Local Public Health COVID-19 Vaccination Frequently Asked Questions
November 20, 2020
New questions are in red. Updated responses 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.*

Update November 4, 2020: *Refer to page 10 of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations Version 2 for more detail*

This committee will be helpful in advocating for and developing strategies to ensure equitable access to COVID 19 vaccination services. Identified by CDC (see Section 4: Critical Populations) as well as representatives from other sectors within the community such as: (see list of on page 10).
Refer to Appendix A: COVID-19 Vaccination Planning Assumptions for Jurisdictions (revised 10/29/2020) in the COVID19 Vaccination Program Interim Playbook for Jurisdiction Operations Version 2.

How will counties request vaccination resources?

Updated November 4, 2020: Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in VTrckS. A. For centrally distributed vaccines, each kit 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)
    - 25-gauge, 1” (if vaccination indicated for pediatric population)
    - 22–25-gauge, 1-1.5” (adult)
- Syringes, 105 per kit (ranging from 1–3 mL)
- 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
- Vaccine needle guide detailing the appropriate length/gauge for injections based on route, age (for children), gender, and weight (for adults)

Ancillary supply kits will not include sharps containers, gloves, and bandages. Additional personal protective equipment (PPE) may be needed depending on vaccination provider site needs. Facilities ordering outside of their jurisdiction’s allocation (i.e., commercial and federal entities with federal MOUs in place) will order directly from CDC, and CDC will be responsible for approval of those orders.

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.

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).

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.

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.

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.

Will vaccine strike teams for long term care facilities provide initial vaccination for residents and staff?

The **Pharmacy Partnership for Long-term Care (LTC) Program** is a federal program that provides end-to-end management of the COVID-19 vaccination process, including cold chain management, on-site vaccinations, and fulfillment of reporting requirements, to facilitate safe vaccination LTC patients while reducing burden on LTC facilities and jurisdictional health departments. The services will be available in rural areas that may not have easily accessible pharmacies. LTCF staff who have not received COVID-19 vaccine can also be vaccinated as part of the program. This will occur in a strike team format for initial vaccine administration and then the second dose of vaccine, but it will not address vaccination needs that occur related to resident or staff turnover. LTC sites and/or their pharmacies will need to register for the provision of long term COVID-19 vaccine access. The state Division of Health Service Regulation (DHSR) pushed out information on the program and how to sign up on 10/23-24/2020 to all types of LTC facilities in the state. Facilities have until 10/30/2020 to opt into the program.

Does every point of dispensing (POD) need a provider agreement, or can an organization have one provider agreement and host multiple PODs at different locations?

When an enrolled provider (e.g., local public clinic) takes vaccine offsite to a temporary location for a one-day vaccination clinic, it is not necessary to complete a provider agreement for that location. The provider named in Section B of the provider agreement should have indicated that a temporary/off-site setting would be used for vaccine administration. However, if an enrolled provider is taking vaccine two or more consecutive days to a particular location, then Section B must be completed for that location. Additional Section Bs of the provider agreement can be submitted at any time.

Will the state provide a summary of updates for stakeholders when the revised COVID-19 Vaccination Plan is posted on the NC DHHS website?

Yes, the state will provide details of updates to the vaccination plan and they will be posted on the NC DHHS website

How will vaccination history impact isolation and quarantine guidance? For example, will vaccinated individuals be required to quarantine following an exposure?

We are unable to answer this question at this time as there is not enough vaccine specific information from clinical trials to determine this.

The Health Resources and Service Administration (HRSA) Program ensures that uninsured individuals don't have to pay for vaccine administration , however, we have seen with COVID-19 testing that some testing locations do not apply the HRSA program and charge individuals for testing. Is there anything being planned to prevent this from happening with the COVID-19 vaccination? Will the requirements of the Vaccination Program Provider Agreement prevent this from happening?
More information on administration fees are pending, however, in the provider enrollment, providers agree to vaccinate without regard to ability to pay. Centers for Medicare and Medicaid Services released COVID vaccine planning **toolkits**. The toolkits were published in conjunction with the October 28th interim final rule (which clarified the rules governing COVID vaccine coverage for various payers), these toolkits provide guidance targeted to:

- Providers furnishing the vaccine to Medicare beneficiaries *(information related to enrollment, billing, and reimbursement)*
- Partners helping consumers *(resources to support public education)*

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

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 Interim Playbook for Jurisdiction Operations Version 1 for more detail.*

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.*

Update November 4, 2020: *Please reference the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations Version 2 Pg.30*

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.

Pharmacy Partnership for Long-term Care Program

Will the Local Health Department (LHD) be involved at any level with distribution of the vaccine to Long Term Care Facilities (LTCF) given the proposed partnership? Will the two pharmacies (CVS & Walgreens) be taking care of all LTCF in the counties, or do LHD need to include LTCF in their distribution planning
Although the CDC is partnering with CVS and Walgreens pharmacies to offer on-site COVID-19 vaccination service for LTCF, LTCF are not required to participate in the Pharmacy Partnership for Long-term Care (LTC) Program. A facility can opt in, opt out, or opt in and submit their current LTC pharmacy partner to coordinate vaccine supply and management services. If an LTCF opts out of the pharmacy partnership program, the LTCF and the pharmacy provider of their choice will be responsible for enrolling as a COVID-19 provider, coordination of and adherence to all vaccine supply chain, storage, handling, administration, and reporting requirements which includes ultra-low cold (ULC) storage and public health reporting requirements. Small facilities may not meet the shipping minimum order of 100 to approximately 1,000 doses depending on the vaccine and would have to work with LHD for vaccine access.

How will COVID-19 vaccine be allocated for distribution to pharmacies?
Through the Federal Pharmacy Partnership Strategy for COVID-19 Vaccination's second phase of vaccine rollout, select pharmacy partners will directly order and receive allocation of COVID-19 vaccine from the federal government. The federal allocation to pharmacies will not cover every pharmacy in the United States. Pharmacies not included in the federal allocation program are still encouraged to be part of the vaccination program and should coordinate with their jurisdictions to become COVID-19 vaccination providers. NC is working to determine what pharmacies will be a part of the federal partnership and will target those that are not.

We received a call from a private pharmacy today stating that they would like to be considered as a provider for COVID-19 vaccines when available. Due to the predicted cold storage requirements for vaccines currently under testing, is the state allowing/encouraging any other facilities besides LHDs/hospitals to provide COVID-19 vaccines?
LHDs and hospitals were the phase 1a targets for provider enrollment. We will be expanding provider enrollment over the next few weeks to include a broad range of providers including Federally Qualified Health Centers (FQHC), primary and specialty care providers, skilled nursing facilities, other long-term care settings, pharmacies, mobile vaccination providers, occupational health for large employers, providers serving incarcerated populations among others into the COVID-19 vaccination program for early narrow and later broad vaccination plans.

Storage and Handling

If the vaccine is shipped in a thermal shipping container to maintain ultra-low cold (ULC) storage, will the vaccine need to be thawed before reconstituting with the diluent?
Yes, the Pfizer vaccine candidate requires reconstituting prior to administration. The frozen vaccine will need to be thawed prior to reconstituting. The needed vaccine should immediately be transferred to a refrigerator. An entire tray will take about 3 hours to thaw; a small number of vials may thaw more quickly. Vials taken directly from ULC to room temperature will take approximately 30 minutes to thaw.

Do we know if moving the multidose vials (MDV) to an ultra-low cold (ULC) freezer "stops the clock"? Yes, moving the vaccine to a free standing ULC freezer would "stop the clock". *Refer to pages 47-49 of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations Version 1 for more detail on ULC storage and handling. However, there will still be limits to the length of time the vaccine can be stored at ULC. Exact information will come as products are approved/authorize.*

Based on the updated Scenario 1 [Updated Vaccine A Scenario], do we recharge the shipping container with dry ice on day 1, day 6, day 11? What should be done with the remaining vaccine after day 16?
Yes, the shipping containers may be recharged with dry ice up to 3 times total, including the initial on day 1 when all storage and handling directions are followed. Shipping containers must be recharged with dry ice within 24 hours of receipt of vaccine (first recharge), may be replenished 5 days following the first recharge, and then once more 5 days after the second recharge. At the end of the recharges for the shipping container, the vaccine can be moved to the refrigerator for an additional 120 hours.

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.

UPDATE: 10/16
The CDC confirmed they will not ask states to hold the second dose. They have worked out internally the ability to manage inventory and hold the second dose for delivery at the appropriate second dose interval. The ultra-low cold (ULC) product has a minimum shipment of 1000 doses and will come in a container that can be refilled with dry ice to maintain the temperature.

How long will the vaccine be viable after it is received if we do not have a freezer to store vaccine at the required ultra-cold temperatures.
The Ultra-Cold vaccine will ship in a special shipping container (thermal shipper) which may be used to store vaccine. Once received, the thermal shipping container will need to be replenished with pelleted dry ice within 24 hours. The container should be replenished with dry ice every 5 days to maintain required temperature. The container may be recharged a total of 3 times (once upon receipt, and two more times thereafter). The vaccine can be stored in the thermal shipping container for 10 days. Once removed from the thermal shipping container the vaccine can be stored at 2-8 degrees Celsius (under refrigeration) for up to 5 days. The vaccine cannot be returned to UCT storage or to the thermal shipper container once moved to refrigeration. These guidelines are preliminary and subject to changes based on the final EUA, and ACIP recommendations.

Not all vaccines will require ULC storage. More information on individual vaccine storage is forthcoming. Stability studies in all vaccines are ongoing in a hope to continue to ease storage and handling requirements.

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.

NC Prioritization of the COVID Vaccine

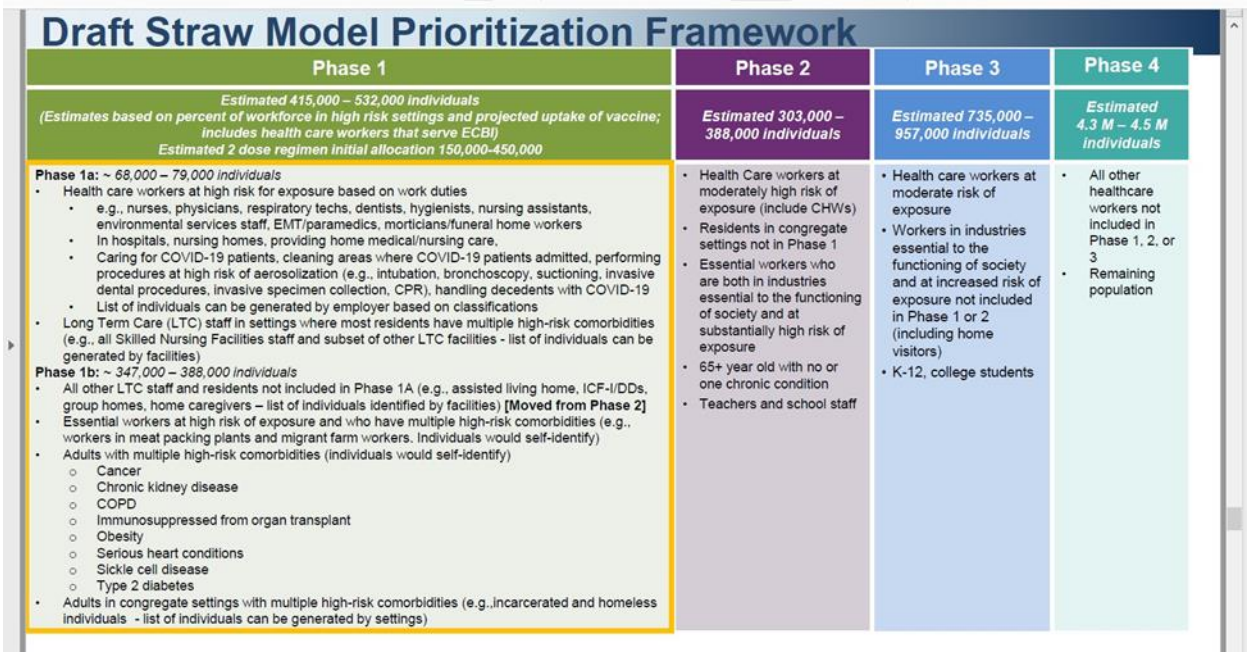
Has there been any discussion about prioritizing people within our priority groups based on if they have been diagnosed with COVID-19 within the last 6 months, last 3 months, etc.?
This is an ongoing discussion that will depend heavily on data from the vaccine trials.

Will our employees of an outpatient facility affiliated with a local hospital have access to vaccine through the health department or a hospital?
Employees of outpatient facilities should work with their health department or hospital and pick up vaccine for their staff or send staff to the LHD if they are doing a POD [Point of Dispensing].

Will there be certain levels for health care workers during the initial phase i.e. front desk receptionist who have limited exposure or medical assistants and physicians who have direct contact with patients?
The prioritization of the vaccination plan is risk based and initial supplies will be very limited to phase 1a and should be focused on Health care workers and COVID responders at high risk for exposure.

Will local public health departments be responsible for vaccinating dentists, morticians, emergency management or other healthcare providers that we will be responsible for in Phase 1A?
Yes, if they have vaccine and resources to support vaccine outreach within their county.

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.
Update Nov.4, 2020*: Refer to page 16 of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations Version 2 for more detail.*



Draft Straw Model Prioritization Framework

Phase 1	Phase 2	Phase 3	Phase 4
Estimated 415,000 – 532,000 individuals (Estimates based on percent of workforce in high risk settings and projected uptake of vaccine; includes health care workers that serve ECBI) Estimated 2 dose regimen initial allocation 150,000-450,000	*Estimated 303,000 – 388,000 individuals*	*Estimated 735,000 – 957,000 individuals*	*Estimated 4.3 M – 4.5 M individuals*

Phase 1a: ~ *68,000 – 79,000 individuals*
• Health care workers at high risk for exposure based on work duties
  ▪ e.g., nurses, physicians, respiratory techs, dentists, hygienists, nursing assistants, environmental services staff, EMT/paramedics, morticians/funeral home workers
  ▪ In hospitals, nursing homes, providing home medical/nursing care,
  ▪ Caring for COVID-19 patients, cleaning areas where COVID-19 patients admitted, performing procedures at high risk of aerosolization (e.g., intubation, bronchoscopy, suctioning, invasive dental procedures, invasive specimen collection, CPR), handling decedents with COVID-19
  ▪ List of individuals can be generated by employer based on classifications
• Long Term Care (LTC) staff in settings where most residents have multiple high-risk comorbidities (e.g., all Skilled Nursing Facilities staff and subset of other LTC facilities - list of individuals can be generated by facilities)
Phase 1b: ~ *347,000 – 388,000 individuals*
• All other LTC staff and residents not included in Phase 1A (e.g., assisted living home, ICF-I/DDs, group homes, home caregivers – list of individuals identified by facilities) **[Moved from Phase 2]**
• Essential workers at high risk of exposure and who have multiple high-risk comorbidities (e.g., workers in meat packing plants and migrant farm workers. Individuals would self-identify)
• Adults with multiple high-risk comorbidities (individuals would self-identify)
  ○ Cancer
  ○ Chronic kidney disease
  ○ COPD
  ○ Immunosuppressed from organ transplant
  ○ Obesity
  ○ Serious heart conditions
  ○ Sickle cell disease
  ○ Type 2 diabetes
• Adults in congregate settings with multiple high-risk comorbidities (e.g.,incarcerated and homeless individuals - list of individuals can be generated by settings)
	• Health Care workers at moderately high risk of exposure (include CHWs)
	• Residents in congregate settings not in Phase 1
	• Essential workers who are both in industries essential to the functioning of society and at substantially high risk of exposure
	• 65+ year old with no or one chronic condition
	• Teachers and school staff
		• Health care workers at moderate risk of exposure
		• Workers in industries essential to the functioning of society and at increased risk of exposure not included in Phase 1 or 2 (including home visitors)
		• K-12, college students
			• All other healthcare workers not included in Phase 1, 2, or 3
			• Remaining population

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.

Update November 4, 2020: *Pg. 33-34 Section 8 COVID Vaccine Storage and Handling Satellite, Temporary and Off-Site Clinic Storage and Handling Considerations of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations Version 2 for more detail*.

Satellite, Temporary, and Off-Site Clinic Storage and Handling Considerations Satellite, temporary, or off-site clinics in collaboration with community or mobile vaccinators may assist jurisdictions in providing equitable access for COVID-19 vaccination. However, these situations require additional oversight and enhanced storage and handling practices.

- The quantity of COVID-19 vaccine transported to a satellite, temporary, or off-site COVID-19 vaccination clinic should be based on the anticipated number of COVID-19 vaccine recipients and the ability of the vaccination provider to store, handle, and transport the vaccine appropriately. This is essential to minimizing the potential for vaccine wastage and spoilage
- COVID-19 vaccines may be transported—not shipped—to a satellite, temporary, or off-site COVID-19 vaccination clinic setting using vaccine transportation procedures outlined in the upcoming COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit. The procedures will include transporting vaccines to and from the provider site at appropriate temperatures, using appropriate equipment, as well as monitoring and documenting temperatures.
- Upon arrival at the COVID-19 vaccination clinic site, vaccines must be stored correctly to maintain appropriate temperature throughout the clinic day.
- Temperature data must be reviewed and documented according to guidance in the upcoming COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit.
- At the end of the clinic day, temperature data must be assessed prior to returning vaccine to fixed storage units to prevent administration of vaccines that may have been compromised.
- As with all vaccines, if COVID-19 vaccines are exposed to temperature excursions6 at any time, the temperature excursion should be documented and reported according to the jurisdiction immunization program's procedures. The vaccines that were exposed to out-of-range temperatures must be labeled "do not use" and stored at the required temperature until further information on usability can be gathered or further instruction on disposition or recovery is received.

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.

UPDATE 10/22 A memo regarding whether EMT's and Paramedics may administer vaccine was distributed on 10/22 to Hospitals, Emergency Management, Healthcare Coalitions, Local Health Directors and Directors of Nursing/Nursing Supervisors and on 10/23 to Preparedness Coordinators.

Will correctional facilities vaccinate their inmates?
NC DHHS is working with the North Carolina Department of Public Safety (NCDPS)-Division of Corrections for state correctional facilities. LHD will not need to account for them. Local health departments should still communicate with jails in their county to understand the jail's plan. Federal prisons will vaccinate their staff and inmates.

Will there be a state or federal consent form that patients must sign to receive COVID-19 vaccine, or will local providers be expected to create their own?
There are no federal or NC requirements mandating the use of a specific consent form. The state is not developing a COVID vaccine consent form for healthcare providers (HCPs). Local health departments (LHDs) may continue to use their current mechanism to obtain a written consent.

Page 68 of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations version 2 mentions to secure consent ahead of time. Since most vaccine products require two doses of vaccine, will consent need to be secured twice?
Yes, the vaccinating healthcare provider (HCP) should obtain consent prior to administering each dose of the COVID vaccine.

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

What system will be used for COVID-19 vaccine administration data collection?
We will not be using NCIR for COVID vaccine administration data collection. Based on CDC requirements for data entry, the increased user volume, system capacity issues, and the need for vendor managed adjustments, NCIR is not the most suitable data system. We will use a new system, the COVID-19 Vaccine Management System (CVMS) that will be web based and provided to all COVID-19 enrolled providers at no charge. The new system is being built to meet COVID-19 data element and time collection requirements, will have English and Spanish options with additional considerations in later releases, support 2d barcoding, be cloud based, support unlimited users, and be customizable to NC. Provider sites can have multiple systems users and will receive additional access information when the system is available. The initial release will not support connection with EHRs, but that is functionality we have as a goal for a later release.

Will we be able to shift any data already in North Carolina Immunization Registry to COVID Vaccine Management System (CVMS)?
No, patient data cannot be transferred from the NCIR to CVMS. Patients will receive a QR code on their mobile device when they register for the appointment. The code will be scanned at the clinic on the day of service to verify the identity of the patient to confirm registration information for accuracy. If a patient does not pre-register, the clinic will be able to enter the patient when they present for vaccination.

What types of identifying data will be required in the COVID Vaccine Management System (CVMS)?
Identifying data will include recipients first and last name, date of birth, address, and sex.

Will COVID Vaccine Management System (CVMS) allow vaccination clinic staff to enter information about a resident from another County?
Yes, clinic staff will be able to enter information about a resident from another county.

Can any guidance be given on the type/brand/specifications of the scanners that should be purchased to fully integrate into the software that will be used to capture COVID-19 vaccination?
There are not specific brands of scanners, however, there are specific types scanners. When choosing a barcode scanner, the most important things to consider are:

1. Product compatibility with both your hardware and software (Electronic Health Record (HER) and/or registry).
2. Ability to read and translate 2D barcodes.
3. Staff preference – if the scanner is not user friendly for the staff, it won't get used.
4. Choose a scanner that is of medical-device quality and "disinfectant ready." Nearly all scanners labeled as a "healthcare scanner" have this feature.

Please refer to the link provided to get more detailed information:
https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunizations/Practice-Management/Pages/barcoding.aspx

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*.

Update 11/4/20: Through the Federal Pharmacy Partnership Strategy for COVID-19 Vaccination, select pharmacy partners will receive a direct allocation of COVID-19 vaccine. This program will provide critical vaccination services for the U.S. population with vaccine administered at retail locations at no cost to recipients.
Refer to pages 74-75 of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations Version 2 for more detail. NC Prioritization of the COVID 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 was submitted to the CDC on 10/16/2020, but there is not requirement for tribes or locals to send plans to the state.

For NON-COVID vaccine providers, is the North Carolina Immunization Registry (NCIR) the recommended place providers should go to see COVID vaccination records for one of their patients?
Yes, per the CDC, NCIR is the source for COVID-19 vaccination records.

Should local health departments consider the acquisition of a vaccine tracking solution? Is this something the State would encourage/support given the potential for a compressed vaccine rollout timeline?

The state is not recommending procuring an external system for COVID vaccine transactions. The system the state is planning to use will track vaccine inventory transactions as well as patient scheduling and administration data according to CDC guidelines for vaccine administration. Information regarding the system the state is planning to use will be provided once it becomes available.

Flu and 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.

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° to 8°C (36° 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

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.

Legal

Is there any chance providers will have immunity for COVID-19 administration?
The Public Readiness and the Emergency Preparedness Act (PREP Act) authorizes the Secretary of the Department of Health and Human Services (Secretary) (HHS) to issue a PREP Act Declaration ("Declaration") that provides immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency. In general, the liability immunity applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of medical countermeasures described in a Declaration. The only statutory exception to this immunity is for actions or failures to act that constitute willful misconduct. A PREP Act Declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations issued by HHS or other government agencies. The PREP Act also authorizes a fund in the United States Treasury to provide compensation to eligible individuals for serious physical injuries or deaths directly caused by administration or use of a countermeasure covered by the Declaration.

The county is not planning to make the vaccine mandatory but is considering making employees sign a waiver saying they turned down the vaccine and will not hold the county liable if they contract COVID-19 from occupational exposure. Is this legal?
It is recommended that jurisdictions consult with their attorney for additional information.

Sources:

Centers for Disease Control. (2020). COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. Version 1. Retrieved 9/17/2020 at https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

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