officially updated to reflect the elimination of the step to first withdraw 70 mL from the saline bag, thus simplifying the preparation of the drug. Please refer to the EUA fact sheet included in the resources list for more information.)

(Eli Lilly also released a short video detailing the preparation and administration of bamlanivimab. Link to the video can be found in the meeting notes.)

Casirivimab / imdevimab updates

In weeks 9-10, California received an allocation of 1,570 treatment courses of casirivimab / imdevimab this week.

Specialty pharmacies received 54 treatment courses.

The remaining 1,516 treatment courses were proportionately allocated to the counties' MHOACs using the same allocation formula as is used for the bamlanivimab product. The MHOACs then allocate the product within their county.

Of the product that was declined by various counties, much was re-allocated to other counties while 112 treatment courses of casirivimab/imdevimab were sent to the CDPH warehouse.

While casirivimab/imdevimab was previously only allocated to acute care hospitals and their affiliated settings, the federal government has expanded the eligible locations casirivimab/imdevimab can be distributed to. Now, CDPH is encouraging the allocation of casirivimab/imdevimab to appropriate non-hospital outpatient settings just like bamlanivimab.

Finally, casirivimab / imdevimab continues to only be shipped in increments of 6, per the distributor Amerisource Bergen. Counties will need to consider these new shipping rules and alter their distribution plan accordingly for this week and all future weeks.

(Please note the [EUA Fact Sheet](#) for casirivimab/imdevimab has been officially updated to reflect the elimination of the step to first withdraw 20 mL from the saline bag, thus simplifying the preparation of the drug. Please refer to the EUA fact sheet included in the resources list for more information.

Note regarding Medi-Cal reimbursement for monoclonal antibody infusions:

The cost of the product remains free, paid for by the federal government. Medi-Cal reimbursement codes for services rendered for monoclonal antibody infusions are expected in the coming weeks. When those codes are activated, a Provider Notification will be shared. Until then, these services are currently payable with an approved treatment authorization request (TAR). Once the codes are activated, a TAR will no longer be necessary.

NIH COVID-19 Treatment Guidelines Panel’s statement on the use of ivermectin for the treatment of COVID-19

On January 14th, the NIH COVID-19 Treatment Guidelines Panel updated its recommendation regarding the use of ivermectin for the treatment of COVID-19.

The recommendation now reads that the panel “has determined that currently there are insufficient data to recommend either for or against the use of ivermectin for the treatment of COVID-19. Results from adequately powered, well-designed, and well-conducted clinical trials are needed to provide more specific, evidence-based guidance on the role of ivermectin for the treatment of COVID-19.”

Note that this represents a shift from NIH’s previous recommendation in which they recommended against the use of ivermectin for the treatment of COVID-19, except in a clinical trial.

The statement cites the results of several randomized trials and retrospective cohort studies that have been published in peer-reviewed journals or made as preliminary, non-peer-reviewed reports since their last revision of the ivermectin section of the guidelines.

“Some clinical studies showed no benefits or worsening of disease after ivermectin use, whereas others reported shorter time to resolution of disease manifestations attributed to COVID-19, greater reduction in inflammatory markers, shorter time to viral clearance, or lower mortality rates in patients who received ivermectin than in patients who received comparator drugs or placebo.”

The statement also cites several limitations to the available data. Namely:

- “The sample size of most of the trials was small.
- Various doses and schedules of ivermectin were used.
- Some of the randomized controlled trials were open-label studies in which neither the participants nor the investigators were blinded to the treatment arms.
- In addition to ivermectin or the comparator drug, patients also received various concomitant medications (e.g., doxycycline, hydroxychloroquine, azithromycin, zinc, corticosteroids), confounding assessment of the true efficacy or safety of ivermectin.

- The severity of COVID-19 in the study participants was not always well described.
- The study outcome measures were not always clearly defined.”

Because of these limitations, the Panel could not draw definitive conclusions about the clinical efficacy or safety of ivermectin for the treatment of COVID-19.

Read the full statement: [Statement on Ivermectin | COVID-19 Treatment Guidelines \(nih.gov\)](#)

Additional Resources

Bamlanivimab links for further information:

- [Bamlanivimab Distribution Fact Sheet \(ca.gov\)](#)
- Fact sheet for healthcare providers: <https://www.fda.gov/media/143603/download>
- Fact sheet for patients, parents, and caregivers: <https://www.fda.gov/media/143604/download>
- FDA FAQ: <https://www.fda.gov/media/143605/download>
- Eli Lilly video for bamlanivimab preparation/administration:
https://www.kaltura.com/index.php/extwidget/preview/partner_id/1759891/uiconf_id/30232671/entry_id/1_i3nkvs7k/embed/dynamic?
- Complete video transcript and more info:
<https://www.covid19.lilly.com/bamlanivimab/hcp/dosing-administration#dosing-and-administration>

Casirivimab / Imdevimab links for further information:

- [Casirivimab and Imdevimab Distribution Fact Sheet](#)
- Fact sheet for health care providers: <https://www.fda.gov/media/143892/download> Fact sheet for patients, parents, and caregivers: <https://www.fda.gov/media/143893/download>
- FDA FAQ: <https://www.fda.gov/media/143894/download>

MHOAC County Contact Information:

<https://ems.ca.gov/medical-health-operational-area-coordinator/>

NIH COVID-19 Treatment Guidelines:

<https://www.covid19treatmentguidelines.nih.gov/whats-new/>

IDSA COVID-19 Treatment Guidelines:

<https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/#toc-10>

VI. Vaccine Update

Dr.Caterina Lui

- To summarize, two COVID-19 vaccines have received FDA emergency use authorization, one from Pfizer, and the other from Moderna.
- Enrollment:
 - COVIDReadi has been replaced by a system named CalVax to handle provider enrollments.
 - General questions about Provider Enrollment can be directed to our COVID Call center at 833-502-1245 or COVIDCallCenter@CDPH.ca.gov
- Doses/allocation
 - As of 1/18/21, 4,069,875 doses of COVID-19 vaccine have been allocated to CA to be administered on a local level to Phase 1A and Phase 1B, Tier 1 populations. 635,700 doses of Pfizer vaccine have been allocated as part of the federal pharmacy partnership

with CVS and Walgreens and 103,670 of those doses have been reported as administered. To date, 3,226,775 doses have shipped in CA. 1,196,206 first doses have been recorded in IISs as administered and 259,774 have been recorded as second doses administered. CDPH is also in the process of creating a dashboard where this information will be published and an interim webpage exists with shipped and administered doses at VaccineDoses (ca.gov).

- Moderna Vaccine Lot # 041L20A Pause on Administration
 - On 1/17/2021, CDPH notified providers that received Moderna vaccine lot 041L20A to briefly pause its use due to a higher-than-usual number of adverse events reported at a clinic last week.
 - All appeared to be experiencing a possible severe allergic reaction during the standard observation period – a type of adverse event that the [CDC reports](#) some people have experienced when receiving a COVID-19 vaccine.
 - In an abundance of caution, CDPH is recommending that providers pause administration of this lot until prompt investigations the patients and the vaccine lot by CDC, FDA, and Moderna and CDPH resolve in the next days. We appreciate the impact this will have on clinic operations for those have received doses from this lot.
 - More than 330,000 doses from this lot have been distributed to 287 providers across the state. The shipments arrived in California between Jan. 5 and 12. The state has not been notified of any other cluster or individual events related to this lot.
 - We expect to provide an update this week as we learn more.
 - Providers of COVID-19 vaccine should continue their routine precautions to recognize and manage allergic reactions and potential adverse events.
 - <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>
 - Vaccination in long-term care facilities continues with the CDC-Pharmacy Partnership program. CVS and Walgreens are reaching out to facilities directly to schedule vaccination clinics. Please provide your facility's best contact information and accurate numbers of staff and residents to be vaccinated. Please review documents, resources, and FAQs directly on pharmacy LTCF webpages:
 - CVS / Omnicare <https://www.omnicare.com/covid-19-vaccine-resource/>
 - Walgreens <https://www.walgreens.com/topic/findcare/long-term-care-facility-covid-vaccine.jsp>
 - Clinical considerations
 - The CDC website is updated with the most recent information about both the Pfizer and Moderna vaccines
 - Vaccination after SARS-CoV-2 infection:
<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>
 - A reminder regarding vaccination of persons with prior COVID-19:
"Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation. This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose. While there is otherwise no recommended minimum interval between infection and vaccination, current evidence suggests that reinfection is uncommon in the 90 days

after initial infection. Thus, persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired."

- Authorized Vaccinators:
<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/Authorized-Licensees.aspx>
 - If you have questions about groups of vaccinators that are not on this list, please email COVIDCallCenter@cdph.ca.gov.
- Prioritization:
 - On January 13th, CDPH released revised allocation guidance for COVID-19 vaccine: <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Revision-of-Allocation-Guidelines-for-COVID-19-Vaccine.aspx>
 - "To prevent hospitalizations and deaths, to more effectively and expeditiously administer vaccines, and to maintain hospital services to all Californians, especially in the most impacted communities, California will prioritize vaccinating health care personnel, including vaccinators, and all persons 65 years of age or older. This policy shall be carried out with a deep commitment to equity, without profiteering, and in a manner that ensures no doses are wasted.
 - All vaccination providers should:
 - Continue vaccinating all persons in Phase 1a.
 - Begin vaccinating persons 65 years of age or older. Based on available supply, prioritize and target outreach efforts as follows:
 - **Age**, with persons 75 years or older prioritized due to increased risk of mortality and other severe disease
 - **Occupational Risk Exposure**, individuals working in sectors in Phase 1b, Tier 1 with high occupational exposure
 - **Residence in vulnerable communities**, as determined by the California Healthy Places Index or comparable local health department knowledge, to address equity and communities disproportionately affected by the pandemic.
 - Health departments and providers may offer doses promptly to people in lower priority groups when:
 - Demand subsides in the current groups or
 - Doses are about to expire according to labeling instructions or
 - Doses that have been thawed and would otherwise go to waste.
 - To achieve the timely and maximum vaccination of Californians, CDPH recommends the use of 50 percent of doses providers have received as second doses to vaccinate individuals as described above.
 - The recommendations continue to be subject to review and further revisions."
 - CDPH will release additional details on sub-prioritization during Phase 1b and 1c.
 - Link to the essential workforce list: <https://covid19.ca.gov/essential-workforce/>
 - Link to the current Phase 1a and 1c guidance: <https://covid19.ca.gov/vaccines/#When-can-I-get-vaccinated>
 - **Additional resources:**
 - On January 7th, CDPH published guidance regarding moving through the vaccine prioritization phases and tiers.

<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Vaccine-Prioritization.aspx>

- 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>
 - Clinical Considerations for Pfizer and Moderna vaccine: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>
- The ACIP's recommendations for prioritization of vaccine during phase 1b and 1c are now online: https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm?s_cid=mm695152e2_w

VII. **Questions and Answers**

Q: I heard that the state agreed to discontinue the regulatory requirement of reporting clip data in NHSN. We are using precious resources to manually abstract and then enter these data. I would rather be using these precious resources to help with pandemic and surge activities that we are experiencing severely here in San Diego. Is that true and is there an AFL that's expected to address discontinuing this regulatory task?

A: No, we absolutely still requiring reporting. We actually action on that data. We don't just collect it to give to NHSN but we actually use it. We are trying to streamline our reporting and dividing out what things can be done on a daily basis versus what are the things that can be done on a weekly basis. We are trying to minimize the reporting burden and how we track and use that data for surge and outbreak response.

A: This was discussed during a recent HAI advisory committee meeting and I believe there's ongoing discussion. Hopefully we will have some updates on that.

Q: Several weeks ago, there was a question by a psychiatric healthcare facility asking if AFL 20-91, California Crisis Care Continuum, applied to their facility. My question is, does it apply to critical access hospitals? In the past under facility type, if it was specific to critical access hospitals, we were listed there. In the previous year, 2020, I don't see any designation for critical access to follow AFLs under the facility type. My question is, are we umbrellaed under GACHs now and there will no longer be specific AFLs for critical access hospitals, and do we need to follow AFL 20-91?

A: It wasn't a purposeful decision to not make that delineation of critical access hospitals. I appreciate you bringing that up as an issue that I can take back to our policy team so that we can go back through our AFLs from 2020. We can follow up offline.

Q: Do you have any recommendations for monoclonal treatments given the variants that are coming up if there's any preference to using a single antibody product versus a dual antibody product? Will there be more reliability given we don't really know much about the variants and their effects on monoclonal?

A: The data is limited as it is regarding these products in the treatment of COVID-19 in general and certainly there is no available data about the variants that are emerging themselves. So I think the best guidance would be just to adhere to the indications that are outlined in the EUA, which is namely that these products are for patients who are symptomatic but have mild to moderate cases not requiring hospitalizations and that meet certain high risk criteria which are fairly well defined but are things like

age greater than 65 or BMI greater than 35. Unfortunately, often we don't have more robust data certainly not more data as it pertains to the new variance.

Q: Do you know if anyone is studying them at all in terms of efficacy or any laboratory data that will be coming out?

A: There's certainly ongoing clinical trials, regarding monoclonal and the treatment of COVID-19, both in the outpatient and still in some hospitalized patients which is not currently approved for. I haven't heard anything specifically about studying of their effectiveness for these new emerging variants. If I come across anything, I'll be sure to share them with the group.

Q: Who are allowed to collect nasal pharyngeal swabs? My understanding is that in California, only LVNs, RNs, PAs, nurse practitioners, physicians, etcetera are authorized to collect NP swabs and that medical assistance and other unlicensed staff are not allowed. I was wondering if you can confirm if that was correct. Are you considering allowing unlicensed staff with appropriate training to collect NP swabs? It would be really helpful as we expand our testing programs and employee surveillance testing.

A: The information is available on the Field Services website for California. You are correct in that medical assistants are not eligible to collect NP swabs. I am not aware if there are efforts to expand that ability. I would say that there are other ways to do testing that don't involve NP swabs. Medical assistants can collect interior nasal swabs. There are ways to do testing with self-collection. The Valencia Branch laboratory employs anterior nasal swabs for collection and if you are interested in doing a community testing site, there is information in the transcript to work with the Valencia Branch laboratory.

Q: If we have staff that tested positive for COVID within the last 90 days and while they were being treated, they received monoclonal antibody or plasma infusion, can they still get the vaccine?

A: CDC guidance states that those who receive the monoclonal could wait for 90 days essentially to receive the first dose or continue the vaccine series. This is essentially based on two reasons. One is that the chance for reinfection in 90 days is still considered low and two, it's thought that there is a theoretical blunting of the immune response if a monoclonal was given fairly recently that would prevent the immune response that you want from a vaccine.

Q: If an individual receives the first dose and was not aware to get another immunization in between getting the second dose, what is the guideline regarding receiving that second dose? Do they have to wait or just get that second dose as scheduled?

A: The CDC guidance does recommend 14 days before and after administration with any other vaccine. If the mRNA vaccine was administered within 14 days of another vaccine, you don't need to repeat it. So, if someone got their first dose and then got another vaccine in between the two, if we go by the CDC guidance, they would recommend a minimum of 14 days after that other vaccine before getting the next COVID dose.

Q: Can you expand on your statement about representative sampling of outbreaks for whole genome sequencing? Is it 5%? 10%? etcetera. Also, it would be nice to know what the lab capacity is at the state for handling whole genome sequencing. How many samples can you handle a week? etcetera.

We have some keen interest in how we are going to look at our population and additional outbreaks in the future.

A: As far as the exact samples we want, I think that's something you should touch base with local health department and then potentially us as well after you've looped them in, and we can figure out how many samples. In general, if you feel concerned that this might be one of those more infectious strains or there is something particularly worrisome about it, those are the ones we want. It's important that when you submit those samples to the lab, to try to let them know not to throw it away. Institutions like yours have such a high volume that they may not have the original sample. As far as what the capacity is, we are ramping that up every day. California has sequenced more than any other state but it's still a fraction of all the testing so I don't have an actual number for you but it is ramping up every day.

Q: There is a lot of literature about the aisle six inhibitors, particularly the remapped cap trial. I was wondering if you can comment on some of that. I know we mentioned ivermectin but if we can also comment on the aisle six inhibitors?

A: I saw a recent update from, I think, from UCSF that comments a little bit about early aisle six inhibitors in critically ill patients with COVID-19. I had a chance to briefly review the preprint. It's a number of therapeutics that we are working on tracking right now. The data is obviously limited and neither IDSA nor NIH has folded into their guidelines. It is one of several classes of medications that we are going to continue to track and possibly one that we bring up with our advisory board. So not much to say on that front right now but we'll update the group as we know more.

Q: Regarding the UK variant, is there a targeted population that we should be looking out for that has gotten this specific variant or is it all across the board of race and age?

A: If you see an outbreak or a situation where there appears to be a very high attack rate, we would want to look at that or something that you think seems unusually infections as far as the numbers of people infected in the household. In addition, any travel to certain areas like the UK or South America, Brazil in particular, or South Africa, that would be pertinent. The whole public health system is really ramping up to do more sequencing. The CDC has recently started a project where they want samples from every state, several dozen in California, which will still be a small number. If you want something sequenced, it's worth talking to the local health department and then possibly to us after they have been notified to see if we can do those.

Q: We have some residents that got the first dose of the vaccine, tested positive for COVID and received monoclonal antibody treatment and they are due for the second dose of the vaccine. Should we wait close to the 90 days before administering the second dose?

A: Yes, that is currently the CDC guidance. Essentially the reinfection risk is low and there's a theoretical risk of blunting the immunological response after the patient has received monoclonal. The thought is to wait the 90 days.

Q: With the new variant showing up more in California, should we change our testing habits? Should we test more often?

A: I don't think it should change testing. With the U.K. variant, in some of the molecular assays, they noticed something called a S dropout, again that spike protein they weren't detecting but the other gene targets were being found. So, it still detects it. There's not that many labs in California that are

using that. For the particular variant that you've been hearing about on the news, the 452, that will still be affected by the molecular assay. You shouldn't necessarily do more testing because of that.

Q: I'm from a group of FQHCs that are providing the COVID vaccine to the public. We are unclear if we should be saving half of our doses for the second dose or if we should go ahead and vaccinate folks with what we have, anticipating that we'll get more.

A: We do anticipate getting more vaccine. Based on our current guidance, the priority is getting as many people vaccinated as possible. I know there is a lot of uncertainty regarding the vaccine supply, but the current recommendations are to reach as many individuals as possible.

Q: If a worker gets vaccinated, can the rapid test be used to meet state testing requirements? My second question is that if a worker is vaccinated then exposed, is the quarantine period shortened? I don't think it is and that leads to my comment, workers are asking these questions and would appreciate an AFL around post healthcare worker vaccination and what the protocols are in terms of exposure and masking and those types of things.

A: Receipt of vaccine should not impact the result of either molecular or antigen based tests for COVID. Prior receipt of vaccine does not influence or change any of the recommendations with regard to the need to test an individual if they have symptoms or if they have had a recent exposure. Stay tuned for any adjustments to the recommendations for routine screening tests for asymptomatic healthcare personnel. Those might be changing but as of now, we have not received any guidance from CDC on that issue.

Q: If a person is vaccinated, will they show as positive on a rapid test? I have confirmed on CDPH calls that it won't show on a PCR but I haven't been able to confirm if you get vaccinated, you will show positive on a rapid test.

A: No. There is no reason that the antigen testing would be positive that we are aware of.

A: To your second question about the need to quarantine after an exposure for a healthcare personnel who's been fully vaccinated, two weeks past the receipt of their second dose. That is another area, similar to the screening testing area that we are waiting for additional guidance and clarification from CDC. Thus far we have been recommending essentially the same infection control considerations and the need for non-pharmaceutical interventions such as masking and distancing all continue to apply even after vaccination. I think that especially important now that we are worried about new variant etcetera. Stay tuned for additional updates on that guidance, but for now, the recommendation is to continue those practices including the screening testing and the quarantine until we know more.

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