

Weekly LHE Meeting with the DSHS Immunization Program

Questions / Answers

DATE OF FORUM: Nov. 20, 2020

The questions (**in bold**) were collected during the weekly forum.

What if we plan to use shipping container for storage, using dry ice, how do we list that in the provider application? As well as temperature data logger use for those containers?

ANSWER: As of 11/23/2020 this is not a question in provider registration. Ultra-cold shippers will come with a data logger that will need to be returned along with the shipper once all vaccine is used.

Good morning, is it too late to sign up/register to give vaccination??

ANSWER: It is not too late! Go to enrolltexasiz.dshs.texas.gov

Can we request links for provider signatures, in case the email sent has been lost? Is there a way to make corrections to enrollment such as emails for signatures needed?

ANSWER: Please contact us at the below so we can assist you with your specific needs.

COVID-19 Registration Support

Email: COVID19VacEnroll@dshs.texas.gov

Toll-Free: (877) 835-7750

Are the signatures that are being referred to part of the provider agreement?

ANSWER: Yes, signatures are required as part of the provider agreement.

Can the Pfizer vaccine be kept frozen, not the ultra cold? And if so, for how long?

ANSWER: The Pfizer vaccine cannot be kept frozen/in the freezer. The storage options are ultra-low temperature freezer for 6 months and refrigerated temperatures for 120 hours.

Can you discuss the 2nd dose window? Separation of 21 or 28 days, depending on specific product but what might be the maximum time before the series would need to be reinitiated? (e.g. what if the patient presents for second dose at 60 days?)

ANSWER: Generally ACIP will have a "recommended interval" i.e 28 days and a minimum interval. We do not yet know if there will be a "maximum" interval in which to complete the series. This should be part of ACIP recommendations for each product.

Can you categorize the types of providers that are signing up based on their patient profiles and the number of patients that they will vaccinate?

ANSWER: As part of the registration process we ask each provider the number of people served within each of several critical population groups.

I am not a medical expert, but what it appears to me from the way it was presented is the "Placebo is safe." Pfizer had 8 vaccine vs 162 placebo. Moderna 5 Vaccine vs 90 placebo. Would you please explain how this trial actually proves this is effective?

ANSWER: I think the data you are referring to is the vaccine efficacy which is different from safety. If out of the 170 people who got sick with COVID-19 during the clinical trial, 8 had received the vaccine and 162 had received the placebo, that means people who got the vaccine were much less likely to get the disease. If a vaccine were not at all effective, we might see the same number of people getting sick in both the vaccine and placebo groups (i.e. 85/170). Hopefully that makes sense. Here's an infographic: <https://scitechdaily.com/images/COVID19-Vaccine-Efficacy.jpg>

Based on these numbers, most of this is divided up by Region, will allocation be based on region or by county?

ANSWER: Currently our allocation plan is based on county.

For the phase 1a portion, and if Pfizer is the only vaccine available, how is the state expecting groups that are smaller to reach the 975-dose minimum?

ANSWER: We recognize the minimum dose may limit the usefulness of that vaccine in smaller settings or rural areas. It's possible the minimum order quantity will change in the future. We may also have other vaccine products, like Moderna, with smaller minimum orders we can target to areas that cannot handle the larger quantity of Pfizer.

Will providers get a choice to choose which vaccine if there are 2 available?

ANSWER: Initially no. During the initial phases of vaccine availability, Texas DSHS will allocate doses to providers and they will have the capability to accept, reduce, or reject the allocation. When vaccine availability increases, which depends on how quickly they can be manufactured, then providers will be offered the opportunity to order the vaccine of their preference.

For rural areas, is the plan to use IDRU/EMTF teams similar to with nursing homes to provide those vaccines??

ANSWER: CDC has established the Federal Pharmacy Partner program to provide on-site vaccination to nursing homes and other LTC facilities within a 75-mile radius of a CVS or Walgreens location. DSHS will be evaluating the list of LTCF's signed up through that program to look for gaps and develop plans with local health entity involvement to address any gaps.

How soon would we know when we are getting a vaccine shipment? What's the turnaround time?

ANSWER: It is currently unknown when the vaccines will become approved. Once they are approved, we will allocate vaccines to providers as soon as the CDC allows us.

Provider and distributors have been used interchangeably. Can there be a brief explanation of each, if different?

ANSWER: Providers are vaccinators. Entities that can provide vaccination services. A distributor simply distributes vaccine to providers.

If we previously registered without ultracold but now have it, how do we add it our registration?

ANSWER: Yes, you can make changes to your registration.

Are there preferred specifications for the refrigeration/freezer equipment? Outside of the temperature/temperature logging capabilities? We want to make sure we do not buy/rent anything that will not work.

ANSWER: The following types of units are recommended: pharmaceutical/purpose built units, stand-alone, single purpose refrigerator and stand-alone single purpose freezer, combination household unit. Please note that dorm style units are not approved any time to store vaccine.

Will pharmacies be involved in Phase 1B?

ANSWER: Yes, some pharmacies are working directly with the CDC on a national level to vaccinate Long-term care facilities during phase 1B. Texas is working with the pharmacies to ensure coverage throughout Texas, but has not limited or targeted any one facility type to provide vaccinations during Phase 1B.

Are Health Inspectors considered essential? Health Inspectors conduct health inspections in schools, nursing homes, hospital and other establishments that serve susceptible population.

ANSWER: The essential worker category has not been defined by Texas yet. Currently, only Phase 1A populations are being refined to ensure we can equitably disseminate vaccines once they are available.

Any reported typical immune responses (subjective fever, myalgias) following vaccination and, if so, what's the typical duration? Just planning on how to structure our rollout plan.

ANSWER: Thus far the current safety data available from the Phase 3 studies for both vaccines are as follows:

- PFIZER- Grade 3 adverse event greater than 2% in frequency was fatigue at 3.8% and headache at 2.0%.
- MODERNA- Grade 3 (severe) events greater than or equal to 2% in frequency after the first dose included injection site pain (2.7%), and after the second dose included fatigue (9.7%), myalgia (8.9%), arthralgia (5.2%), headache (4.5%), pain (4.1%) and erythema/redness at the injection site (2.0%)

Additional data and guidance on safety will be available after ACIP recommendations are finalized.

I didn't see EMS listed. Are you assuming it is included in 'healthcare workers'?

ANSWER: Texas DSHS will issue final guidance as to how EMS will be prioritized.

As a local health department, I've found it challenging to enroll multiple clinics when one person can't enroll all clinics and it requires a different email address/registrant to enroll each clinic.

ANSWER: The enrollment system is set up to have a 1:1 relationship between the user and the enrollment form. If you have a personal email, you could fill out an additional enrollment form. We are working with the system developers to have this issue corrected so that one person can fill out multiple enrollment forms.

It is expected that providers without access to ultra cold freezers will receive the Pfizer vaccine?

ANSWER: Yes, the Thermal Shipper that Pfizer will ship the vaccine in can be used as a temporary storage options provided the dry-ice replenishment scheduled is followed.

Can you draw a dose up and put the vial back in the refrigerator?

Understand must be used within the time limit, but hate to have staff get used to leaving vaccine vial on the counters. We can mark the exp. date on the vial but keep it in the refrigerator during the day it is being used?

ANSWER: Once a vial is brought at Room Temperature and dose is withdrawn, it needs to be used within the specified time for the respective vaccine. Both vaccines are preservative free, so once a dose has been drawn, the remainder of the doses must be used within the specified time frame (Moderna, 12 hours and Pfizer 6 hours post-dilution).

This may be getting into the weeds a bit, but will HCP have to provide proof of employment to receive the vaccine in the early phase of vaccination availability?

ANSWER: We don't have any guidance on that at this time. More information should be coming out soon on implementation of the phased response.

Is DSHS monitoring the completion of these provider enrollments? We have had a few providers contact us requesting status updates on their applications, and after contacting DSHS, they were informed they did not complete the entire process. Is there any push coming from DSHS central office to encourage providers to complete their enrollment?

ANSWER: DSHS is approving providers at an expedited rate; however, there is some delay due to the prioritization of providers. Phase 1A providers have been prioritized for review and approval.

A provider should contact us at the below so we may address their concerns.

COVID-19 Registration Support

Email: COVID19VacEnroll@dshs.texas.gov

Toll-Free: (877) 835-7750

We've had an issue where it appears two provider applications from our LHD got merged into one. What's the best avenue to address that?

ANSWER: The DSHS COVID-19 Vaccine Provider hotline at (877) 835-7750, 8 a.m. to 5 p.m., Monday through Friday or email COVID19VacEnroll@dshs.texas.gov.

Does Education Workers include higher education, or does faculty and staff at an institution of higher ed fall under Colleges and Universities?

ANSWER: These recommendations will be made by the Expert Vaccine Allocation Panel (EVAP) to the DSHS Commissioner. The estimates in the meeting included them as education workers.

Does the number of providers map include pharmacies?

ANSWER: Yes, it includes those pharmacies that have registered as COVID-19 vaccine providers.

Do we have any information on what the recommendations are if a patient misses the recommended 21-day or 28-day second dose administration? Is there a maximum allowable amount of time to receive the second dose if they do not return in 21 or 28 days depending on vaccine received?

ANSWER: Generally ACIP will have a "recommended interval" i.e 28 days and a minimum interval. We do not yet know if there will be a "maximum" interval in which to complete the series. This should be part of ACIP recommendations for each product.

Will the vials have barcodes on them with the lot and expiration date?

ANSWER: Yes.

Will providers need to wait to give the SECOND dose until a certain time? Recalling "if given 1,000 doses, give to 1,000 people" so when do we know to give second doses? Thank you.

ANSWER: Yes, each product will have a recommended interval between the first and second dose. If providers have a reminder recall system in place they can also use that to remind patients when their second dose is due.

It is my understanding that this is a multi-dose vaccination. Will there be any restrictions (quarantine or other) in between the first and second dose?

ANSWER: No, if someone is not ill or positive for COVID-19 disease, there should be no need to quarantine or restrict them. However, it's important to understand you are not fully protected until 1-2 weeks following the final dose of most vaccinations. Additional data may become available specific to COVID-19 vaccines. People should continue to follow other recommendations to minimize the risk of transmission.

Is there a way for local jurisdictions to see why a provider has not been approved to be a provider so that we may be able to assist them in getting approved? For example: we know of a provider that said they registered but are not in the DSHS database of registered providers.

ANSWER: No, the local jurisdiction cannot see why a provider has not been approved. Those issues should be referred to the contact information listed below. Local jurisdictions can help by ensuring the primary facilities within their jurisdiction are registered to become COVID-19 vaccinators. If not, it would be very beneficial if the local jurisdiction could connect with the provider in question and encourage them to enroll through the enrollment website.

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Does the Phase 1 group include the Family Members of the targeted essential groups?

ANSWER: These recommendations will be made by the EVAP to the Commissioner.

For the second dose of either vaccine, will the client have to return for the second dose on exactly day 21 or day 28 after the first dose? Or will there be a leeway of a couple days past the 21- or 28-day mark?

ANSWER: Generally, ACIP will have a "recommended interval" i.e 28 days and a minimum interval. We do not yet know if there will be a "maximum" interval in which to complete the series. For most vaccines, giving the second dose a bit later than recommended is less of a concern than giving it too soon after dose 1. This should be part of ACIP recommendations for each product.

I have heard on the news that CVS & Walgreens will have the vaccine. So when do you project that will happen?

ANSWER: CVS and Walgreens are participating in the Federal Pharmacy Partners program. They will be able to vaccinate specifically in nursing homes and long-term care facilities in Phase 1. The rest of the direct federal pharmacy allocations do not start until phase 2. However, any pharmacy or any provider of any type may receive vaccine in any phase if they are registered providers and serve the target population.

Do the people who have tested positive need to get a vaccine too?

ANSWER: ACIP has not yet made recommendations on this.

Will this be a yearly vaccine like flu or is this one set of two doses and that is good for long term?

ANSWER: There is not enough data to know the answer to this question yet.

Should race/ethnicity not be explicitly taken into account in some cases in 1B? For example, tribal communities. Why not all congregate settings such as detention facilities--will those not be in 1B? Based on outbreaks that would make sense. Do local communities have ability to tailor?

ANSWER: Draft guidance from ACIP and CDC includes People from racial and ethnic minority groups and People from tribal communities as critical populations. Tribal communities have the option to receive special allocation directly through the Indian Health Services.

Is Public Health included in the Healthcare category? Thanks.

ANSWER: These recommendations will be made by the EVAP to the Commissioner. The critical population estimates in the meeting included them.

How will we know if we didn't fill in the provider enrollment correctly?

ANSWER: DSHS COVID-19 staff will contact you and request you revise your enrollment.