California Department of Public Health
Weekly Facility COVID-19 Update Call
December 1, 2020
8:00 am – 9:00 am

AT&T Meeting Recording: 1 (866) 207-1041
Access Code: 2454884
Available after 10am 12/01/2020

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

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

- None Provided

III. **Laboratory Update** — **Dr. Deb Wadford**

Diagnostic vs. Screening testing for SARS-CoV-2

Diagnostic testing for SARS-CoV-2 is intended to identify current infection at the individual level and is performed when a person has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2.

Screening testing for SARS-CoV-2 is intended to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2. Screening testing is performed to identify persons who may be contagious so that measures can be taken to prevent further transmission.

There is no difference in reporting of Diagnostic testing results and screening testing results, both of which are to be reported to the persons whose specimens were tested and/or to their healthcare provider.

Additionally, both diagnostic testing results and screening testing results (positive and negative) must be reported to the local, state, tribal, or territory health department in accordance with state, federal, and local regulations and with the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act).

Any laboratory or testing site that performs diagnostic or screening testing must have a Clinical Laboratory Improvement Amendments (CLIA) certificate and meet all requirements to perform testing. For more information, see the Centers for Medicare & Medicaid Services (CMS) summary of the CLIA regulations. Assays and test systems used for COVID-19 diagnostic or screening testing must have received an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) or be offered under the policies in FDA's Policy for COVID-19 Tests.

See CDC's Overview of Testing for SARS-CoV-2, https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html, and FDA's FAQs on Testing for SARS-CoV-2.

Point of Care Antigen tests for SARS-CoV-2 with FDA EUA:

1. Quidel Sofia SARS Antigen FIA assay (test within 5 days of onset)
2. Quidel Sofia 2 Flu + SARS Antigen FIA assay (within 5 days of onset)
3. BD Veritor System for Rapid Detection of SARS-CoV-2 (within 5 days of onset)
4. Abbott BinaxNOW COVID-19 Ag CARD (within 7 days of onset)
5. LumiraDx SARS-CoV-2 Antigen Test (within 12 days of onset)
6. CareStart™ COVID-19 Antigen (within 5 days of onset)

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-antigen

IV. Healthcare-Associated Infections — Dr. Erin Epson

1. Last week, CDPH disseminated AFL 20-88 Coronavirus Disease 2019 (COVID-19) Testing Recommendations for Patients and Health Care Personnel (HCP) at General Acute Care Hospitals (GACHs), which provides guidance for weekly SARS-CoV-2 screening testing for HCP and recommendations for the testing of newly admitted patients.

   The purpose of screening testing for hospital HCP is to aid in early identification and work exclusion of infected HCP, and thereby reduce transmission risk to other HCP and patients, and prevent hospital outbreaks in an effort to maintain patient safety and preserve the critical HCP workforce. Whether exposed in the community or while at work (both of which increasingly likely during the current surge) infected HCP can transmit to other HCP (through close contact in break rooms and other common areas) as well as their patients; the HAI program is aware of > 100 hospital outbreaks throughout the state since the beginning of the pandemic, and this is likely a substantial underestimate of the burden of hospital outbreaks, since the AFL providing outbreak investigation and reporting thresholds and definitions for hospitals was disseminated in late September. Hospital outbreaks have involved various combinations of nurses, respiratory therapists, physicians and techs, but also non-clinical personnel such as security staff; and of course, patients have acquired COVID while in the hospital for another condition.

   CDPH is therefore instructing hospitals to develop and implement a program of weekly screening testing for SARS-CoV-2 among HCP. Ideally, to maximize the strategy for prevention of outbreaks, all HCP should be included in the weekly screening testing program, since it's not just the clinical personnel that can introduce and expose others in the hospital. As such, HCP are defined as all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air.

   Recognizing the need to develop their plans and procedures for implementing a hospital-wide HCP testing program, CDPH recommends hospitals initially prioritize weekly screening testing the week of December 7th in HCP whose work carries a higher risk of SARS-CoV-2 exposure to patients with

unknown COVID-19 status for whom optimal exposure control measures might not be in place; although as I stated, limiting testing to this group of individuals is not likely to eliminate the potential for introduction of outbreaks from staff who work anywhere in the hospital but are exposed in the community. CDPH recommends hospitals begin weekly screening testing of all HCP by December 14, 2020.

HCP with signs or symptoms consistent with COVID-19 should be tested immediately. Hospitals should not delay testing of symptomatic HCP until scheduled screening testing. HCP who had a positive viral test in the past three months and are now asymptomatic do not need to be retested as part of facility-wide testing; testing should be considered again (e.g., in response to an exposure) if it is more than three months after the date of onset of the prior infection, or if new symptoms occur. For HCP who develop new symptoms consistent with COVID-19 during the three months after the date of initial symptom onset, if an alternative etiology cannot be identified, then retesting can be considered in consultation with infectious disease or infection control experts.

In general, HCP with COVID-19 should be excluded from work for the duration of their isolation period; hospitals experiencing staffing shortages should follow CDC Guidance on Mitigating Staffing Shortages for strategies prioritizing allowance of exposed or positive asymptomatic HCP to work under specified circumstances.

Finally, CDPH recommends hospitals test all patients prior to (or upon) admission and monitor all patients for the development of COVID-19 symptoms, promptly testing any newly symptomatic patients and patients who are exposed to a suspected or confirmed case during their hospital stay.

2. **From:** Berg, Eric@DIR <EBerg@dir.ca.gov>
Sent: Tuesday, September 1, 2020 12:55 PM
To: Jennifer Wieckowski <JWieckowski@hsag.com>
Cc: Steinecker, Heidi@CDPH <Heidi.Steinecker@cdph.ca.gov>; Epson, Erin@CDPH <Erin.Epson@cdph.ca.gov>
Subject: Re: SNF Follow Up Comments for Cal OSHA

It's not in our guidelines yet but use of one disposable respirator for a single 16-hour shift is acceptable if the CDC recommendation that disposable respirators are put-on and taken-off a total of no more than 5 times can be met.

The purpose of screening testing for hospital HCP is to aid in early identification and work outbreaks, since the AFL providing outbreak.

V. **Remdesivir Update** **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, at this time we are only distributing via acute care hospital infusion settings.

Bamlanivimab updates

For week three, California received an allocation of 3,230 doses which was about 6.5% of the national allocation.

This week, CDPH will slightly alter the distribution formula to now use acute care hospital data of the 7-day average of new COVID-19 admissions and conversions in a county and also the number of new COVID-19 diagnoses in a county to proportionately distribute bamlanivimab via the counties' Medical and Health Operational Area Coordinator (MHOAC). Previously CDPH had used only the hospitalization data.

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

To date most of the allocation have gone to clinical sites affiliated with acute care hospitals as these locations had existing infrastructure to receive the medication from AmeriSource Bergen, had capacity to infuse treatments, and have access to high-risk patients in outpatient settings in their networks. Starting in the next 1 – 2 weeks, CDPH will also start allocating some bamlanivimab to skilled nursing facilities (SNFs) and select federally qualified health centers (FQHCs) in the state. The plan for SNFs is to allocate bamlanivimab to multiple large specialty pharmacies that serve many of the SNFs in the state. Medical directors or other authorized prescribers at the SNFs could order bamlanivimab from one of these specialty pharmacies if they have a patient that qualifies for treatment. The pharmacy would prepare the product for infusion and send to the SNF for infusion. The plan for FQHCs is to pilot the provision of bamlanivimab at 4 FQHCs in California. HHS has offered to send us additional product to pilot the use of bamlanivimab in FQHCs and we hope to learn lessons to inform use in other FQHCs statewide. FQHCs are not required to participant or wait for this pilot and can also be independently designated a site for bamlanivimab treatment by their county MHOAC.

Casirivimab / imdevimab updates

We are in the first week of casirivimab / imdevimab allocations and California received an allocation of 2,328 doses. The same formula is used to proportionately distribute casirivimab / imdevimab to the counties' Medical and Health Operational Area Coordinator (MHOAC) per the established Multi-Agency Coordination Group (MAC Group) process. The MHOAC then allocates casirivimab / imdevimab within their county. Initially the plan is to other allocate to acute care hospitals and their affiliated settings as casirivimab / imdevimab is more complex to prepare. Details on the week one allocation will be posted later this week.

Grand Rounds

Finally, I want to draw your attention to an exciting upcoming grand rounds cosponsored by CMA and CDPH on Tuesday, December 8th at noon. The topic is "*The National COVID-19 Surge and Hope for 2021 - A Conversation with State Leaders and Members of President-Elect Joe Biden's Coronavirus Task Force*". The grand rounds will include a conversation with Dr. Robert Rodriguez and Dr. Eric Goosby who are two physicians that hold central roles on President-Elect Joe Biden's Coronavirus Task Force as well as Dr. Seema Jain from CDPH who is an expert in the epidemiology of winter respiratory viruses and will discuss an approach to viral co-infections with COVID-19.

Link: https://www.cmadocs.org/event-info/sessionaltcd/CME20_1208_GRCOVID

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. **Questions and Answers**

Q: There was a recommendation of extended use of N-95 respirators for up to 16 hours of use, but there was no written documentation of the answer in the meeting minutes. Although the answer was yes, can today's minutes please reflect the answer for documentation purposes?
A: Dr. Epson: CAL OSHA did indicate in an email that the extended use of an N-95 respirator could extend on a single shift out to 16 hours with the consideration that it shouldn't be docked and re-donned more than 5 times during the course of the shift.

Q: There are a lot of questions from staff asking if they can bring their own face shields from home and if they can take it home? Can I have an update if it can be used multiple days and what the decontamination process would be and if they can take the face shields home?
A: Dr. Epson: We have not specified about taking home in between use, but in general that is not a good practice since we can't assure what happens in terms of the level of cleanliness and storage of reusable Personal Protective Equipment (PPE) at home. We would encourage facilities to develop a situation for storage of individual healthcare personnel reusable PPE within the hospital that can be maintained in a sanitary fashion. For the face shield when used for extended use it does not need to be decontaminated between each patient so long as the healthcare personnel hasn't touched or manipulated the face shield during providing patient care or completing patient care. If that does occur the healthcare personnel does need to perform proper hand hygiene and the face shield or goggles

would need to be decontaminated at the end of their shift before storing in a clean place for the next use.

Q: Do you recommend for healthcare professionals to wear the face shield all shift or just when administering patient care?
A: Dr. Epson: the recommendation for universal eye protection is for personal protective equipment and not source control. Whereas the facemask for source control always needs to be worn by healthcare personnel when they are at the healthcare facility, including non-patient care areas, maintaining physical distancing, etc. The face shield or eye protection is meant for individual PPE in areas with high community transmission and when carrying out patient care activities. That can be used per extended use during a shift and removed during breaks, but again with the consideration around storage in a clean space and performing hand hygiene before and after re-donning.

Q: Can the face shield be used for many days if it was properly stored?
A: Dr. Epson: Yes as long as the face shield remains intact without compromise to the material.

Q: Regarding Bamlanivimab monoclonal antibodies, there was indication in the CDC guidelines for criteria among it for Body Mass Index (BMI) greater than 35 and patients 65+ and other comorbid conditional. There was some recent recommendation that we can only use it for patients over 65 AND BMI greater than 35. I was wondering if the two criteria's must be fulfilled.
A: For the criteria it is not over 65 AND BMI over 35. It's one OR the other and if you look at the Emergency Use Authorization (EUA) there are a lot of criteria that qualify for treatment and those criteria are valid. If you look at the clinical trial for Bamlanivimab it seems to benefit people who were older than 65 OR BMI greater than 35. It's an OR and not an AND condition. I would certainly acknowledge that there are other clinical situations beyond those two indicators where people are high risk for progression to severe disease and would be good candidates if they could be treated early enough, but those two indicators (older than 65 OR BMI greater than 35) are likely the two most common risks for severe infection.

Q: Regarding the emergency use does this require an internal review committee before allowing us to use it or just fulfilling the criteria would be ok to use indications.
A: I think each institution should have their own protocol for how they are going to implement and what situations they would offer to patients, but the requirement for the EUA is to review the FAQ sheet with patients and care providers (depending on the individual patients situation) that you review that fact sheet with them that explains it's an investigational product. Outline the benefits, outline things we don't know, potential side effects and then the person would verbally say they would like to receive the product. This gets documented in their chart, so that there's not a separate informed consent that people are signing to receive the products.

Q: Is there any benefit to the cocktail or BAM?
A: The EUAs are identical to each other than how the products are prepared. The Bamlanivimab has more data published and the Casirivimab and Imdevimab combination cocktail has no data published on it. There aren't too many head to head data published, please note that both are very much investigational product classification. I believe that these products were moved by the FDA is because

of the surge that is going on with hospitalization and one of the benefits is that it can reduce hospitalization given early enough to the right patient population.

Q: If this is the case how would you verify the individual benefits? In other words, preventing hospitalization and other complications. What should we be looking for after we give the medication to a patient?
A: In the short term, making sure there is no infusion reaction. Only in a clinical trial would you be able to distinguish if this product is causing benefits or not, or if the virus is resolving on its own or not. In the trial when people were presenting symptoms, they saw a quicker resolution of symptoms in those who were treated. In the short term making sure there is no infusion reaction and making sure that its people are aware that if their clinical condition is worsening then they need to contact their healthcare provider right away.

Q: Regarding the mitigation plan and links, how long does it take for them to respond to guidance? The COVID staffing mitigation when there is a staff shortage?
A: Per Heidi S.: All facilities can always submit a resource request through the Medical Health Operational Area Coordinator (MHOAC) program once you've exhausted all options of contracts, registries, etc. Local MHOAC program may be able to fulfill at the county level. If they don't have any staff available at local level, they may send the request up to the regional level. If they don't have anything at the regional level, then it will be sent up to the state ops center. The state ops center does have some combat teams, national guard team and contractors. We are also pulling staff from Australia for help.

Q: CAL OSHA describes an exposure of a close contact to be with someone within six feet for more than 15 minutes cumulative, and they say this is regardless of a face mask. The Centers for Disease Control and Prevention (CDC) guidelines for Healthcare workers does not have that as their definition of exposure. Can you clarify which definition we should be referring to?
A: Dr. Epson: CAL OSHA's general exposure criteria for community setting are what you described within six feet for 15 minutes or longer regardless of source control. CDC's Guidance for evaluation and management of potentially exposed healthcare personnel takes a bit more nuanced approach. Regarding the type of procedures that might be involved with aerosol generating procedure, which is a higher risk, and with types of things that would not normally happen in the community. The CDC's guidance discusses different levels of PPE worn, and considers those to be higher or lower risk based on all these criteria. The guidance Also assumes from the standpoint of the healthcare personnel that the healthcare personnel is trained in the use of PPE where we normally wouldn't be able to assure that in community settings.

Q: Several Community health centers have ordered the Abbott ID now machines, but we are having trouble obtaining cartridges and I was wondering if there's an update on when they'll be available or how they'll be distributed?
A: Per Dr. Jacobson, just to clarify you are talking about the Abbott ID which is a rapid point of care PCR test. Historically there have been challenges with shortages with both reagents and cartridges. I understand that it's again an issue and there was thought that there would be enough supply this time around. In short, I don't have a definitive timeline as to when those shortages will be resolved.

Q: For many months now despite the data provided by CDPH numerous hospitals have been struggling to obtain reagents for multiple platforms. National testing lab are limiting specimen submission to help control turnaround time, multiple private labs have limited capabilities and I was wondering if the state has a definitive plan to enable hospitals to obtain the necessary reagents to perform all these tests that you are asking for based on the new AFL.
A: Dr. Jacobson: The instruments you were referring to, the Abbott now, ROCHE, serologic panthers, the issue with those testing platforms are that they are proprietary testing platforms and they will not allow outside supplies to be used, you have to use their particular platforms. The other piece of this are testing platforms that are open platforms where the possibility does exist to use other supplies. The state Valencia regional lab is using Perkin Elmer equipment which are open platform equipment. These supplies can be used on 20 different platforms that are considered open platform and not proprietary, so It is possible to get supplies form companies like Perkin Elmer.
A: Dr. Wadford: In terms of obtaining reagents for certain assays we are all in the same situation, we have tried to diversify at the state, and we are looking forward to Valencia Branch Laboratory ramping up to its expected capacity.

Q: Those supplies won't be in regard to asymptomatic screening correct?
A: Dr. Wadford: According to Dr. Time Stenzel during a nationwide call, Dr. Stenzel said that off label use of antigen test, they (FDA) don't have a problem with that and there have been few studies showing testing of asymptomatic is reliable.

Q: Would that be considered acceptable as a methodology? Regarding screening purposes?
A: Heidi S.: If you have a specific question about your particular plan please work with local district office and the local public county office to flush out your plan to get some technical assistance in regards to capacity, their own staff, their own patients, and their own community. Best practice would be to take this offline and if there's a specific question regarding your particular plan or particular region and to include both your district office and your county office to what would work best for your situation.

Q: 95% of healthcare workers acquire disease through community exposure and not following social distancing or PPE guidelines at work. What do you think the asymptomatic positive rate is going to be? And do you have data that this is going to make a difference in outbreak control in facilities that already have good plans in place?
A: Heidi S.: We do have data from the HAI data sets that 70% of hospitals have some sort of healthcare professional related outbreak. The goal really is that testing is one tool in the toolbox to try and understand where the disease is to isolate or be able to have information available to make use of action.

Q: What I'm hearing for the first time is that the antigen test may be considered acceptable for asymptomatic testing for screening?
A: Heidi S.: What we are talking about is a serial approach, I know that our testing taskforce is working on a research on the skilled nursing side where we are looking at how to use these machines more effectively. We are trying to add more tools to the toolbox.

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