California Department of Public Health
Weekly Facility COVID-19 Update Call
December 22, 2020
8:00 am – 9:00 am

AT&T Meeting Recording: 1 (866) 207-1041
Access Code: 9641065
Available after 10am 12/22/2020

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

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

- None Provided

III. **Laboratory Update** **Dr. Jill Hacker**

Brief update on UK SARS-CoV-2 variant virus

From A. Rambaut, et al. (https://virological.org/t/preliminary-genomic-characterisation-of-an-emergent-sars-cov-2-lineage-in-the-uk-defined-by-a-novel-set-of-spike-mutations/563)

Recently a distinct cluster of a SARS-CoV-2 variant virus (called lineage B.1.1.7) was detected within the UK and has been growing rapidly over the past 4 weeks. Several aspects of this cluster are noteworthy for epidemiologic and biologic reasons. This (B.1.1.7) lineage accounts for an increasing proportion of cases in parts of England. The number of B.1.1.7 cases and number of regions reporting B.1.1.7 infections, are growing. A few cases of this variant outside the UK have been reported by Denmark and the Netherlands and, according to media reports, in Belgium. There is one documented imported case from the UK to Australia.

B.1.1.7 has 17 mutations, an unusually large number of genetic changes, 8 of which are located in the spike protein (S). Three of these S mutations have potential biological effects including:

1. Mutation N501Y is within the receptor-binding domain (RBD) of the viral Spike protein and has been identified as increasing binding affinity to human cell receptor, ACE2. N501Y has been associated with increased infectivity and virulence in a mouse model (Gu et al. 2020).
   - In South Africa, N501Y has emerged (unrelated to B117) that appears to be associated with rapid spread (anecdotal at this point)
2. A deletion mutation of 2 amino acids at residues 69 and 70 ("69-70del") has been associated with:
   - Evasion of immune response
   - Diagnostic failure in some assays targeting the S gene including the three-target TaqPath Combo assay and the two-target BioFire assay

3. Mutation P681H occurs at the furin cleavage site, known for biological significance in membrane fusion promoting entry into respiratory epithelial cells and transmission in animal models (Hoffmann, Kleine-Weber, and Pöhlmann 2020; Peacock et al. 2020; Zhu et al. 2020).

Both N501Y and P681H have been observed independently but not in combination before now.

From ECDC Threat Assessment
(https://www.ecdc.europa.eu/en/publications-data/threat-assessment-brief-rapid-increase-sars-cov-2-variant-united-kingdom):
While it is known and expected that viruses constantly change through mutation leading to the emergence of new variants, this variant has accumulated 17 mutations at a rate much higher than the typical 1-2 changes per month. ECDC reports that preliminary analysis in the UK suggests that this variant is significantly more transmissible than previously circulating variants, with an estimated potential to increase the reproductive number (R) by 0.4 or greater with an estimated increased transmissibility of up to 70%…
Important to note that **transmissibility** is different from **infectivity** – which is likely what has increased, NOT transmissibility.

Infectivity expresses the ability of the disease agent to enter, survive and multiply in the host; **infectiousness** indicates the relative ease with which a disease is transmitted to other hosts.

There is no indication at this point of increased infection severity associated with the new variant.

From CDC call 12/21/20:
The strain may have originated in an immunocompromised person, or a person who received immune plasma therapy, or monoclonal antibody therapy.

- Longer replication period may lead to more mutations, or the possibility of co-infection with another strain leading to a recombination event.
- Coronaviruses have antigenic drift like influenza, but at 1/3 the rate of influenza.

Persons infected with this strain have a 3-4 times greater viral load, even though they don't appear to have more severe illness.

From CDPH (via CAHAN to be sent out soon):
Currently, this variant virus has not been identified in California. However, the California Department of Public Health requests that health care providers take several steps to help collect specimens for genetic sequencing to monitor for this and other variant viruses. Please collect and submit specimens for sequencing from individuals with COVID-19 with the following characteristics:

- Recent travel to the United Kingdom or Europe
- Exposure to persons with recent travel to the United Kingdom or Europe
- Marked differences in real-time RT-PCR viral target(s) Ct values (e.g., ORF1ab target Ct=27, N target Ct=26, and S target **Not Detected**)

See also:
https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-emerging-variant.html
https://www.sciencemag.org/news/2020/12/mutant-coronavirus-united-kingdom-sets-alarms-its-importance-remains-unclear?s=03
https://www.biorxiv.org/content/10.1101/2020.12.14.422555v2.full.pdf

https://khub.net/documents/135939561/338928724/SARS-CoV-2+variant+under+investigation%2C+meeting+minutes.pdf/962e866b-161f-2fd5-1030-32b6ab467896?t=1608470511452
https://twitter.com/mugecevik/status/1341094836682838021?s=03

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

CDPH recently posted updated guidance on the duration of quarantine for SARS-CoV-2 exposed individuals. An AFL is forthcoming that specifies exposure risk assessment and the duration of quarantine for SARS-CoV-2 exposed healthcare personnel (HCP) working in hospitals, and for HCP and residents of skilled nursing facilities (SNF).

Hospital HCP

The AFL will reference the CDC's risk assessment framework to assess exposure risks of HCP to patients, visitors, or other HCP with confirmed COVID-19 in a healthcare setting, as well as CDC guidance for assessing travel- and community-related exposures for HCP with exposures outside of work (e.g., household) as well as exposures among HCP exposed to each other while working together in non-patient care areas.

Hospitals should follow CDPH guidance for the duration of quarantine of exposed HCP, and exclude from work HCP with higher risk exposures as defined by CDC's risk assessment framework for healthcare-associated exposures in HCP, and HCP identified as close contacts (within 6 feet of an infected person for a cumulative total of 15 minutes or more over a 24-hour period) in the community or while working in non-patient care areas. For the duration of quarantine and work exclusion for hospital HCP, CDPH recommends:

- Asymptomatic HCP may discontinue quarantine after Day 10 from the date of last exposure with or without testing.
- During critical staffing shortages when there are not enough staff to provide safe patient care, exposed asymptomatic HCP are not prohibited from returning after Day 7 from the date of last exposure if they have received a negative PCR test result from a specimen collected after Day 5.

Hospitals may follow CDC staffing shortage mitigation strategies to determine when it is appropriate to allow asymptomatic HCP who have had an unprotected a high risk exposure but are not known to be infected to continue to work or to return to work before completing quarantine during a critical staffing shortage when lacking the staff to provide safe patient care. As for all HCP, exposed HCP must continue to wear a facemask or respirator for source control at all times within the facility, and still report temperature and absence of symptoms each day. Healthcare facilities should understand that shortening the duration of work restriction might result in additional transmission risks.

SNF HCP and Residents

SNF should also generally use the CDC's risk assessment framework to assess exposure risks of HCP to patients, visitors, or other HCP with confirmed COVID-19 in a healthcare setting, and CDC guidance for assessing travel- and community-related exposures for HCP with exposures outside of work (e.g., household). CDPH guidance for the duration of quarantine recommends that SARS-CoV-2 exposed individuals who reside or work in a high-risk congregate living setting (e.g., SNF residents and HCP) should still quarantine and be excluded from work (for HCP) for 14 days in the absence of staffing shortages. During critical staffing shortages when there are not enough staff to provide safe patient care, exposed asymptomatic HCP are not prohibited from returning after Day 7 from the date of last exposure if they have received a negative PCR test result from a specimen collected after Day 5. In general, during an outbreak in a SNF, all HCP are considered potentially exposed and are allowed to continue working as long as they remain asymptomatic and are being serially tested as part of facility-

wide outbreak response testing; as for all HCP, exposed HCP must continue to wear a facemask or respirator for source control at all times within the facility, and still report temperature and absence of symptoms each day.

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

To summarize, two investigational monoclonal antibody products have received an emergency use authorization (EUA) for the treatment of mild-to-moderate COVID-19 in non-hospitalized adult and pediatric patients. Bamlanivimab received an EUA on November 9th and is a single monoclonal antibody. Casirivimab/imdevimab received an EUA on November 21st and is a cocktail of two monoclonal antibodies. 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 is only to treat symptomatic outpatients. Finally, since bamlanivimab is less complex to prepare for infusion than casirivimab/imdevimab, CDPH is allocating to appropriate non-hospital outpatient settings that can provide access to this medication. As casirivimab/imdevimab is more complex to prepare, we continue to only distribute via acute care hospital infusion settings.

General updates

The Health and Human Services Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR) have changed the frequency of the federal allocation of the monoclonal products to the states from weekly to once every two weeks. Thus, allocations of the monoclonal products from CDPH to specialty pharmacies and counties will occur every two weeks moving forward.
Please also note that for the week of Christmas, allocations from the federal government will be made one day earlier. 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.

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. 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.

Bamlanivimab updates

For week six, California received an allocation of 6,420 doses.
335 vials of bamlanivimab were distributed directly to large specialty pharmacies requesting the product to serve skilled nursing facilities (SNFs).

Medical directors or other authorized prescribers at SNFs and PACE programs who contract with these pharmacies can order bamlanivimab if they have a patient that qualifies for treatment. The pharmacy would prepare the product for infusion and send to the SNF or PACE program for infusion. The 9 pharmacies that have received at least one weekly allocation of bamlanivimab since week 1 are Pacific West Pharmacy, Skilled Nursing Pharmacy, Consonus Pharmacy Services, AlixaRx, Pharmerica, Citrus Pharmacy, Ron's Pharmacy, OmniCare, and AmeriPharm. The state will also be adding Owens Pharmacy in next week's allocation.

The remaining 6,085 doses of bamlanivimab that were not distributed to these specialty pharmacies 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 a few counties, most was re-allocated to other counties and 150 vials were sent to the CDPH warehouse.
This information is updated weekly and posted publicly in greater detail here (under the "Other" section and titled "California Monoclonal Antibody Allocation").

To date most of the allocation of bamlanivimab has gone to clinical sites affiliated with acute care hospitals because of the existing infrastructure to infuse an outpatient medication but 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.
The state is also currently working with the California Department of Corrections and Rehabilitation to allocate directly to their facilities.

Please note the EUA fact sheet 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.

Casirivimab / imdevimab updates
In week 6, California received an allocation of 1,380 doses of casirivimab / imdevimab this week. The same formula is used to proportionately distribute casirivimab / imdevimab to the counties' MHOACs. The MHOACs then allocate casirivimab / imdevimab within their county. The ongoing plan is to allocate to acute care hospitals and their affiliated settings as casirivimab / imdevimab is more complex to prepare. The casirivimab / imdevimab product is also not well labelled and is prepared in two different doses which adds complexity for the pharmacy.

Finally, beginning this week (Week 6), casirivimab / imdevimab will begin shipping only 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.

Additional Resources

Bamlanivimab links for further information:
https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Bamlanivimab-Fact-Sheet.aspx
Fact sheet for healthcare providers: https://www.fda.gov/media/143603/download

Casirivimab / Imdevimab links to the EUA including information for healthcare providers and patients is included in the meeting notes.
FAQ: https://www.fda.gov/media/143894/download
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

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** **Caterina Lui**

- Two COVID-19 vaccines now have FDA Emergency Use Authorization and have been recommended by ACIP: Pfizer-BioNTech (EUA 12/11), Moderna (EUA 12/18).
- Enrollment:
  - General questions about Provider Enrollment into COVIDReadi can be directed to our COVID Call center at 833-502-1245 or COVIDCallCenter@CDPH.ca.gov
- Doses/allocation
  - As of 12/21/20, 560,625 doses of Pfizer vaccine and 672,600 doses of Moderna vaccine have been allocated to CA and 92,731 doses have already been administered. New guidance from the FDA states that the Pfizer vials may contain up to 6 doses of vaccine.
  - We will be sharing a link when available to where you can print additional cards because the current ancillary kits are running out of cards from the additional doses.
  - We'll also be sending out guidance about how to incorporate the additional inventory from the extra doses into CAIR.
- Clinical considerations
  - The CDC website is updated with the most recent information about both the Pfizer and Modern 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
- Co-administration with other vaccines: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
  - "Coadministration with other vaccines: Given the lack of data on the safety and efficacy of mRNA COVID-19 vaccines administered simultaneously with other vaccines, the vaccine series should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines. If mRNA COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine."
- Prioritization
  - Prioritization during Phase 1a, which includes outpatient providers: https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/CDPH-Allocation-Guidelines-for-COVID-19-Vaccine-During-Phase-1A-Recommendations.aspx
  - The ACIP released new recommendations on Sunday for the prioritization of vaccination during Phase 1b (frontline essential workers, persons 75 and older) and Phase 1c (persons 65-74, persons 16-64 with high risk medical conditions and other essential workers). California's Drafting Guidelines workgroup will provide final guidance for California in the coming days. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-20/02-COVID-Dooling.pdf
- Additional resources:
  - COVID-19 Vaccine Provider Update, Fridays 9-10am
    - Event link for ATTENDEES: https://cdph-conf.webex.com/cdph-conf/onstage/g.php?MTID=e50fed540a27d3a3015fb54994fa930d4
      - Event Number: 145 583 3915
      - Event Password: Immunize2020!

VII. **Questions and Answers**

Q: Does the Phase 1 priority 2 include the Home Care Aides that are registered with the Department of Social Services Home Care Service Bureau?
A: It was meant to be broad and I believe that they are providing in home support services and should be included. I can get back to you and confirm that for you.

Q: When someone is coming in from out of state for non-essential travel must the quarantine for 10 or 14 days? It would be nice to make it clear that if you are coming in from out of state that if its non-essential travel that you need to quarantine. I'm assuming that if the person is traveling here for medical reasons, that would be essential travel and they don't need to quarantine.
A: That wasn't specifically address, that somebody that might have been exposed and doesn't have a known exposure, I wouldn't think that we would be more strict with them than we would with somebody in the general public who has a known exposure. So I would think it would be 10 days.

Q: And just to clear up, if you are coming from out of state on essential travel, there is no quarantine period?
A: I can't answer really because that really hasn't come up. I will check up on that and get back to you.

Q: Are hospital healthcare personnel still going to be required to be tested once a week once they receive the vaccine?
A: Not yet. We are waiting for additional results from initial analyses and CDC recommendations that will be based on the determined effectiveness of the vaccine, in not only preventing symptomatic illness and severe disease as it has great efficacy but in the ability of it to prevent asymptomatic infection and transmissibility. We can't make recommendation but stay tunes. Also, healthcare personnel need to understand that receipt of the vaccine does not change any of our other infection control recommendations and those do still include universal face mask or respirator where appropriate for source control while in the facility. At this time, those recommendations have not changed and as we understand more about the ability of the vaccine to prevent transmissibility, then we can adjust those recommendations.

Q: How do we get on the list for the distribution of notes?
A: If you reach out to the CHCQ duty officer, they can assist you.

Q: For someone who has been vaccinated, does the quarantine days change?
A: At this time, we do not treat vaccinated individuals any differently if they are exposed because we don't have data yet that permits us to do that.

Q: Do you have an expectation on when you will have more data? Are we talking about a year from now? 6 months from now?
A: I wish I could tell you. I hope it's not that long. We just must see how the vaccine works in the real world. I'm optimistic that will happen at some point but not yet. What I'm hearing from colleagues at the CDC is that they anticipate results of initial analyses potentially in the next three to four months. We will provide updates as we learn more.

Q: Regarding requesting fit testers, do we just follow the MHOAC (Medical Health Operational Area Coordinator) process and submit a resource request that way?
A: Yes, that is correct. You would use the same resource requests that you would for staffing, PPE and other things.

Q: Is there any other information that you need me to supply with that like how many staff members, how many fit test kits I have.
A: Yes, that is ideal if you could put that in your initial request. We appreciate any detail that you can provide on the front end.

Q: Someone mentioned that there was going to be an AFL coming out this week regarding vaccination. Can you mention in generality terms on what that's expected to include?
A: We worked with the Immunization Branch and our HAI Team to provide a little more information and a little bit of information regarding the distribution of the vaccines and some guidance and thoughts around post vaccine because we are getting a lot of questions right now about changing testing and other infection control protocols. Currently, there is not enough evidence to be able to release those precautions yet. There is also a link on how the prioritization works. This is primarily directed to Skilled Nursing Facilities that are currently prioritized for the vaccination of their healthcare personnel and residents. Some information about post vaccination symptoms and consent requirements and procedures and other implementation considerations.

Q: What is the recommendation for frontliners who have recovered from the COVID infection as to when they can receive the COVID vaccine?
A: The CDC does have clinical guidance. They recommend that the person has recovered from their acute illness and that they also met the criteria for discontinued isolation as the earliest point at which they can be vaccinated. The CDC also notes that it is very unlikely for people to be re-infected within 90 days so in the setting of limited supply, they recommend considering deferring vaccination for those individuals who are more recently infected.

Q: Are there any restrictions for the COVID vaccine and PPD skin testing for our employees whether they should get the PPD placement after or before vaccination. If there are restrictions, how long should they wait?
A: There is no specific guidance from the CDC about waiting for PPD. The only guidance they have is about recommending other vaccinations, that more than 14 days pass between prior vaccinations and the COVID vaccine but not about PPD.

Q: Are there specific vaccinations like MMR, varicella? Is that a 14 day wait period.
A: The CDC has a general statement saying that there's lots of evidence that they would recommend in general, waiting 14 days. However, if someone does end up getting vaccinated there is no need to change anything about their COVID vaccine.

Q: And that just these four correct?
A: I think it's mainly since they don't know about the effects of combining vaccines although in general the CDC does recommend multiple vaccines that are susceptible to multiple vaccines in the same day.

Q: So just to reiterate, it's a wait period of 14 days before getting the COVID vaccines and there are no restrictions after for any MMR or varicella to get that after the vaccine.
A: No, and I think the main concern would be the reactogenicity of multiple vaccines is what they're more concerned about. I want to correct my prior statement. The CDC website does say that the vaccine should be 14 before and after to avoid other vaccines.

Q: About the B117 variant being some consideration that it might be at a higher likelihood of occurring in immunocompromised patients who received the monoclonal antibody. Is there consideration that we should screen for compromised patients that within that subgroup that would otherwise get monoclonals and whether or not to proceed with that. The second question is to clarify what you said last week on the call regarding community healthcare providers, that they would be in tier 2 or tier 3. I'm wondering how that meshes with the recent release of saying that Phase 1b is people greater that or equal to 75 years of age and frontline workers. I would imagine community healthcare providers are considered frontline workers.
A: No, I believe that monoclonal antibody treatments are supposed to be initiated as soon as possible in recognition of infections. The statement that referred to linking that therapy with the emergence of this variant is a speculation from long term shedders, so those who have an infection and detection of virus for long periods of time at which some point, they may have been provided the convalescent plasma and or monoclonal antibody. I don't think that now with the clinicians and healthcare providers, of which I am not one, implement monoclonal antibody therapy, there shouldn't be a risk of the intro host evolution. Community healthcare providers are considered part of Phase 1a.

Q: Can you share any information you have on the impact of the mutation seen in the UK on vaccine efficacy?
A: To be honest, we do not know if we must wait for more time elapse. There are some studies going on in Europe looking at neutralization and antibody response, but we don't have the data yet. We expect to have some data by the end of the week hopefully.

Q: In regard to the fit testing, will there be anyone available from the MHOAC to be able to come train the staff so they can be testers moving forward so we are not tapping that resource as much if you are aware of that or if there is a special request we should be doing?
A: We do have technical assistance available even on our website we've got lots of different videos that Cal OSHA has provided for training. In addition to that, if there is something else that is needed in a virtual format or out to be deployed, we can do so as well.