Local Public Health COVID-19 Vaccination Frequently Asked Questions October 16, 2020
New questions are in red. Updated questions are highlighted.

General Questions

What partners should we bring to the table during planning & implementation of a COVID vaccination program?
Consider representatives from your immunization program, preparedness program, emergency management agency, health care coalition, media/public affairs, and crisis and emergency risk communications to develop plans and coordinate activities.
Consider establishing COVID-19 vaccine implementation committee(s) of community members with expertise in care and access issues for critical populations to enhance development of plans, reach of activities, and risk/crisis response communication messaging and delivery.
Include representatives from key vaccination providers for groups identified by CDC as being at increased risk of severe COVID-19 and others likely to be prioritized for initial vaccination.
Include representatives from other sectors within the community, such as health systems, pharmacies, long-term care/assisted living facilities, business, education, corrections, religious, tribal, and racial and ethnic minority-serving organizations, etc. Refer to page 9 of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations Version 1 for more detail.

How will counties request vaccination resources?
Ancillary supplies will be packaged in kits. A minimal supply of personal protective equipment (PPE), including surgical masks and face shields, for vaccinators will be in the kits and shipped separately from the vaccine, but timed to arrive together. If you need additional resources, you may submit a request using the usual request process via WebEOC and/or ReadyOp form.
Ancillary Supply kits will contain supplies to administer 100 doses of vaccine, including:
• Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
• Syringes, 105 per kit
• Alcohol prep pads, 210 per kit
• 4 surgical masks and 2 face shields for vaccinators, per kit
• COVID-19 vaccination record cards for vaccine recipients, 100 per kit

Should the LHD wait on the State vaccine plan to being planning?
No. Local health departments should begin planning now. Consider reviewing your H1N1 plan and after-action/improvement plans from the H1N1 pandemic. Refer to page 6-9 of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations Version 1 for more detail.

What should LHDs be doing right now?
Consider convening internal planning and coordination team(s) whose members represent a wide array of expertise. Assign roles and responsibilities based on areas of expertise. Assess your capacity for offsite vaccination clinics, and other resources needed COVID-19 vaccination efforts. Also, review your All Hazards Mass Vaccination Plan. Begin development of a list of providers in your county that can provide COVID-19 vaccine.
What documents are available now for LHDs to reference?
Local health departments may reference the following documents: CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, the CDC vaccine plan template, the Operation Warp Speed (OWS) Vaccine Distribution Process Infographics, and From Factory to the Frontlines OWS strategy for Distributing a COVID-19 Vaccine. Keep in mind, the playbook is a programmatic guide for state programs, however there are many key points that are pertinent to LHDs.

After providing vaccination cards to patients upon administering the first vaccine dose, will local public health be responsible for providing manpower to follow up with patient reminders (e.g., calls, texts, etc.) to return for second doses?
All providers, including LHDs, will be expected to assist with second dose reminders to those they vaccinate.

a. For most COVID-19 vaccine products, two doses of vaccine, separated by 21 or 28 days, will be needed. Because different COVID-19 vaccine products will not be interchangeable, a vaccine recipient’s second dose must be from the same manufacturer as their first dose. Second-dose reminders for vaccine recipients will be critical to ensure compliance with vaccine dosing intervals and achieve optimal vaccine effectiveness. COVID-19 vaccination providers should make every attempt to schedule a patient’s second-dose appointment when they get their first dose.

b. The NCIR has reminder/recall functionality to identify patients in need of a second dose using a 28-day interval between dose one and dose two. CDC has indicated there will be a COVID vaccine which that requires a minimum interval of 21 days between dose one and dose two. The NCIR does not have this functionality, but we are investigating with our technical vendor to make this modification. CDC developed a national application, VAMS, to fulfill COVID vaccine reporting requirements, which states can use if their state specific registry cannot meet all CDC and OWS reporting requirements or support clinical requirements such as min intervals.

How should local health departments handle patients if they return for their second vaccine dose outside the recommended dosing interval?

a. To help avoid this scenario, providers should take every opportunity to educate on the second dose interval including verify the minimal interval for the second dose and list it on the patient vaccination record, educate the patient on the minimal interval for the second dose, and provide the written reminder card to the patient to remind them when to return.

b. There are several factors that are unknown about the products due to their clinical trials investigation status, and this includes dosing outside of the products stated dosing interval. Additional guidelines will be forthcoming from the ACIP recommendations, CDC storage guidelines and, FDA EUA guidance specific for each product.

Are local health departments eligible for inclusion in the State COVID Vaccination Weekly Touch Point calls? If so, how would a health department sign up for inclusion in these calls?
Vaccine Planning updates for local health departments will be provided during the LHD COVID-19 Weekly Update Call, as vaccine planning updates become available from federal partners and state health officials. Local health departments are represented on the state vaccination planning team by Stacie Saunders, Buncombe County Health Director, and Jim Madison, Beaufort County Health Director.

What is an IIS?
An IIS is an immunization information system. For NC, our IIS is the North Carolina Immunization Registry (NCIR).
Where can I find a copy of the State’s COVID-19 vaccination plan?
The NC COVID-19 vaccination plan can be found on the NCDHHS COVID-19 website. This plan was submitted to the CDC on October 16, 2020.

Vaccine Trials

How can people enroll in trials?
People interested in enrolling in COVID-19 vaccine trials may visit the following website https://www.coronaviruspreventionnetwork.org/clinical-study-locations/.

Are all US vaccine trials on the same timeline for potential approval and distribution?
Under Operation Warp Speed – The broad strategy is to accelerate development, manufacturing, and distribution of COVID-19 countermeasures by having many of the processes happen simultaneously instead of one after the other. Over 125 vaccines are currently in development; over 25 in clinical trials are currently running. Two COVID-19 vaccines approved in other countries (Russia and China), however none are currently approved for use in the US. Six manufacturers already have federal contracts for vaccine purchase when the vaccines are approved.

Distribution and Receipt of Vaccine

Will ancillary supplies be shipped with the amount of vaccine or will we need to request that separately?
Ancillary supply kits will come with the vaccine and will include needles, syringes, alcohol prep pads, COVID-19 vaccination record cards for each vaccine recipient, and a minimal supply of personal protective equipment (PPE), including surgical masks and face shields, for vaccinators. Refer to page 1 above to see exact supplies and amounts and page 25 of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations Version 1 for more detail.

When the COVID-19 vaccine is available, will it ship directly to the facilities approved for vaccinations? Or will it all come to the LHD’s for distribution?
We believe vaccine (and adjuvant, if required) will be shipped to provider sites within 24 hours of approval by CDC. If a provider is enrolled in the COVID-19 vaccination program and can administer the minimum ship quantity (100 doses in most cases, but 1000 doses for at least 1 vaccine) they can receive shipments directly to their site.
Regarding the question about LHD’s having to distribute vaccine, NC has submitted questions to CDC related to what they may consider redistribution and what may not be considered redistribution particularly as it related to vaccines that have large minimum shipment quantities. We anticipate that LHDs may need to provide vaccine doses (if permitted by CDC) to places within their county that do not meet the minimum ship to quantities. Additional information will be provided as it becomes available during the LHD Weekly COVID-19 Update Call and this FAQ document.

How will the vaccine be distributed?
CDC will use its current centralized distribution contract to fulfill orders for most COVID-19 vaccine products as approved by jurisdiction immunization programs. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer. COVID-19 vaccination providers will be required to report administration within 24 hours of the administration and ongoing COVID-19 vaccine inventory at least daily.
Vaccine orders will be approved and transmitted by the state in CDC’s Vaccine Tracking System (VTrckS) for vaccination providers. Refer to pages 25-26 of the COVID-19 Vaccination Program
Storage and Handling

Should we purchase a freezer unit now to prevent a delay in receiving vaccine if these ultra-low temp freezers are not available?
Local health departments are not advised to purchase ultra-low temperature freezers at this time. Ultra-cold vaccine may be shipped from the manufacturer in coolers that are packed with dry ice. Refer to page 45 of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations Version 1 for more detail.

Does the state have any more information about the dry ice shortage being reported? Since LHD’s are not supposed to purchase ULC storage equipment, is there a back-up plan if dry ice is not available?
NC is aware of shortages of dry ice being reported. NC DHHS is also working with state partners to assess dry ice capacity in NC. Additional information will be provided as it becomes available during the LHD Weekly COVID-19 Update Call and this FAQ document.

If we receive 100 doses of the vaccine and need to hold 50 of those doses for a patient’s second dose to be administered 21-28 days later how should we plan best to keep the vaccine at the appropriate temperature if it requires ultra-cold storage?
Please know that neither you (LHD) nor providers are expected to hold back vaccine for a second dose. The second dose will be held at the Federal level, and all vaccine that is received in phase 1A should be used on as many people as possible.

Vaccine Administration

What considerations should we consider while maintaining the 3 W’s during a mass vaccination clinic?
CDC has updated guidance for satellite, temporary, and off-site clinics, which can be found at https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html. The guidance provides information on procedures for protecting patients and staff during the COVID-19 pandemic. However, programs will need to keep in mind recommendations for social distancing and considerations for events and gatherings during the COVID-19 pandemic and ensure mitigation strategies are in place to the extent possible.

Do you know if there are PPE requirements vaccinators should follow when administering vaccine during the COVID-19 pandemic?
CDC has issued “Interim Guidance for Immunization Services During the COVID-19 Pandemic” to help immunization providers in a variety of clinical settings plan for safe vaccine administration during the COVID-19 pandemic, see https://www.cdc.gov/vaccines/pandemic-guidance/index.html. For healthcare workers PPE information see https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html. Additional guidance when COVID-19 vaccine is available will be provided, as necessary.
Will health departments be allowed to administer ULC and/or frozen COVID Vaccine candidates offsite from the health department such as in a Closed POD for nurses to administer?
Theoretically yes, LHDs could monitor vaccine and take to it Closed PODs for administration, however there are several factors that are unknown about the products and the ULC storage solution the vaccine will be shipped in. Additional guidelines will be forthcoming from the ACIP recommendations, CDC storage guidelines and, FDA EUA guidance specific for each product. Some vaccines will require thawing and mixing prior to administration. Exact details on those processes are not yet available but will need to be factored into POD administration planning. Additionally, we have submitted questions to the CDC to determine what they may consider redistribution and what may not be considered redistribution.

Is the State working on guidance for EMT and/or Paramedics to administer the COVID-19 vaccine?
Paramedics & Advanced EMTs (different than EMT Basics) can administer vaccinations under their medical direction. Most fire departments have EMT Basics or Medical Responders and so they would NOT be allowed to administer the vaccine. Each county does it a little different so if a fire department happens to employ paramedics or Advanced EMTs AND they have a medical director that is willing to allow them to administer that would be an option.

Accountability, Data Management, Reporting, Billing & Insurance (Administrative Functions)

Will there be a cost to the public for the vaccine?
The goal of the federal government is for there to be no upfront costs to providers and no out-of-pocket cost to the vaccine recipient. Various plans, supported by the CARES Act and the Families First Coronavirus Response Act, are under development with the objective of ensuring no one will be charged any out–of-pocket expenses for the administration of the vaccine either. The objective is to ensure no one desiring vaccination will face an economic barrier to receiving one. Section 3203 of the CARES Act (P.L. 116-136) requires health insurance issuers and plans to cover any ACIP-recommended COVID-19 preventive service, including vaccines, without cost sharing within 15 days of such recommendation to the CDC. Refer to page 7 of the USDHHS From Factory to the Frontlines the Operation Warp Speed strategy for Distributing a COVID-19 Vaccine.

Will the state accept a plan from the Eastern Band of Cherokee Indians or local health departments? If so, who does it need to be sent to?
The state is required to submit a plan that includes how we are planning for tribal groups and local health departments, among others. The state plan is due to CDC by 10/16/2020, but there is not requirement for tribes or locals to send plans to the state.
Flu and COVID-19

Is there any guidance on cold-chain management for Influenza vaccine?
In all cases, manufacturer packaging information should be consulted for authoritative guidance regarding storage and handling of influenza vaccines. In general:

- Vaccines should be protected from light and stored at recommended temperatures.
- Influenza vaccines are recommended to be stored refrigerated between 2°C to 8°C (36°F to 46°F).
- Vaccine that has been frozen should be discarded.
- Single-dose vials should not be accessed for more than one dose.
- Multidose vials should be returned to recommended storage conditions between uses, and once initially accessed should not be kept beyond the recommended period of time.
- Vaccines should not be used after the expiration date on the label.
- Multidose vials may have a labeled Beyond Use Date (BUD) in addition to the expiration date. The BUD specifies the number of days the vaccine may be used once accessed for the first time. If no BUD is provided, the listed expiration date should be used.

For guidance on specific situations not addressed in packaging materials, contact the manufacturer directly. Additional information may also be found in the *Vaccine Storage and Handling Toolkit*, which is available at: [https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html](https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html)

The "flu" vaccine will not prevent COVID-19, but how will it help keep respiratory systems healthier?
It is likely seasonal flu and the virus that causes COVID-19 will both spread this fall and winter. While getting a flu vaccine will not protect against COVID-19, it does reduce the risk of flu illness, hospitalization, and death as well as saves healthcare resources for the care of patients with COVID-19.

How dangerous could it be to get COVID-19 as well as the flu?
It is possible to have flu, as well as other respiratory illnesses, and COVID-19 at the same time. Contracting COVID-19 and the flu could lead to severe respiratory illnesses. Many people at higher risk from flu also seem to be at higher risk from COVID-19. If you are at high risk, it is especially important for you to get a flu vaccine this year.

For more information on the 2020-21 seasonal Flu vaccine recommendations you may visit the CDC website at [https://www.cdc.gov/flu/professionals/acip/summary/summary-recommendations.htm](https://www.cdc.gov/flu/professionals/acip/summary/summary-recommendations.htm).
NC Prioritization of the COVID Vaccine

Where does NC stand with the prioritization framework for the vaccine?
The NC Institute of Medicine has convened a COVID-19 Vaccine Advisory Committee to assist the state in multiple areas of COVID-19 vaccine planning. The first area is vaccine prioritization as it is expected that the prioritization groups provided from the federal government have populations exceeding the available supply of vaccine in the early stages. As of September 24, 2020 NCDHHS, has developed the draft framework for vaccine prioritization below. This draft is based on information from many sources including CDC, the National Academy of Medicine and John’s Hopkins. The ACIP is expected to release information on priority groups as well, but their September 22, 2020 vote has been delayed and not yet rescheduled. Upon its release the draft NC Framework will be reviewed with the ACIP framework and discussed for any revisions by the Advisory Group.

Has there been any discussion about prioritizing people within our priority groups based on if they have been diagnosed with COVID-19 within the last 6 months, last 3 months, etc.?
This is an ongoing discussion that will depend heavily on data from the vaccine trials.

Vaccination Provider Outreach & Enrollment

What role does the state plan to take in making contact with hospitals, pharmacies, etc. statewide to integrate them into the COVID vaccination response (e.g., provide vaccine provider agreements, etc.)?
The state is currently planning arrangements, in accordance with federal guidance, with hospitals and pharmacies using the Vaccine Provider Agreement for enrollment. The state will send the provider enrollment form directly to hospitals and pharmacies as we roll out the enrollment process, but we ask the health departments share the agreements as we roll out enrollment as well. The first enrollments will be specifically targeting health departments and hospitals.
Where can I review the current draft provider agreements for administering COVID-19 vaccine?
The provider agreements are provided by CDC and must be completed as is. We will be providing an electronic mechanism to complete the provider agreements.

Where do we send the Vaccine Agreement to, once signed?
The COVID-19 Vaccination Agreement should be returned to the NC Immunization Branch. Copies of the COVID agreement were emailed to all Local Health Departments (LHDs) to read and become familiar with the enrollment requirements and to provide an opportunity for LHDs to ask questions about the agreement. The electronic mechanism for LHD enrollment was sent on Friday, October 9th to all LHDs. This will be the only way to submit the provider enrollment agreement – we will not accept paper copies.

Who is the point of contact at the hospitals for the provider agreement?
Hospitals were contacted, through their pharmacy department, and asked to provide COVID-19 Vaccine Planning Points of Contact (POC). All vaccine related communications going to hospitals are sent to the POC. Tim Davis (on behalf of the Healthcare Preparedness Program) is the lead for communicating with the hospitals. A memo with instructions on how to enroll as a COVID-19 Vaccination Program Provider was sent to all the hospital points of contact on Tuesday, October 13th.

Are EBCI PHHS and/or Cherokee Indian Hospital are included in the COVID vaccine provider enrollment roll-out?
EBCI and its facilities have elected to receive their vaccine allocations from IHS. This will be reflected in the state plan. Regular reporting to the state will still be required.

How does a medical director sign a provider enrollment agreement if they are not on-site?
At the end of the provider enrollment survey, a code will be provided. It is critical that this code be written down and saved. If others, such as a medical director or vaccine coordinators, need to access the agreement to review/sign, the link to the agreement can be shared along with the code to gain entry. The original link for provider enrollment was sent to local health directors by Mark Benton on Friday, October 9, 2020.

The provider enrollment agreement has medical director (MD), Doctor of Osteopathic Medicine (DO), nurse practitioner (NP), and physician assistants (PA) as the only persons who can administer the COVID vaccines. Are registered nurses not allowed to administer the vaccine?
The agreement is asking for those who would potentially order the vaccine to be administered and not those who will be physically administering it. It is advised to list the medical director, the signee of standing orders, and any MDs, NPs, or PAs who might work in your clinic who have prescriptive authority.
Sources:


USDHHS. From Factory to the Frontlines. The Operation Warp Speed strategy for Distributing a COVID-19 Vaccine.