California Department of Public Health
Weekly Facility COVID-19 Update Call
December 15, 2020
8:00 am – 9:00 am

AT&T Meeting Recording: 1 (866) 207-1041
Access Code: 6309036
Available after 10am 12/15/2020

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

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

- None Provided

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

- None Provided

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

Post-Vaccination Management and Testing Considerations for Symptomatic Healthcare Personnel (HCP) and Skilled Nursing Facility (SNF) Residents

Systemic signs and symptoms, such as fever, fatigue, headache, chills, myalgia, and arthralgia, can occur following COVID-19 vaccination. Data from mRNA COVID-19 vaccine trials indicate that most systemic post-vaccination signs and symptoms are mild to moderate in severity, occur within the first three days of vaccination (the day of vaccination and following two days, with most occurring the day after vaccination), resolve within 1-2 days of onset, and are more frequent and severe following the second dose and among younger persons compared to those who are older (>55 years). Cough, shortness of breath, rhinorrhea, sore throat, or loss of taste or smell are not consistent with post-vaccination symptoms, and instead may be symptoms of COVID-19 or another infection.

For HCP:
Healthcare facilities should follow CDC guidance for management of HCP with symptoms following COVID-19 vaccination. Symptomatic HCP who are within 14 days of an unprotected exposure to SARS-CoV-2 in a community or a higher risk exposure in a healthcare setting should be excluded from work and evaluated for SARS-CoV-2 infection.

For HCP who have received COVID-19 vaccination in the prior 3 days (including day of vaccination, which is considered day 1) and are not known to have had unprotected exposure to SARS-CoV-2 in a community or healthcare setting in the previous 14 days and with:

- Signs and symptoms that may be from **either COVID-19 vaccination, SARS-CoV-2 infection, or another infection** (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) may continue or return to work without testing if:
  - Feeling well enough and willing to work

    - Afebrile
    - No other signs or symptoms of COVID-19 such as cough, SOB, sore throat, change in taste/smell

    If not improving in 2 days, these HCP should be excluded from work and tested for SARS-CoV-2.

- Signs and symptoms **unlikely to be from COVID-19 vaccination, including ANY systemic signs and symptoms consistent with SARS-CoV-2 infection** (e.g., cough, shortness of breath, rhinorrhea, sore throat, loss of taste or smell) or another infectious etiology (e.g., influenza) that are not typical for post-vaccination signs and symptoms:
    - Exclude from work pending evaluation for possible etiologies, including SARS-CoV-2 infection, as appropriate.
    - Criteria for return to work depends on the suspected or confirmed diagnosis

For SNF Residents:
SNF should follow CDC guidance for management of residents with symptoms following COVID-19 vaccination. For residents who have received COVID-19 vaccination in the prior 3 days (including day of vaccination, which is considered day 1) and with:

- Signs and symptoms that may be from **either COVID-19 vaccination, SARS-CoV-2 infection, or another infection** (e.g., fever, fatigue, headache, chills, myalgia, arthralgia):
    - Restrict to their current room (except for medically necessary procedures) and closely monitor until:
        - Fever (if present) resolves and
        - Symptoms improve
    - Healthcare personnel caring for these residents should, ideally, wear all personal protective equipment (PPE) recommended for residents with suspected or confirmed COVID-19 while evaluating the cause of these symptoms.
    - If the resident's symptoms resolve within 2 days, precautions can be discontinued; fever, if present, should have resolved for at least 24 hours before discontinuing precautions.
    - Viral testing for SARS-CoV-2 should be considered for residents if their symptoms are not improving or persist for longer than 2 days; residents residing in facilities with active transmission, or who have had prolonged close contact with someone with COVID-19 in the prior 14 days, should be tested for COVID-19.
- Signs and symptoms **unlikely to be from COVID-19 vaccination, including ANY systemic signs and symptoms consistent with SARS-CoV-2 infection** (e.g., cough, shortness of breath, rhinorrhea, sore throat, loss of taste or smell) or another infectious etiology (e.g., influenza) that are not typical for post-vaccination signs and symptoms:
    - Place in a single person room (if available) and implement transmission-based precautions for residents with suspected or confirmed COVID-19 pending evaluation
    - Test for SARS-CoV-2 and other pathogens (e.g., influenza)
    - Do not cohort with residents with confirmed COVID-19 unless also confirmed to have COVID-19
    - Criteria for discontinuing transmission-based precautions depends on results of evaluation

Note: Prior receipt of the Pfizer-BioNTech COVID-19 vaccine will not affect the results of SARS-CoV-2 nucleic acid amplification or antigen tests.

Post-Vaccination Infection Control Considerations

Because information is currently lacking on vaccine effectiveness in the general population; the resultant reduction in disease, severity, or transmission; or the duration of protection, vaccinated HCP should continue to follow all current infection prevention and control recommendations to protect themselves and others from COVID-19, including:

- Facemask use for source control and adherence to physical distancing (within and outside the workplace)
- Use of all appropriate PPE for care of residents with suspected or confirmed COVID-19
- Following CDPH quarantine guidance after an exposure to someone with COVID-19 (including considerations for management of exposed HCP in facilities with critical staffing shortages).

V. Monoclonal Antibody Updates — Dr. Philip Peters

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, bamlanivimab is less complex to prepare for infusion than casirivimab/imdevimab and CDPH is looking at appropriate non-hospital outpatient settings to provide access to this medication. As casirivimab/imdevimab is more complex to prepare, we are currently only distributing via acute care hospital infusion settings.

Bamlanivimab updates

For week five, California received an allocation of 4,450 doses.

In week five, the 8 large specialty pharmacies, which were allocated doses of bamlanivimab to provide to skilled nursing facilities (SNFs) and PACE programs in week 4, were still awaiting their shipments. Therefore, no further bamlanivimab were allocated to these specialty pharmacies with the exception of one new specialty pharmacy (AmeriPharm) which was added to this list of eight and which was allocated 10 doses of bamlanivimab in week 5.

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 for this distribution of bamlanivimab are Pacific West Pharmacy, Skilled Nursing Pharmacy, Consonus Pharmacy Services, AlixaRx, Pharmerica, Citrus Pharmacy, Ron's Pharmacy, OmniCare, and AmeriPharm.

The remaining 4,440 doses of bamlanivimab that were not distributed to these specialty pharmacies were proportionally allocated to the counties' Medical and Health Operational Area Coordinators (MHOACs) based on their 7-day average of new COVID-19 hospitalization and 7-day average of overall new COVID-19 diagnoses.

Details on the allocations are here:
https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/CA-Monoclonal-Allocation-11-27-20.xlsx

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 is encouraging 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.

Casirivimab / imdevimab updates

California received an allocation of 1,240 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. Initially the 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 in 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 to accordingly.

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 Liu & Amy Pine**

Update on Pfizer approval/expected Moderna approval

- The Pfizer-BioNTech vaccine was granted FDA EUA on Friday 12/11, and recommended by for clinical use by the Advisory Committee on Immunization Practices and Western States Safety Group on 12/12/20.
- For the Moderna vaccine, the FDA is expected to meet on Thursday 12/17, and EUA is expected soon afterwards. ACIP and the Western States Safety Group will provide clinical recommendations after FDA EUA is granted.

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
- The next wave of providers will be invited to enroll in COVIDReadi will include Federally Qualified Health Centers.

Doses/allocation

- To date, 327,600 doses of Pfizer vaccine and 672,600 doses of Moderna vaccine have been allocated to CA. The first shipments of Pfizer vaccine began arriving in CA yesterday, and more vaccine will arrive this week. Moderna vaccine, if granted FDA EUA on Friday, will likely begin arriving as early as December 21 (next Monday).
- This first vaccine has been allocated based on a jurisdiction's proportion of health care personnel and long-term care residents. For example, if a county has 5% of California's population of health care personnel and long-term care residents, they receive 5% of the currently available vaccine.

- The CDC Pharmacy Program with CVS and Walgreens was activated this past weekend for Skilled Nursing Facilities. Vaccine to be used in this program is taken off of the top of CA's overall allocation. The next wave of vaccine that CA is due to receive is 393,900 doses of Pfizer vaccine, from which, close to 85000 doses will be taken off of the top to put toward this program, with vaccination in SNFs anticipated to begin the week of 12/28. .

Clinical considerations

- The CDC website is updated with the most recent information about the Pfizer vaccine and clinical considerations.
    - Main landing page: https://www.cdc.gov/vaccines/covid-19/hcp/index.html
    - Clinical Considerations for Pfizer vaccine: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html
- Consent:
    - There is no federal requirement to obtain written consent for COVID-19 vaccination
    - Patients should be provided with the EUA Fact sheet, which will also be available in multiple languages on the FDA website. https://www.fda.gov/media/144414/download
    - CDPH is developing guidance on the use of declination forms for healthcare workers and will share that when it is ready.
    - The CDC notes that federal pharmacy partners may ask for written consent forms.
        - Here is CDC's language about consent or assent in long-term care facilities https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/LTCF-residents.html
- Staggering vaccinations:
    - The CDC recommends consideration of staggering vaccination to minimize the impact of post-vaccination systemic signs and symptoms on healthcare staffing. They understand that not all facilities will able to implement this
        - Other strategies include: Vaccinating HCP preceding 1-2 days off, during which they are not required to be in the facility.
        - The CDC website also provides guidance on the management of patients and healthcare personnel who have signs and symptoms after vaccination, as discussed earlier.
        - https://emergency.cdc.gov/coca/ppt/2020/COCA-Call-Slides_12-14-2020.pdf

Additional resources:

- COVID-19 Vaccine Provider Update, Fridays 9-10am
  Event link for ATTENDEES:
  https://cdphconf.webex.com/cdphconf/onstage/g.php?MTID=e50fed540a27d3a3015fb54994fa930d4
  Event Number: 145 583 3915
  Event Password: Immunize2020!
- CDPH sub-prioritization guidance during Phase 1a:
  https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/CDPH-Allocation-Guidelines-for-COVID-19-Vaccine-During-Phase-1A-Recommendations.aspx
- Consolidated link of CDC/CDPH Vaccine Links: https://eziz.org/assets/docs/COVID19/VaccineResources.pdf
- Vaccination in setting of recent exposure
    - Here is CDC's guidance on people who had previous exposure: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html#vaccination-infected-exposed
        - "Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purposes of vaccine decision-making is not recommended.
        - "Persons in the community or outpatient setting who have had a known COVID-19 exposure should not seek vaccination until their quarantine period has ended to avoid potentially exposing healthcare personnel and other persons to SARS-CoV-2 during the vaccination visit."
        - "For persons residing in congregate healthcare settings (e.g., long-term care facilities) where exposure and transmission of SARS-CoV-2 can occur repeatedly for long periods of time, residents with a known COVID-19 exposure may be vaccinated."

- CDC guidance on precautions for vaccination: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html#contraindications-precautions

VII. Questions and Answers

Q: Is the state reevaluating the expectations of Acute Care Facilities and AFL 20-88?

A: No we are not. We have asked everyone to submit their hospital plan and we gave them until the 14th. Hopefully hospitals have been getting their plans in. We will be following up with those who didn't submit plans.

Q: We heard that there were going to be further FAQs regarding AFL 20-88, we have not seen them and regarding physicians that are out in the community, where to they fit in when it comes to receiving the vaccine for them and their staff?

A: The Drafting Guidelines Workgroup does have a guidance on the different tiers for which health care provider within Phase 1 fall and depending on what their specialty is, they would fall in to tier 2 or 3. They will be soon be invited to enroll in COVID Ready so that can receive and deliver the vaccine. Until that time, they can make arrangements with their Local Health Departments. So they would be after the first tier of providers.

A: With the FAQs, unfortunately what happened was that we ended up using the minutes and distribute them through CAHAN. Those notes are also available on our website as well. We collect all the notes from all of our meetings.

Q: Since testing results are taking about three or four days from our labs where previously it was 24 hours and we are relying on these results for discharge purposes to lower levels of care from our Skilled Nursing Facilities, can we use the BD Veritor or the BinexNOW testing results to discharge to a lower level of care?

A: I think it would be best to check with your local health department in case there are more stringent requirements in terms of receiving patients especially during a surge.

Q: I see that we will be getting a gray CDC COVID vaccination record card. Will the WHO purple access card be adjusted to have a spot for the COVID vaccine or do we just have them write on that as well or just carry the gray card for international travel as well.

A: We do not know. It too early to have clear information about that.

Q: I heard someone mention that there is growing evidence regarding the effectiveness of antigen testing in asymptomatic patients and I wanted to know if you could share a little bit about that evidence and wondering if there is anything published?

A: U.C. San Francisco's Joe DeRisi and Diane Havlir, I believe are in the process of publishing that data. I think it's going to be published in the next couple of weeks but it depends on how well trained the personnel are that are actually reading the test. I will be having a follow up conversation with both Joe and Diane and I can find out what the timing is on them publishing that data and will share that with the rest of you in a follow up.

Q: Are there any changes regarding the threshold for reporting positive staff member output and the requirements to test all health care workers?

A: No, there are no planned changes. We would still recommend the threshold of three or more cases in healthcare personnel with epi linkage. Among healthcare personnel, epi linkage is defined as having the potential to have been within 60 feet for 15 minutes or longer while working in the facility during the 14 days prior to onset of symptoms or positive test. That is for facilities in jurisdictions where they have more than 4 new daily cases per 100,000 or greater than 5% test positivity in the past week.

Q: Would you recommend a negative COVID test or maybe a health questionnaire from the staff regarding potential or recent exposure prior to providing vaccines to the staff?

A: The CDC recommends that people that have previously had COVID19 can be vaccinated. In a setting of limited vaccines, for someone who has been infected in the last 90 days, reinfection is less likely so they recommend deferring those people. They do not recommend vaccinating people in the setting of active COVID19 infections. In terms of people who are exposed, they don't prohibit the vaccination of people that have been exposed. I don't think there is a specific need, unless someone is symptomatic, to test them for COVID. In terms of the screening questionnaire, that is something that we are discussing whether or not to recommend. The CDC does have some guidance on specific contraindications and cautions and their special populations. It may be reasonable to provide a screening form just to make sure you capture those considerations. But we do not have a specific from that we are recommending right now.

A: For health care personnel who had a recent exposure who are seeking vaccination in a community or outpatient setting, CDC does recommend deferring vaccination until the quarantine period has ended and that's to avoid having any exposures to other healthcare personnel during the or other persons during the vaccination visits. For SNFs, residents that have been exposed to COVID during the 14 days prior and that could be during a facility outbreak when we're considering in many instances entire units or wards or even the entire facility to be exposed, those residents can be vaccinated even with recent exposure.

Q: Would it be possible to send guidance out to the local health jurisdiction to include EMS workers

A: I'll take that back to the Vaccine Task Force. EMS workers are supposed to be with that first tier. We will take that back to EMSA to see if they will have any specific guidances that they are planning on delivering or if it will come from the Vaccine Task Force.

A: Medical First Responders are on included in Tier 1 of Phase 1a. That guidance is on the CDPH website and has been published by the Drafting Guidelines work group.

Q: Do you have any additional info on Prep Mod. We were told yesterday from our Local Health Depart that we would have to wait until the Prep Mod is up and ready before we can administer vaccines.

A: An announcement will be going out to all providers that are enrolled in COVID Ready about Prep Mod.

Q: Has CDPH considered waiving all staffing ratios in Skilled Nursing?

A: At this time we have not. At this time, we are prioritizing all of our staffing deployments from the state to Skilled Nursing Facilities first above all else because when we did a root cause analysis, staffing was a bug piece of that. You do have the ability to submit a 5000a form for a waiver depending on the situation. We can look at

that and see if it's something we can approve as well as see if there are staffing available through that state that we can deploy out.

Q: At what point should we be looking at the possibility of the patient being exposed via healthcare worker?

A: There are a number of factors to take into account in terms of the timing of the positive result relative to when the healthcare personnel worked also the nature of the interaction between healthcare personnel and the patient which of course, higher risk of patient exposure. It's best to check with your Local Health Department to help make some of those determinations for exposure.

Q: My question is about antigen testing. Is there any guidance or recommendations from the state for using antigen testing to screen healthcare workers for example as part of a program to mee the AFL 20-88 notice?

A: At this point we want to evaluate the most updated data and assess whether we should update our guidance based on that data. We haven't physically seen it in our hands yet to be able to really look through it and evaluate it. We are continuing to asses and reassess but don't have any definitive plans to change that at this point in time.

Q: Can you please advise me where to find guidance on how to handle asymptomatic healthcare workers who are associated with the protein testing?

A: Asymptomatic healthcare personnel that test positive should be excluded from work until they meet the criteria for return to work which would be using the time or symptoms based strategy and of course with asymptomatic healthcare personnel, you'll use the time based strategy which is 10 days from the date of the positive test. Now if your facility is experiencing a critical staffing shortage, there are considerations from CDC that describe mitigation strategies that allow asymptomatic or mildly symptomatic healthcare personnel who are well enough to work, to work as long as they are working with positive residents or patients in a cohort setting. Special care needs to be taken to ensure that the positive personnel are strictly adhering to source control measures.

Q: Is this included in any of the AFLs or other guidance documents?

A: In the updated quarantine guidance, there are links to CDC guidance on mitigating staffing shortages. If you can go to the CDPH guidance that was just posted on December 14th, you can find a link to the CDC contingency strategies. Under the set of considerations about healthcare employers with critical staffing shortages, it describes the allowance of asymptomatic healthcare personnel to work. I believe will be a AFL that will describe more for the healthcare facility context.

Q: Is there any guidance regarding hospitalized patients who are COVID positive regarding the administration of the flu vaccine?

A: Mild illness in not a contraindication for influenza vaccine administration. For example, a hospitalized patient who has COVID and has stabilizes and is ready for discharge, that individual could be vaccinated for influenza at the time of discharge.

A: Following up on the previous question about a positive healthcare personnel who is asymptomatic. I would just add that if the positive is identified by an antigen test, that individual could be tested with a nucleic acid or PCR test to confirm the result. Of course we would still in general recommend excluding that positive healthcare personnel pending results of confirmatory PCR testing. But again, antigen tests that are positive in asymptomatic individuals should be confirmed with a PCR test.

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