North Carolina Interim COVID-19 Vaccination Plan
Executive Summary
October 16, 2020

Introduction

North Carolina's COVID-19 Vaccination Plan builds on the foundation of the state's overall goals and pillars of response to the pandemic: Prevention, Testing, Tracing, Isolation and Quarantine. North Carolina took early and aggressive action to slow the spread of the virus, built statewide capacity for testing, PPE supplies and contract tracing, developed hospital surge plans, and promoted aggressive prevention strategies.

Guiding Principles for North Carolina's COVID-19 Vaccine Plan:

1) All North Carolinians have equitable access to vaccines.
2) Vaccine planning and distribution is inclusive; actively engages state and local government, public and private partners; and draws upon the experience and expertise of leaders from historically marginalized populations.
3) Transparent, accurate, and frequent public communications is essential to building trust.
4) Data is used to promote equity, track progress and guide decision-making.
5) Appropriate stewardship of resources and continuous evaluation and improvement drive successful implementation.

The ultimate goal is to immunize everyone who is eligible for and wants a COVID-19 vaccine.

Phased Approach to COVID-19 Vaccination

North Carolina's approach to COVID-19 vaccination is based on current assumptions and information available from the Food and Drug Administration and the Centers for Disease Control and Prevention. **Four phases** of work will be carefully executed and evaluated.

- ***The planning phase,*** already underway, will continue throughout the vaccination campaign. Planning phase accomplishments to-date include: establishing a unified command structure with cross-disciplinary state government teams with an independent External Vaccine Advisory Committee to guide plan development and implementation; finalizing priority populations for vaccination based on risk of exposure and risk of morbidity and mortality from COVID-19 with input from the External Advisory Committee; designing a process to identify and enroll providers who are able to reach the priority populations.
- ***The implementation phase*** will begin when the first, initially limited, vaccine doses are allocated to North Carolina, and focus on the logistics required to receive and administer vaccines to prioritized populations.
- ***The adjustment phase*** will begin when larger amounts of vaccine are available and focus on building capacity of providers to order vaccine based on local demand.
- ***The transition phase*** will begin when there is sufficient vaccine to immunize anyone in the state who wants to be vaccinated in more established delivery channels similar to influenza vaccination campaigns.

Author: North Carolina COVID-19 Vaccination Planning Team. Publication Date 10/16/20.

North Carolina Interim COVID-19 Vaccination Plan
Executive Summary
October 16, 2020

Critical Populations

North Carolina's prioritization framework was developed based on the National Academy of Medicine (NAM) framework and in consultation with the External Advisory Committee. Principles guiding prioritization were equity, maximization of benefits, transparency, operational feasibility, reliance on a strong evidence base, and "do no harm."

Health care providers at high risk for exposure and who are vital to the initial COVID vaccine administration efforts and staff in long term care will be prioritized first. People at high risk for clinical severity and high risk of exposure will be prioritized next. This will include residents in Long-Term Care settings, people over 65 and staff of congregate living settings (migrant farm camps, jails and prisons, and homeless shelter) and anyone with two or more chronic conditions identified by the CDC to be high risk for COVID complications.

Historically marginalized populations are represented in the early phase prioritization groups. Subsequent phases will target lower-risk populations and have more of a focus on decreasing transmission through the populations.

COVID-19 Vaccination Provider Recruitment and Enrollment

North Carolina will prioritize early outreach, recruitment and enrollment of key providers and agencies who serve populations with high risk of clinical severity and high risk of exposure. The Advisory Committee will help to identify and engage those providers. North Carolina has created a streamlined electronic process for provider enrollment applications, licensure verification, storage and handling assessments, and approval and denial letters. Enrollment is already underway with local health departments, hospitals and health systems.

COVID-19 Vaccine Storage and Handling

North Carolina will assess cold-storage capacity across the state and will develop, coordinate, and support an ultra-cold chain storage system if an approved vaccine candidate requires it. This effort will be informed by guidance from Operation Warp Speed (OWS), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), vaccine manufacturers, and NC state health officials.

COVID-19 Vaccination Second-Dose Reminders

Robust data, reporting and performance tracking systems are under development for managing provider enrollment, vaccine dose administration, patient scheduling, patient doses and vaccine ordering records. Reports and dashboards for heterogeneous internal and external audiences will also be developed. North Carolina is exploring the use of the federally supported web-based Vaccine Administration Management System application as well as an alternative end to end system to support data collection and tracking efforts. These systems will allow us to track doses administered and support second dose reminders via these data collection systems and provider systems as well as the vaccine administration cards provided at the time of administration.

North Carolina Interim COVID-19 Vaccination Plan
Executive Summary
October 16, 2020

COVID-19 Vaccination Program Communication

Vaccine hesitancy is expected to be high, especially among historically marginalized people who are highly represented in prioritized populations, so public communication efforts will focus on building a foundation of trust. The goals for broad public communication about COVID-19 vaccinations are that North Carolinians will: 1) Trust the information that they receive from NCDHHS and Local Health Departments; 2) Understand the benefits and risks; 3) Make informed decisions; 4) Know how and where to get a COVID-19 vaccination.

Key initial goals will be to: 1) Increase knowledge of vaccine and the process of COVID-19 vaccine development; 2) Set expectations for limited availability at the onset of the vaccine delivery; 3) Raise awareness and recognition of historical injustices to mitigate vaccine hesitancy. As historically marginalized people have been disproportionately affected by COVID-19, engaging, including and serving them well will be essential to the success of North Carolina's vaccine efforts.

COVID-19 Vaccine Safety Monitoring

Clinically important, adverse events following any vaccination must be reported by healthcare providers to the Vaccine Adverse Event Reporting System as required of all COVID-19 vaccination providers. Adverse events will also be monitored through electronic health record and claims-based systems (e.g., Vaccine Safety Datalink).

COVID-19 Vaccination Program Monitoring

North Carolina will continuously assess new information and guidance from the federal government and evolving data and science as well as incorporate lessons learned to refine its vaccination approach and facilitate equitable access to vaccine, particularly for residents at the greatest risk for exposure and severe illness.

Additional Information

As new information becomes available, the NC COVID-19 Unified Leadership may reassess, adjust, or otherwise modify the proposed approach.

State of North Carolina

Interim COVID-19 Vaccination Plan

The intent of this document is to describe North Carolina's plan to vaccinate the state's population and inform state and local partner plan development.

Prepared by:
NC Vaccination Planning Team
Revision 10/16/2020|Version #1

Promulgation Document

To All Recipients:

Provided herewith is the North Carolina COVID-19 Vaccination Plan. This plan will provide a framework and guidance for state agencies and local governments to meet the vision of success, outline key tasks to accomplish the strategy, and define a chronological operational concept. This plan is also intended to provide information and guidance to local, Tribal, and state partner agencies in their own plan development to support this state level plan.

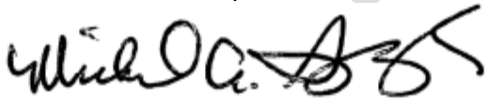
This North Carolina COVID-19 Vaccination Plan includes four [4] phases of operation:

1. Planning (Phase 0)
2. Implementation (Phase 1)
3. Adjustment (Phase 2)
4. Transition (Phase 3)

The NC COVID-19 Vaccination Planning Team is responsible for the development and maintenance of the North Carolina COVID-19 Vaccination Plan. This Plan is in accordance with all existing federal, state, and local statutes. All recipients are requested to advise the COVID-19 Vaccination Planning Team regarding recommendations for improvement.

This Plan will continue to be revised as further information and guidance is received from the CDC and other federal agencies and as we progress through our planning and operational stages. This Interim North Carolina COVID-19 Vaccination Plan has been reviewed and is supported by the lead agencies of North Carolina's unified COVID-19 command structure.

Mandy Cohen
Secretary
North Carolina Department of Health and Human Services



Michael Sprayberry
Executive Director
North Carolina Division of Emergency Management
North Carolina Department of Public Safety

Implementation and Vision of Success

It is the intent of the State of North Carolina and the Unified Command of the North Carolina Department of Health and Human Services (DHHS) and North Carolina Department of Public Safety/Division of Emergency Management that within 9 months of vaccine becoming available the following end-state will be achieved:

At the end of this campaign, success will be having vaccinated all residents of North Carolina that can and wish to receive the vaccine.

Our values will serve as the guiding principles for the desired end state.

Guiding Principles:

6) All North Carolinians have equitable access to vaccines.
7) Vaccine planning and distribution is inclusive; actively engages state and local government, public and private partners; and draws upon the experience and expertise of leaders from historically marginalized populations.
8) Transparent, accurate, and frequent public communications is essential to building trust.
9) Data is used to promote equity, track progress and guide decision-making.
10) Appropriate stewardship of resources and continuous evaluation and improvement drive successful implementation.

Record of Changes record creation, changes and amendments

Change Number	Date Changed	Name and Position of Person Making Change	Comments

Record of Distribution

Title and Name of Person Receiving Plan	Agency of Person Receiving Plan	Date of Delivery and Distribution Method	Number of Copies Delivered

Table of Contents

State of North Carolina COVID-19 Vaccination Plan

BASE PLAN

Purpose

This operations plan supports the North Carolina COVID-19 Incident Action Plan (IAP) and outlines the actions and procedures that the COVID-19 Unified Command Group will take to vaccinate all people living in North Carolina.

Scope

This plan will provide a framework and guidance for state agencies and local governments to meet the campaign's vision of success, outline key tasks to accomplish the strategy, and define a chronological operational concept. This plan is also intended to provide information and guidance to local, state, and Tribal partner agencies and governments in their own plan development to support this state-level plan.

Situation Overview

North Carolina has an estimated population of 10,488,084. As of October 14, 2020, there were 236,407 laboratory confirmed cases, 3,856 deaths, and 3,459,943 completed tests, and 1152 were hospitalized. On January 24, 2020, North Carolina initiated its response to COVID-19 with the activation of the Division of Public Health's Incident Command Coordination Center. The Governor's Coronavirus Task Force convened on February 17, 2020. On March 10, 2020, Governor Cooper declared a state of emergency and North Carolina instituted a Unified Command incident management structure shared between the NC State Emergency Response Team (SERT) and North Carolina Department of Health and Human Services.

North Carolina's COVID-19 Vaccination Plan builds on the foundation of the state's overall goals and pillars of response to the pandemic. Since the start of the pandemic, North Carolina took early and aggressive action to slow the spread of the virus, managed shortages of testing and PPE supplies, developed hospital surge plans, built testing and contact tracing capabilities, and promoted prevention strategies. Our collective actions flattened the curve of new cases, prevented our healthcare systems from being overwhelmed, and provided valuable time to build our state's capacity to respond to the crisis.

Our COVID-19 pillars of response are:

A. Prevention: provide guidance, training, technical assistance and education; maximize communications and engagement; establish and enforce requirements; build a trusted and effective vaccination infrastructure.
B. Testing: ensure adequacy of supply and access; drive demand; surge resources in hardest hit communities and populations.

C. Contact Tracing: build statewide infrastructure for rapid outreach to cases and contacts, follow up and effective case investigations; hire contract tracers that are members of the communities hardest hit to promote trust.
D. Isolation and Quarantine: build statewide access to non-congregate shelters; build referral infrastructure and availability of support services that enable people to miss work and safely stay at home.

North Carolina's overall objectives in the fight against COVID-19 are:

1. Protect ourselves, our loved ones, and our neighbors from getting seriously ill.
2. Restore our economy and get North Carolinians back to work safely.
3. Get our children back to school so they can learn, play, and thrive.
4. Address the disproportionate impact of COVID-19 on historically marginalized populations.

To determine the effectiveness of our strategy and to determine adjustments, we monitor the following key COVID-19 trends and capacity metrics:

1. COVID-like syndromic cases in the emergency departments.
2. New daily cases.
3. Positive tests as a percentage of total tests.
4. Hospitalizations.
5. Testing.
6. Contact tracing.
7. Personal Protective Equipment (PPE).

Planning Assumptions

These planning assumptions directly reflect the latest guidance and information from the U.S. Centers for Disease Control and Prevention (CDC) as well as Operation Warp Speed.

COVID-19 Vaccine

- Limited COVID-19 vaccine doses may be available during the fourth quarter of calendar year 2020, but this supply will increase substantially in 2021.
- Initial supply of COVID-19 vaccines will most likely be authorized for use under an Emergency Use Authorization (EUA) rather than a full Biologic License Approval issued by the U.S. Food and Drug Administration (FDA).
- Cold chain storage and handling requirements for each COVID-19 vaccine product will vary from refrigerated (2°C) to frozen (-20°C) to ultra-cold (-60° to -80°C) temperatures, and ongoing stability testing may impact these requirements.
- Two doses of COVID-19 vaccine, separated by either ≥ 21 or ≥ 28 days, will be needed for immunity, and second-dose reminders for patients will be necessary. Both doses will need to match each other (i.e., be the same vaccine product). A vaccine requiring only one dose may be available later in the vaccination campaign.

- Vaccines may require reconstitution with diluent or adjuvant at the point of administration.

COVID-19 Vaccine Allocation

- The Advisory Committee on Immunization Practices (ACIP) has issued preliminary guidance on groups to prioritize for initial COVID-19 vaccination. Based on information already released by groups such as the National Academy of Medicine, we anticipate that populations of focus for initial COVID-19 vaccination will likely be the critical workforce that provides healthcare and maintains essential functions of society (see https://www.cisa.gov/identifying-critical-infrastructure-during-covid-19), staff and residents in long-term care facilities, and people with two or more co-morbidities that put them at high risk for complications from COVID-19. We anticipate further refinement of that guidance.
- Allocations of the COVID-19 vaccine to jurisdictions will be based on multiple factors, including, but not limited to, populations recommended by the ACIP (with input from the National Academy of Medicine), current local spread and prevalence of COVID-19, and COVID-19 vaccine production and availability.
- Jurisdictions should anticipate that allocations may shift during the response based on supply, demand, and risk.
- Each jurisdiction should plan for both high-demand and low-demand scenarios.
- No doses should be held back at the jurisdiction or provider level. The federal government will hold back product initially to ensure second doses are available. Jurisdictions should allocate the doses they have available to them at the dose level.

COVID-19 Vaccination Provider Outreach and Enrollment

- To receive and administer COVID-19 vaccine and ancillary supplies, vaccination providers must enroll in the United States Government COVID-19 vaccination program, coordinated through their jurisdiction's immunization program, by signing and agreeing to conditions outlined in the COVID-19 Vaccination Program Provider Agreement and completing the COVID-19 Vaccination Provider Profile form.
- CDC will make this agreement available to each jurisdiction's immunization program for use in conducting outreach and enrolling vaccination providers. Jurisdictions will be required to maintain these agreements on file for a minimum of three years.
- Jurisdictions will be required to collect and submit to CDC information on each enrolled vaccination provider/site, including provider type and setting, patient population (i.e., number and type of patients served), refrigerated/frozen/ultra-cold temperature storage capacity, and logistical information for receiving COVID-19 vaccine shipments.
- Some multi-jurisdictional vaccination providers (e.g., select large drugstore chains, Indian Health Service, and other federal providers) may enroll directly with CDC to order and receive COVID-19 vaccine. These direct partners will be required to report vaccine

supply and uptake information back to each respective jurisdiction. CDC will share additional information when available on these procedures to ensure jurisdictions have full visibility for planning and documentation purposes.

- Jurisdictions may choose to partner with commercial entities to reach the initial populations of focus.
- Routine immunization programs will continue.

COVID-19 Vaccine Ordering and Distribution

- The federal government will provide directed funding to the state, tribal and local health departments (LHDs) to execute the vaccination campaign. In North Carolina, 85 LHDs serve all 100 counties. The Eastern Band of Cherokee Indians in North Carolina are in a unique position to administer and provide coordination for COVID-19 vaccination. All are challenged to stretch further without sufficient funding.
- COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. CDC will share more information about reimbursement claims for administration fees as it becomes available.
- CDC will use its current centralized distribution contract to fulfill orders for most COVID-19 vaccine products as approved by jurisdictional immunization programs. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer in shipping solutions that will maintain appropriate temperature for extended periods.
- Jurisdiction-enrolled vaccination providers will follow the jurisdiction's vaccine ordering procedures. COVID-19 vaccination providers will be required to report ongoing COVID-19 vaccine inventory.
- Vaccine orders will be approved and transmitted in CDC's Vaccine Tracking System (VTrckS) by jurisdiction immunization programs for vaccination providers they enroll.
- Vaccine (and adjuvant, if required) will be shipped to provider sites within 24 hours of order approval by the immunization program if supply is available.
- Ancillary supply kits and diluent (if required) will ship separately from the vaccine manufacturer due to different cold chain requirements, but shipment will be timed to arrive with or before the vaccine.
- Ancillary supply kits 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.
    - Each kit will include supplies needed to administer 100 doses of vaccine.
    - Jurisdictions may need to plan for additional PPE, depending on vaccination site needs.
    - For COVID-19 vaccines that require reconstitution with diluent or mixing adjuvant at the point of administration, these ancillary supply kits will include

additional necessary syringes and needles, and other supplies for this purpose.
    - Sharps containers, gloves, bandages, and other supplies will not be included.
- Minimum order size for CDC-centrally-distributed vaccines will be 100 doses per order for most vaccines. Minimum order size for direct-ship vaccines may be much larger. CDC will provide more detail as it becomes available.
- Vaccine will be sent directly to vaccination provider locations for administration or designated depots for secondary distribution to administration sites (e.g., chain drugstores' central distribution points).
- Once vaccine products have been shipped to a provider site, the federal government will not redistribute product.
- Jurisdictions will be allowed to redistribute vaccines while maintaining the cold chain. However, with the challenge of meeting cold chain storage requirements for frozen or ultra-cold vaccines, jurisdictions should be judicious in their use of redistribution and limit any redistribution to refrigerated vaccines only. Entities permitted to redistribute COVID-19 must sign and agree to the conditions in the COVID-19 Vaccine Redistribution Agreement.
- Jurisdictions are not advised to purchase ultra-cold storage equipment at this time; ultra-cold vaccine may be shipped from the manufacturer in coolers that are packed with dry ice, can store vaccine for an extended period of time, and can be repacked for longer use. CDC will provide additional detail as it becomes available.

COVID-19 Vaccine Administration Data Reporting

- Jurisdictions will be required to report CDC-defined data elements related to vaccine administration daily (i.e., every 24 hours). CDC will provide information on these data elements to jurisdictions.
- All vaccination providers may be required to report and maintain their COVID-19 vaccination information on CDC's Vaccine Finder.
- CDC's Vaccine Administration Management System (VAMS) will be available to jurisdictions/provider sites that need assistance with patient registration and scheduling, clinic flow, supply management, patient record management, and reporting.
- CDC has prioritized jurisdiction onboarding to the IZ Gateway to allow Immunization Information Systems (IISs) to receive data directly from national providers, non-traditional vaccination providers, and VAMS, as well as to report vaccine administration data to CDC, under IZ Gateway "Connect" functionality. IZ Gateway "Share" functionality will allow exchange of immunization information across jurisdictions.
- Data Use Agreements (DUAs) will be required for data sharing via the IZ Gateway and other methods of vaccine administration data sharing with CDC and will be coordinated by each jurisdiction's immunization program.

Communication

- CDC will develop communication resources for jurisdictions to use with key audiences. These resources will be available on a public-facing website currently under development, but jurisdictions will likely need to tailor messaging and resources specific to special populations in their communities.
- CDC will work with national organizations to disseminate key messages.
- Communication and educational materials about COVID-19 vaccination provider enrollment, COVID-19 vaccine ordering, COVID-19 vaccine storage, handling, administration (i.e., reconstitution, adjuvant use, administration techniques, etc.) will be available in a variety of formats.
- When vaccine supply is available for expanded groups among the general population, a national COVID-19 vaccine finder will be available on the public-facing Vaccine Finder.
- A screening tool on the CDC website will help individuals determine their own suitability for COVID-19 vaccine and direct them to the Vaccine Finder.

COVID-19 Vaccine Safety

- Clinically important, adverse events following any vaccination should be reported by healthcare providers to the Vaccine Adverse Event Reporting System (VAERS), as required by the Provider Agreement.
- Adverse events will also be monitored through electronic health record (EHR) and claims-based systems (e.g., Vaccine Safety Datalink).
- Additional vaccine safety monitoring and regulatory considerations may be required under the EUA.
- If applicable, jurisdictions should ensure providers know where to find provider and recipient EUA fact sheets, have read and understand them, and are clear on the requirement to provide the recipient fact sheet to each client/patient prior to administering vaccine.

Key Tasks

1) Establish and utilize internal organizational structure and external partner involvement

a. Utilize internal planning and coordination team with members representing a wide array of expertise and clearly defined roles and responsibilities.
b. Establish external advisory committee and engage external partners, stakeholders, local and state agencies, and tribal leaders 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.
c. Ensure budgeting and contracting follows state procurement rules and regulations and is completed in consultation with appropriate staff.

2) **Establish continual quality improvement processes to identify and address gaps in preparedness, planning, and execution**
   a. Utilize and ensure all partners have existing and forthcoming CDC-provided COVID-19 planning assumptions.
   b. Establish reporting systems to continue to assess readiness and gaps and quickly respond to identified gaps in planning or execution of the plan.

3) **Ensure capacity for data collection and data sharing for immunization information system (IIS), other reporting systems, and data systems**
   a. Determine baseline and enhance IIS capacity and capabilities to onboard providers and capture and report CDC-required reporting elements.
   b. Maintain visibility on doses administered by priority group and location as well as on-hand inventory levels.
   c. Execute needed agreements for data sharing.
   d. Proactively report data on public dashboard.
   e. Ensure a backup system is available and ready if the primary system becomes unusable for any reason.

4) **Identify and Prioritize Critical Populations**
   a. Establish priority groups and sub-priority groups for each phase of vaccine availability in a transparent way utilizing federal guidance and external COVID-19 External Advisory Committee.
   b. Estimate numbers for priority groups.
   c. Establish an allocation formula that is transparent and defendable.

5) **Create access points for vaccine administration**
   a. Identify and enroll providers into the COVID-19 vaccination program for early narrow and later broad vaccination plans.
   b. Include broad-based healthcare partners (primary and specialty care providers, skilled nursing facilities, other long-term care settings, local public health agencies, hospitals and health systems, pharmacies, mobile vaccination providers, occupational health for large employers, providers serving incarcerated populations, and payers).
   c. Prepare for vaccinations through regular healthcare channels and new mobile or community-based mass vaccination sites.
   d. Include community partners to increase accessibility, uptake, and reach.
   e. Create a transition plan from low supply/high demand to high supply/low demand.

11) **Create proactive and inclusive communication plan**

   a. Be guided by research in understanding barriers, values, and motivations for vaccine uptake across different populations.
   b. Lead with transparency with early and frequent communication about process and plans; identify and determine process, opportunities, and settings for frequent communication with stakeholders.

c. Determine proactive and culturally sensitive and linguistically responsive communication approaches for critical populations as well as the general public.
d. Communicate clearly and in an impactful way with all stakeholders from start to finish in appropriate languages with tailored and tested messages for target populations.
e. Engage respected community leaders and sources to promote trust.

Concept of Operations

This vaccination campaign will be accomplished in four phases: Planning, Implementation, Adjustment, and Transition.

A. Phase 0: Planning

Planning will be a continuous operation throughout the vaccination campaign. In the initial planning stages, we will establish priority groups and data reporting mechanisms including ordering and inventory as well as vaccine administered. Priority populations will be based on COVID-19 exposure risks, risk of morbidity, and mortality, among other factors as described in the prioritization annex. Using our priority populations list, we will identify and enroll vaccinating providers critical to reaching those populations. Enrollment will be based on CDC-provided agreements. Enrolled providers, along with other data sources, will identify the numbers of priority populations each provider serves or can reach. The planning process will provide extensive detail for each of those operations. Written plans will signal readiness to move to implementation.

B. Phase 1: Implementation – Potentially limited supply of COVID-19 vaccine doses available

Implementation will begin when first vaccine doses are allocated to North Carolina. In this initial phase, vaccine supplies will be very limited and targeted to those priority populations identified in the planning phase. These populations will most likely include critical healthcare workers at high risk of exposure, essential workers (e.g., emergency management, fire, etc.), and long-term care staff and residents. These vaccines will most likely be administered in closed settings for employees or residents. Further, we are prioritizing populations with high risk of morbidity and mortality of COVID-19, especially those in settings or occupations with increased risk of exposure, e.g., people living in congregate settings (migrant farm workers, incarcerated people, people in homeless shelters), workers in high-density occupation and frontline workers. Vaccinations for these groups will most likely be administered through a combination of vaccination clinics administered by local health departments for critical populations or through arrangements for on-site vaccination clinics. Historically marginalized populations (HMPs) are over-represented in the prioritized populations categories. First doses will be allocated to administration locations across the state based on priority populations that can be reached as well as minimum shipment increments determined by CDC. Early vaccine is likely to be shipped in increments of 1,000 due to vaccine storage needs at ultra-cold conditions. Administration locations serving numbers greater than the minimum shipment will be eligible to receive

shipments direct to their locations. However, large shipment minimums will also require providers and settings who serve smaller numbers of priority populations to work together, likely with local health departments, to receive vaccine for early vaccine administration. Some vaccine may be available in shipment increments of 100 for smaller priority providers. Providers will be required to report vaccine administered in near real time through electronic systems detailed in Annex F. Also, during the implementation phase, we will continue to enroll providers that will provide COVID-19 vaccine to priority populations beyond the initially targeted priority populations.

C. Phase 2: Adjustment – Large number of vaccine doses available

The next phase will be when more vaccine is available, and we have higher supply and high demand. During this phase we will transition from allocation to providers to providers ordering for themselves based on population needs and local demand. Also at this time, we anticipate the shipment minimum will be reduced to 100 . This phase will require more points of access, mass vaccination clinics, and broad vaccination sites with maximum throughput of persons to be vaccinated. Adjustments will be needed based on things that change as vaccine becomes available, rendering the current plan unworkable for any number of reasons.

D. Phase 3: Transition – Sufficient supply of vaccine doses for entire population (including a possible surplus of doses)

The third phase will be moving to a time of high supply/lower demand. We will be transitioning to fewer mass, mobile, or community-based vaccination clinics and sites and continuation of vaccination in more established channels of vaccine. The final stage of the vaccine campaign will be that of transition to what future COVID vaccination will look like. This is likely to be similar to annual seasonal flu vaccine campaigns. Throughout the process, data systems will be established and used to monitor progress, inform needed changes, and allow for transparent reporting to stakeholders, partners, and the public.

Response Organization and Roles/Responsibilities

Command, Control, and Management

The overall COVID-19 and vaccination organizational response structure is presented in the charts below and in Appendix 2. Figure 1 depicts the North Carolina DHHS organizational structure and Figure 2 depicts the associated vaccination planning team organizational structure. The organizational structure of the State Emergency Response Team (SERT) is in Appendix 2. These three structures interact under the unified command principle through a series of daily and weekly synchronization meetings.

Figure 1. COVID-19 DHHS Response Structure:

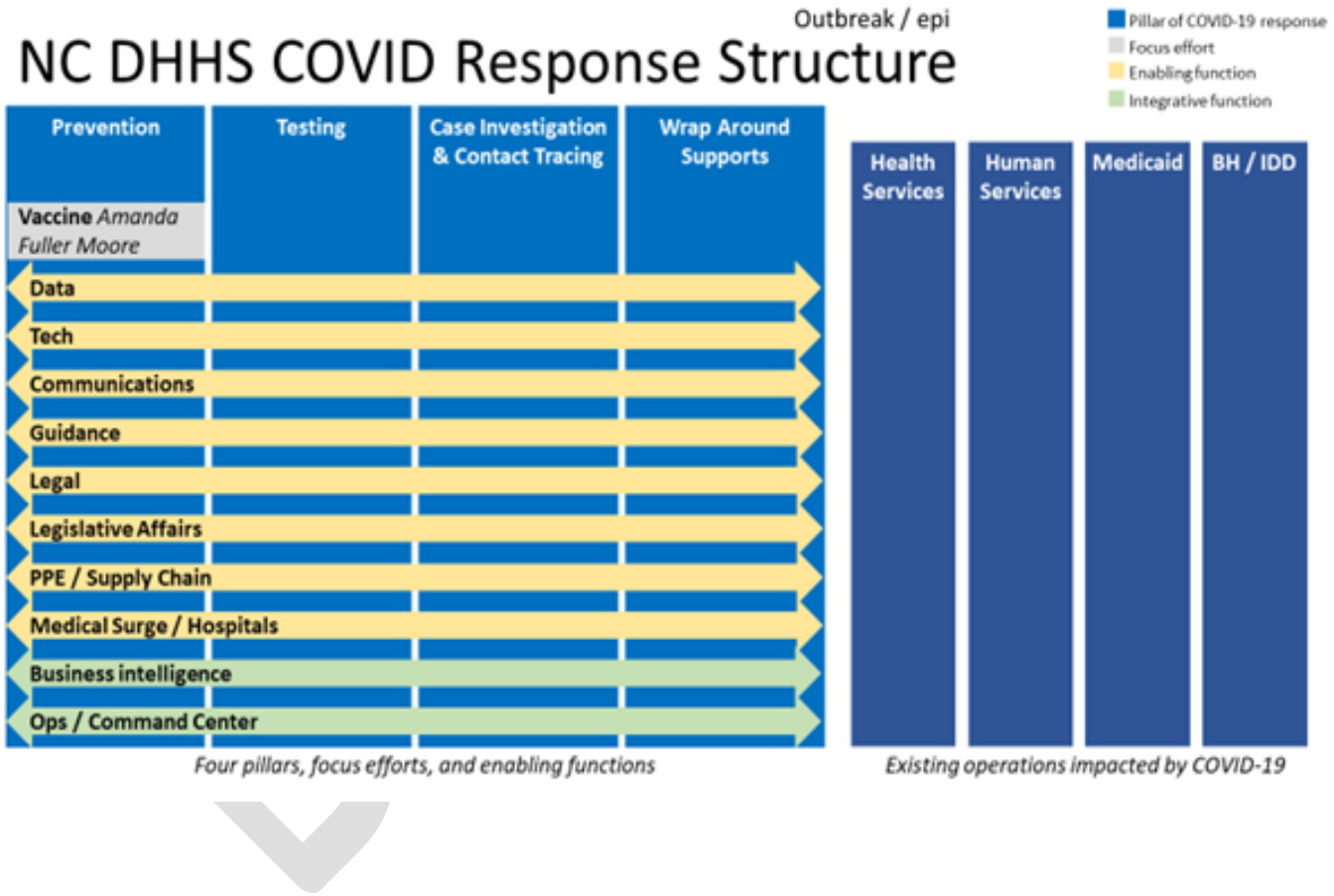
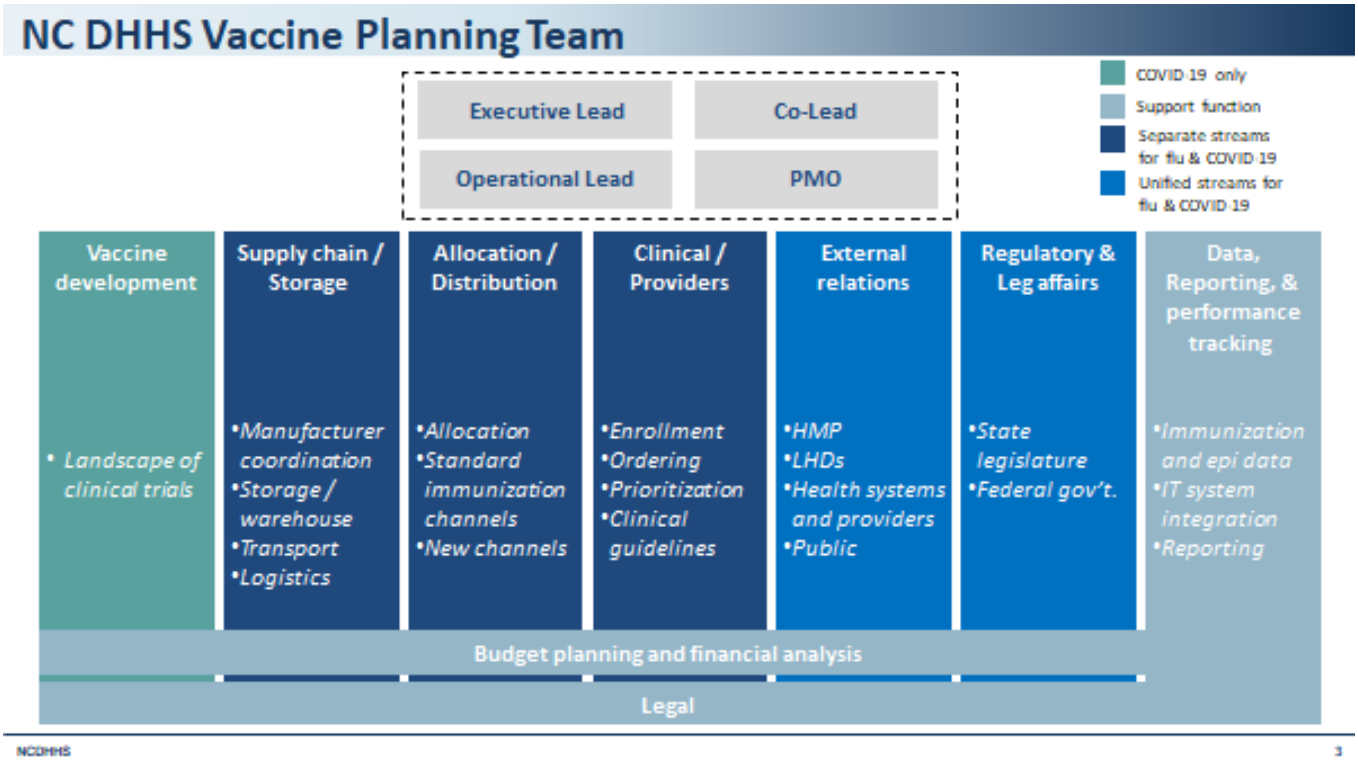


Figure 2. Vaccination Planning Team Structure:



COVID-19 SERT Overall Organizational Structure: Refer to Appendix 2.

External Advisory Committee

The North Carolina Institute of Medicine has convened a COVID-19 External Advisory Committee of key stakeholders and partners to work with the North Carolina Department of Health and Human Services.

Organizational Members of the Advisory Group:

Organization	
Wake Forest University	NC State AFL-CIO
UNC School of Public Health	Blue Cross NC
Clinton Medical Clinic/NC Med Society	UNC Chapel Hill, School of Government
NC Institute for Public Health	NC Association of County Commissioners
Roanoke Chowan Community Health Center; Ahoskie, NC	UNC Chapel Hill, School of Medicine
UNC Health	Disability Rights North Carolina
Duke	Legal Aid - Farmworker Unit
BuncombeCounty Health Department	NC Retail Merchants Association
UNC School of Medicine	NCACC
Duke	Guilford County Emergency Management
Nash County Emergency Management	Racial Equity Institute; Guilford County Schools
BCBS North Carolina Foundation; Blue Cross NC	NC Justice Center
NC NAACP	North Carolina Commission of Indian Affairs
El Pueblo	Temple Beth Or
El Centro Hispano	Islamic Association of Raleigh
Episcopal Farmworker Ministry	Sandhills NC Black Nurses Association
NC Agromedicine Institute	Roanoke Chowan Community Health Center
Eastern Band of Cherokee Indians Public Heath and Human Services	CCNC
Lumbee Tribe of North Carolina	NC Society for Human Resource Management
NC Department of Public Safety	Senate, NCGA
NC Council of Churches	House, NCGA
Old North State Medical Society	DCDEE
NC Academy of Family Physicians	Department of Administration
NC Association of Free and Charitable Clinics	NC Pandemic Recovery Office
NC Association of Community Health Centers	Office of the Governor
North Carolina Nurses Associalton	NC Association of Educators
NC Health Care Facilities	NC Sheriffs Association
NC Senior Living Association	NC Association of Rescue and EMS
AARP; The Generations Study Group	NC Academy of Physician Assistants
Vidant Health	ECU Brody School of Medicine
Wake Forest Baptist Health System	Friends of Residents in Long Term Care
College of Nursing, Doctor of Nursing practice Program; Brody School of Medicine	League of Municipalities
Duke Human Vaccine and Clinical Trials Unit	Kate B. Reynolds Charitable Trust
UNC School of Medicine	Delhaize America
Novant	NC AHEC
Immunization Branch, Ft Bragg	Academy of Doctors, Dentists, and Pharmacists; UNC
NC State, Student Health	NC Community College System
Atrium Health	Wake Forest SOM
DPI	WFU
NC Board of Pharmacy	NC Mutual
Biologics by McKesson	NCSU
NC Chamber Foundation	

Charge of the Committee includes to:

- Inform an equitable, safe, and feasible distribution of COVID-19 vaccine
- Refine detailed prioritization of groups to direct initial provider enrollment so that people can clearly align themselves with a group
- Enhance reach of vaccine activities, including provider recruitment and engagement, expansion to non-traditional channels and sites, and operationalizing distribution sites
- Support and provide guidance on ongoing messaging and communications, outreach to the public, especially HMPs, and serve as spokespeople for vaccine campaign.

Plan Development and Maintenance

Development

The North Carolina DHHS Vaccination Planning Team is responsible for the development of this plan and annexes.

Maintenance

The vaccination planning leads will maintain, distribute, and update the plan. Responsible officials in state or local agencies should recommend changes and provide updated information periodically (e.g., changes of personnel and available resources). Revisions will be forwarded to those on the distribution list.

Review and Update

Plan Revision

A revision is a complete rewrite of an existing plan or annex that essentially results in a new document. Revision is advisable when numerous pages of the document have to be updated, when major portions of the existing document must be deleted or substantial text added, or when the existing document was prepared using a word processing program that is obsolete or no longer available. Revised documents should be given a new date and require new signatures by officials.

Formal Plan Change

A formal change to a planning document involves updating portions of the document by making specific changes to a limited number of pages.

Changes are typically numbered to identify them and are issued to holders of the document with a cover memorandum that has replacement pages attached. The cover memorandum indicates which pages are to be removed and which replacement pages are to be inserted in the document to update it. The person receiving the change is expected to make the required page changes to the document and then annotate the record of changes at the front of the document to indicate that the change has been incorporated into the document. A change to a document does not alter the original document date; new signatures on the document need not be obtained.

References

A. Federal

1. Vaccine Prioritization Guidance (ongoing development).
2. COVID-19 Vaccine Provider Agreement (ongoing development).
3. Comprehensive Preparedness Guide (CPG) 101: Developing and Maintaining State, Territorial, Tribal, and Local Government Emergency Plans, Federal Emergency Management Agency, March 2009.
4. Homeland Security Exercise and Evaluation Program (HSEEP), February 2007.
5. National Incident Management System (NIMS), Department of Homeland Security, December 2008.
6. National Response Framework, Federal Emergency Management Agency, January 2008.

B. State

1. State Vaccine Prioritization guidance (in development).
2. North Carolina Medical Board Approved Medications and Approved Skills for Credentialed EMS Personnel – Revised 06/19/2018.
3. Delegation of immunization administration to UAP in declared state or national emergencies or federal/state DHHS- or CDC-initiated mass immunization campaigns.
4. North Carolina Emergency Operations Plan (NCEOP).

SUPPORT ANNEXES

Annex (A): External Relations

- **Annex (A-1): External Relations (Healthcare)**
- **Annex (A-2): External Relations (Historically Marginalized Populations)**
- **Annex (A-3): External Relations (Local Health Departments)**
- **Annex (A-4): External Relations (Public)**

Annex (B): Clinical Providers

Annex (C): Prioritization of Critical Populations

Annex (D): Allocation/Distribution

Annex (E): Supply Chain/Storage

Annex (F): Data, Reporting, and Performance Tracking

APPENDICES

Appendix 1: COVID-19 Vaccination Plan List of Acronyms

Appendix 2: COVID-19 SERT Organizational Structure

Appendix 3: North Carolina Legal Authority to Address COVID-19 Pandemic

Appendix 4: NCIR and Dashboard Technical Specifications

Appendix 5: Communications Matrix

Appendix 6: Prioritization Process

Appendix 7: Tribal Planning Tool

Appendix 8: Safety Data Sheet – Dry Ice

Appendix 9: Dry Ice Safety Instructions

Appendix 10: COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, September 16, 2020

Appendix 11: Managing Workplace Fatigue During COVID-19

Annex A: External Relations

Annex (A-1): External Relations (Healthcare)

Purpose, Scope, and Situation Overview

Purpose

The purpose of this document is to inform local, state, tribal, and federal governments, relevant agencies, organizations, and other stakeholders of the response plans specifically related to how the North Carolina Office of Emergency Medical Services (OEMS) Healthcare Preparedness Program (HPP) will assist in carrying out the state's overall mission of vaccinating every North Carolinian that can and wishes to receive a COVID-19 vaccine.

This concept of operations is based upon current guidance from the Centers for Disease Control and Prevention (CDC) and the Assistant Secretary for Preparedness and Response (ASPR). This information is subject to change as more COVID-19 vaccine information becomes available and the overall situation evolves or changes.

Scope

This annex is relevant to all participating healthcare providers/systems, independent hospitals, long-term care facilities, healthcare coalitions, pharmacies, first responder agencies, emergency management, and other healthcare providers within North Carolina.

Situation Overview

COVID-19 vaccine is a medical countermeasure that will protect against symptomatic illness in recipients and significantly reduce COVID-19 transmission among the population. It is anticipated that the first doses of COVID-19 vaccine will become available on a limited basis as early as November 1, 2020. While many federal and state organizations are currently working on prioritization of vaccine recipients, it is anticipated that healthcare workers and first responders who are at high risk of exposure to COVID-19, long-term care staff and facility residents, and people with two or more co-morbidities that put them at high risk for complications from COVID-19 will be included in some of the highest-priority groups and therefore be among the first North Carolinians to be vaccinated.

Concept of Operations

A. Phase 0: Planning

- Identify all relevant vaccine stakeholders (in no priority order) in the healthcare/first responder sector:
    - Hospitals
        - Private Systems & Independents
        - State-Operated Facilities

        - Cherokee Indian Hospitals
        - Veterans Affairs Hospitals
        - Military Hospitals
    - Skilled Nursing Facilities (including state operated facilities)
    - Adult Care Homes
    - Assisted Living
    - Group Homes
    - Intermediate Care Facilities for People with Intellectual and Developmental Disabilities (including state-operated facilities)
    - Primary and Specialty Care Providers
    - Urgent Care Clinics
    - Travel Clinics
    - Local Health Departments
    - Dentists
    - Respiratory Technicians
    - Home Healthcare and Hospice Agencies
    - Correctional Facilities
    - Nursing Associations
    - Pharmacies
    - Occupational Health/Mobile Health Agencies (especially those serving critical infrastructure businesses such as food processing and manufacturing)
    - Morticians/Funeral Home Workers
    - Dialysis Clinics
    - Federally Qualified Health Centers (FQHC)
    - Rural Health Clinics
    - Free and Charitable Clinics
    - Community Health Workers
    - Fire and Emergency Medical Services Agencies
    - State and Local Law Enforcement Agencies
- Perform outreach and establish lines of communications to each stakeholder within the categories listed above.
    - Identify COVID-19 vaccine points of contact for each stakeholder
    - Leverage partner relationships to assist with communication to stakeholder groups (see Appendix 4: Communications Matrix for responsibilities)
- Share opportunities for required training developed by the North Carolina Immunization Branch regarding the following COVID-19 vaccination topics:
    - North Carolina External Advisory Committee COVID-19 vaccine priority recommendations and the Advisory Committee on Immunization Practices recommendations when available
    - How to order and receive vaccine

    - COVID-19 vaccine storage and handling
    - Vaccine administration, reconstitution, and use of any adjuvants or diluents
    - Required documentation and reporting of vaccine administration
    - Management of COVID-19 vaccine inventory
- Determine which identified stakeholders will serve as vaccine administration locations.
    - For each administration location, determine the following:
        - Vaccine storage capability including ultra-low, standard frozen and refrigerated storage
        - Population served, broken down into categories that match vaccine prioritization groups
    - Ensure each identified vaccine administration site signs the federally required COVID-19 Vaccine Provider Agreement
- Ensure stakeholders identified as vaccine administration sites have access to North Carolina Immunization Branch guidance and resources needed to successfully store, administer, track, and report vaccine usage.
    - Assist North Carolina Immunization Branch as needed with enrolling administration sites into the appropriate IT system(s) chosen by the state to be used for this campaign (NCIR, VAMS, etc.).
- Ensure stakeholders are accurately represented in priority vaccination guidance created by federal and state workgroups.
    - Clearly communicate prioritization guidelines to each stakeholder group
- Provide continuous updates and education related to vaccine planning and implementation by presenting the most current vaccine information via the following avenues:
    - Monthly hospital/EMS coordination webinar
    - Monthly Office of Rural Health/healthcare coalition webinar
    - Weekly conference calls with healthcare coalition leaders
    - Quarterly healthcare coalition meetings for all eight healthcare coalitions statewide
    - Weekly leadership calls with local health directors and local emergency management
    - Twice-a-month Public Health Office hours with providers
    - Twice-a-month webinar with Medicaid providers
    - Monthly webinars hosted by Community Care of North Carolina and North Carolina Area Health Education Centers, in partnership with North Carolina Academy of Family Physicians, North Carolina Pediatric Society, and North Carolina Psychiatric Association
    - Monthly COVID-19 behavioral health provider calls
    - Weekly long-term care “office hours” calls

    - Establish additional webinar opportunities with targeted audiences as needed, for example evolving behavioral health managed care organizations
    - Direct email to identified vaccine points of contact at each stakeholder
- Encourage stakeholders to exercise their individual COVID-19 vaccination campaign plans (i.e., leveraging seasonal flu vaccination campaign).
    - Provide technical support and guidance as requested
    - Share After Action Reports/Improvement Plans among stakeholders to better inform planning
- Connect stakeholders with their local health departments to ensure a whole community approach to local COVID-19 vaccination campaigns.
- Provide planning support and technical assistance related to mass vaccine clinic design to stakeholders serving as administration sites as needed.
- Identify non-traditional vaccinators that may be able to assist with mass vaccination campaigns (EMS, dentists, veterinarians, farmworker health outreach workers, etc.).
    - Work with regulatory agencies/boards that oversee these groups to ensure all necessary rules are waived or declarations are in place to allow them to assist with mass vaccination
    - Inform stakeholders of non-traditional vaccinator options

B. Phase 1: Implementation

- Prioritize communication to healthcare providers vaccinating the groups in the higher-priority categories.
- Continue providing updates and education about vaccine to stakeholders via the avenues mentioned above.
    - Updates will include, but not be limited to:
        - State allocation strategy and outcomes
        - Information about overall vaccine supply
        - Current recommended vaccine priority groups
        - Vaccine storage, handling, reconstitution, and administration
        - Best practices and lessons learned from other stakeholders
    - Frequency of updates provided to stakeholders will be adjusted based on rate of information change and pace of allocations
- Ensure vaccine administration sites are accepting/denying their allocations in a timely manner via the IT system chosen by the state.
- Ensure vaccine administration sites understand and are adhering to finalized vaccination priority guidance.
- Communicate with stakeholders who are not serving as vaccine administration sites about opportunities for them to receive the vaccine when appropriate based on vaccination priority guidance.
- Respond to any technical assistance requests or resource requests related to vaccine

administration.

- Mobilize non-traditional vaccinators to support vaccination campaigns as needed.

C. Phase 2: Adjustment

As vaccine supply improves and we move into phase 2, HPP will take the following actions:

- Expand channels of communication to vaccinating providers for broader populations. Continue to communicate changes in vaccine prioritization, availability, and guidelines for use by all stakeholders via the avenues mentioned above.
- Continue to provide or share opportunities for training regarding COVID-19 vaccine to new stakeholders identified as vaccination providers that come onboard as vaccine availability improves.
- Continue to respond to any technical assistance requests or resource requests related to vaccine administration.

D. Phase 3: Transition

As vaccine supply improves further, HPP will take the following actions:

- Continue to communicate changes in vaccine prioritization, availability, and guidelines for use by all stakeholders via the avenues mentioned above.
- Continue to provide or share opportunities for training regarding COVID-19 vaccine to new stakeholders identified as vaccination providers that come onboard as vaccine availability improves.
- Continue to respond to any technical assistance requests or resource requests related to vaccine administration.

Organization and Assignment of Responsibilities

A. General

The North Carolina Office of Emergency Medical Services Healthcare Preparedness Program (OEMS HPP) will leverage existing partnerships and develop new ones as needed to ensure successful implementation of the state COVID-19 vaccination plan.

B. Assignment of Responsibilities

1) OEMS HPP

a. Serves as lead for this annex of the North Carolina COVID-19 Immunization Plan.

2) Regional Healthcare Coalitions

1. Serve as a conduit of information to stakeholders regarding vaccination planning and implementation.
2. Provide technical assistance and help with resource requests from stakeholders within their region.
3. Facilitate connections between healthcare providers and local health

departments.

3) **HPP stakeholders identified as vaccine administrators**
   a. Provide designated COVID-19 vaccine points of contact upon request.
   b. When prompted, complete and sign COVID-19 Vaccination Program Provider Agreement to enroll in State COVID-19 Vaccination Program.
      i. Ensure all fields of the COVID-19 Vaccination Program Provider Profile section of the provider agreement are complete.
   c. Register for access to vaccine IT system chosen by the state.
   d. Receive and store vaccine in accordance with federal/state guidelines.
   e. Administer vaccine to employees and patients in accordance with federal and state prioritization guidelines.
   f. Report vaccine inventory and use in accordance with state guidelines.
   g. Adhere to all requirements of any Emergency Use Authorizations (EUAs) that may be in place.
   h. Report clinically important adverse events following COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS) as required by the COVID-19 Vaccination Program Provider Agreement.

4) **HPP Stakeholders who are NOT vaccine administrators**
   a. Provide designated COVID-19 vaccine points of contact upon request.
   b. Stay current with the latest vaccine information.
   c. Review and understand vaccine prioritization guidance and seek vaccine when appropriate based on guidance.

Communications

Key stakeholders for external relations, the lead agency and person responsible for communication with that stakeholder group, the main methods of communication used to reach that stakeholder, any third parties or secondary agencies that may assist in reaching that stakeholder are identified in Appendix 4: Communications Matrix.

References

A. Federal

1. Vaccine Prioritization guidance (in process of being developed)
2. CDC COVID-19 Vaccination Program Provider Agreement
3. Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act

Comprehensive Preparedness Guide (CPG) 101: Developing and Maintaining State, Territorial, Tribal, and Local Government Emergency Plans, Federal Emergency Management Agency, March 2009.

Homeland Security Exercise and Evaluation Program (HSEEP), February 2007.

National Incident Management System (NIMS), Department of Homeland Security, December 2008.

National Response Framework, Federal Emergency Management Agency, January 2008.

B. State

1. State Vaccine Prioritization guidance (in process of being developed)
2. North Carolina Medical Board Approved Medications and Approved Skills for Credentialed EMS Personnel (136 KB PDF) – Revised 06/19/2018
3. Delegation of immunization administration to UAP in declared state or national emergencies or federal/state DHHS- or CDC-initiated mass immunization campaigns
    a. State EOP
    b. State map with homeland security and emergency management regions

C. Local

1. Local EMS protocols related to immunization administration

External Relations (Healthcare) SME – NC OEMS, NC PHP&R (MCM)

2. Local EOPs
3. Inter-local agreement(s)

Annex (A-2): External Relations (Historically Marginalized Populations)

Purpose, Scope, and Situation Overview

Purpose

To recommend effective strategies and important considerations in order to reach historically marginalized populations (HMPs) with the COVID-19 vaccination.

Scope

HMPs in this annex include African Americans, LatinX people, federal- and state-recognized American Indian tribes, Asian Americans, immigrants (regardless of legal status), refugees, LGBTQ+, and people with disabilities.

North Carolina leaders will include state-recognized American Indian tribal leaders and organizations in vaccine rollout planning efforts. Indian Health Service (IHS) will provide vaccination services to the Eastern Band of the Cherokee Indians (EBCI); health/medical facilities will need to work with state authorities to receive vaccination for state-recognized tribes. North Carolina will reach out to the eight non-federally recognized tribes to ensure access to vaccination services, since these groups will not be served by IHS.

Situation Overview

Location:
Statewide considerations for reaching these populations will differ for those in large areas (Charlotte, Raleigh, etc.) vs. the most rural areas where access to any medical care is severely limited.

Demographic:
North Carolina HMPs have experienced significant disparities in COVID-19 diagnoses and deaths. At the beginning of the pandemic, African American populations were experiencing disproportionate rates of infections and deaths.

- African Americans make up 22% of the North Carolina population; however, as of April 2020, African Americans accounted for 38% of confirmed and probable COVID-19 cases and 40% of COVID-19 related deaths. Since that time, the disparity in rates of infection has improved and as of October 14, 2020, African Americans account for 23% of cases. However, disparity in deaths, while improved, has continued, with African Americans comprising 30% of COVID-19-related deaths.
- LatinX people are 9.8% of the North Carolina population. Earlier in the pandemic, the LatinX population made up 40% of lab-confirmed COVID-19 cases. While it has

improved, significant disparity in infection rates still exists with LatinX populations, accounting for 32% of confirmed and probable cases and 9% of COVID-19-related deaths in North Carolina, as of October 14, 2020.

- Alaskan/Native Americans (non-Hispanic) are 1.2% of North Carolina's population; they are 2% of North Carolina COVID-19 cases, and 1% of North Carolina COVID-19-related deaths (as of October 14, 2020).
- Asian Americans/Pacific Islanders (non-Hispanic) are 3.3% of North Carolina's population; they are 2% of North Carolina COVID-19 cases, and 1% of North Carolina COVID-19-related deaths (October 14, 2020).
- All other HMPs are currently captured together: they are 4% of North Carolina COVID-19 cases, and 2.2% of North Carolina COVID-19-related deaths.

Historically Marginalized Populations are more likely to be low-income, primarily uninsured or under-insured, and rural, thus also experiencing structural barriers around transportation, access to medical care and medical homes, and access to social supports. All these barriers put HMPs at higher risk for COVID-19 infection and adverse clinical outcomes due to lack of care.

All of this speaks to the critical importance of prioritization of HMPs in vaccine distribution. Although we do not list race or ethnicity groups as the sole criteria for prioritization, the prioritization of groups by risk of exposure and chronic conditions promotes equity. Historically marginalized populations are disproportionately represented among the prioritized high-risk populations, frontline and high-density occupational setting workforce, and congregate living settings. For example, nationally, African Americans and Latinx people comprise over 40% of long-term care workers. In North Carolina, 51% of homeless people and 52% of incarcerated people are African American. Ninety-nine percent of farmworkers are of Latinx ethnicity. Farmworkers are critical infrastructure workers and most live in congregate housing. Further, prioritizing essential workers promotes equity. According to a Kaiser Family Foundation survey (May 2020), "Compared to others who are currently employed (most of whom are presumably able to do their jobs from home), essential workers working outside the home are more likely to be Black (15% vs 5%) and have a household income of less than $40,000 (31% vs 19%)."

However, despite being at higher risk of infection or severe complications of COVID-19, studies and surveys across the U.S. and in North Carolina have clearly shown that there is considerable COVID-19 vaccine hesitancy among HMPs.

A September 2020 WRAL/Survey USA poll found:

- Few North Carolinians (23%) are willing to be vaccinated as soon as a COVID-19 vaccine is released, with black (9%), female (13%), and rural North Carolinians (17%) the least likely.
- There is considerable uncertainty, particularly among black (19%) and rural (21%) North Carolinians who say they are not sure when they would likely get a vaccine.
- A September 2020 poll by Suffolk University/USA Today Network has similar findings:

- 21% of all North Carolinians, 18% of female North Carolinians, and 7% of black North Carolinians would take a vaccine as soon as they could.
- 24% of all North Carolinians and 30% of black North Carolinians would not take the vaccine.

The vaccination approach is informed by the historical mistrust of government and the medical establishment, created by centuries of abuse of black and brown people. Due to this history, it will be critical to provide consistent, accurate, and clear information about COVID-19 vaccination and find methods to build trust in communities of historically marginalized people. Special consideration for HMPs must be made, inclusive of outreach, communication, trust, prioritization of these populations when vaccine becomes available, and vaccine accessibility for these populations.

Concept of Operations

A. Phase 0: Planning

1. Build trust:

a. Explicitly acknowledge the past wrongs perpetuated by governments and healthcare institutions against HMPs in medical settings.
   i. Based on recommendations from HMP advisors, create a PSA with leading North Carolina government leaders (e.g., State Health Director, Secretary of Health and Human Services) speaking to a trusted HMP medical leader, together in video and print.
   ii. Partner with the NC Chapter of the National Medical Association (Old North State Medical Society).

b. Work with Community Health Workers and the Communications team to develop communication plans and messaging.

c. Be guided by research in understanding barriers, values, and motivations for vaccine uptake across different populations.
   i. Hold focus groups to gain input regarding effective messaging to gain trust.

d. Engage trusted community leaders and sources to promote trust.
   i. Utilize HMP workstreams and External Advisory Committee to identify and invite speakers to host webinars and town hall meetings, utilizing faith-based organizations (FBOs) and others, as necessary.

e. Lead with transparency with early, frequent, and consistent communication about process and plans.

f. Enlist and inform community health workers (CHWs) and trusted community leaders to carefully explain key messages described in the communications annex, including:
   i. What vaccines are and how they work.

ii. How vaccines are being tested and approved:
    - How the COVID-19 trials are similar to regular trials (e.g., what processes have changed with Operation Warp Speed and what implications exist).
    - What risks are currently known and how they are outweighed by the benefits, particularly for HMPs who have been critically and disproportionately affected by COVID-19.
    - Describe known adverse reactions and side effects.
    - Include patients that are recovering from COVID to offer personal testimony on the serious potential consequences of the virus and to promote vaccination.

iii. How the vaccine will be distributed once available (e.g., the purpose of vaccine administration tracking logs).

2. Build capacity to educate HMPs about COVID-19 vaccine and assist in distributing vaccine to HMPs:

a. Work with community health workers, community-based organizations (CBOs), faith-based organizations (FBOs), and leaders to identify and operationalize methods to disseminate vaccine information. Methods will include distributing flyers, sending mass emails, and discussing key messages during virtual meetings or services.

b. Educate and update agencies and partners (e.g., General Assembly, academic institutions, cultural advocacy groups) about vaccine, tracking, and trial results within the HMP community.

3. Create messaging:

Create or identify public-facing culturally and linguistically competent content in multiple languages using a variety of venues/platforms to communicate and engage HMPs (TV, radio, newspaper, website, social media, virtual townhalls, etc.), ensuring it is inclusive and accessible to those with disabilities.

- Develop and test messaging with community partners via established focus groups for African Americans, LatinX, Native Americans, Asian Americans, refugees, immigrants, LGBTQ+, and people with disabilities.
- Develop a cadre of social media influencers to counter misinformation about the vaccine on Facebook, Instagram, and Twitter.
- Seek photos, video, and personal testimony of HMP leaders, celebrities, and other trusted messengers receiving vaccine as early adopters.
- Develop a communications and operational plan to respond to a patient having an adverse response to a vaccine to counter negative media and potential resistance.

4. Partner with local health departments (LHDs) and HMP-serving agencies on

vaccine planning:

a. Identify and invite local HMP-serving organizations and LHDs to convene local workgroups (CBOs, FBOs, etc.) to determine the best way to build trust, add capacity, and deliver vaccine locally. Methods will include holding focus groups, conducting PSAs, and developing other collateral materials for use on social media and other communication venues.
b. The established local work groups will help identify vaccine sites for mobile distribution to prioritized populations where HMPs have been clearly identified as both essential workers and as being at great risk for COVID-19 exposure, including but not limited to meat plant and farm workers, community health workers, and cleaning staff and cafeteria workers in hospitals caring for COVID-19 patients. Mobile distribution will be especially critical in rural areas.

B. Phase 1: Implementation

1. Release statewide messaging appropriate to each phase of distribution to address trust and vaccine safety, including but not limited to the following organizations/agencies to disseminate to their members:
   a. Faith-based organizations
   b. The National Panhellenic Council
   c. Refugee-serving organizations or organizations that serve historically marginalized communities
   d. Public and private school-age children in top relevant languages
   e. Public-serving locations (e.g., driving schools or DMV, post office, voter registration, etc.)
   f. Advocacy organizations (e.g., NAACP, Equality North Carolina, North Carolina Asian Americans Together, etc.)
   g. Farmworker Advocacy Network
   h. North Carolina Native American tribal organizations (as referenced by UNC American Indian Center and the North Carolina Commission of Indian Affairs)
   i. Others, including common businesses that have traditionally served as trusted places of communication and influence such as barber shops, hair salons, and nail salons
2. Mirror/leverage best practices and community partnerships used in North Carolina's Community testing and High priority And Marginalized Populations (CHAMP) testing effort that successfully increased COVID-19 testing among HMPs to bring COVID-19 vaccine to the same geographic areas and populations.
3. Ensure providers who serve HMPs (e.g., members of Old North State Medical Society) are registered as vaccine providers for early vaccination phases via outreach from professional societies, health systems, targeted emails, and other forms of communication.

a. LHDs, community health centers, free and charitable clinics, occupational health providers that serve front-line workers and other agencies
b. Stand up identified mobile locations for HMPs in pre-identified areas
c. Work with church medical auxiliaries to host vaccination events for members and the community

C. Phase 2: Adjustment

1. As the COVID-19 vaccine becomes more readily available, continue to disseminate messaging regarding phases in vaccine distribution using the modes of communication discussed in Planning.
2. Utilize HMP workgroups to identify sites for community-based mass vaccination clinics that are accessible, convenient, and trusted by HMPs.
3. Continue to phase in access for children in Phase 3, assuming vaccines are approved for those populations.

D. Phase 3: Transition

1. As the vaccine becomes routinely available for all groups, develop new campaign of messaging that is culturally relevant, and developmentally and linguistically appropriate, like the annual flu campaign.
   a. DHHS Communications will work directly with HMP workstreams and community partners to continue public awareness of the availability of the COVID-19 vaccine using established and informal platforms and work groups.
   b. Reach out to community to create PSAs in multiple languages, with messages delivered by native speakers.

Organization and Assignment of Responsibilities

A. Organization

1. HMP:

a. DHHS will partner with LatinX, Native American, African American, and refugee organizations to raise vaccine awareness statewide by disseminating information. Organizations will be responsible for disseminating updated information throughout their constituency. Examples of organizations are included below but are not limited to:
   i. Local health departments: North Carolina Association of Local Health Directors (NCALHD) and its 10 regions to assist in establishing work groups of local HMPs/HMP-serving organizations
   ii. Faith-based organizations (e.g.,North Carolina General Baptist State Convention, AME Zion)
   iii. AMEXCAN
   iv. NAACP

v. Farmworker Advocacy Network (FAN)
vi. NC Growers Association
vii. Agricultural Cooperative Extension
viii. Blueberry Assoc of NC, NC Sweet Potato Commission
ix. NC Christmas Tree Association
x. Agrimedicine Institute
xi. Refugee Community Partners
xii. Asian Americans Together (NCAAT)
xiii. Equality NC
xiv. North Carolina Commission of Indian Affairs and/or the UNC American Indian Center
xv. North Carolina Council on Disabilities and/or The Arc of North Carolina
xvi. Panhellenic Council
xvii. Refugee-serving organizations
xviii. Schools (public and private)
xix. Old North State Medical Society

Communications

As described in Planning: All public-facing communications must be culturally and linguistically competent content in multiple languages using a variety of venues/platforms to communicate and engage HMPs (TV, radio, newspaper, website, social media, virtual townhalls, etc.), ensuring they are inclusive and accessible to those with disabilities. HMP workstreams will be included at beginning of communication planning in an advisory capacity, including engagement of partners listed above and existing groups in the state.

External Relations (HMP) SME – Minority Health and Health Disparities

Local EOPs

1. Inter-local agreement(s)

Annex (A-3): External Relations (Local Health Departments)

Purpose, Scope, and Situation Overview

Purpose

The purpose of this document is to inform local, tribal, state, and federal governments, relevant agencies, organizations, and other stakeholders of the response plans specifically related to how North Carolina local health departments (LHDs) will assist in carrying out the state's overall mission of vaccinating every North Carolinian who can and wishes to receive a COVID-19 vaccination.

This concept of operations is based upon current guidance from the Centers for Disease Control and Prevention (CDC). It is subject to change as more COVID-19 vaccine information becomes available, and the overall situation evolves or changes. Updates will be managed by the External Relations (LHD) SMEs, NC DPH Local Technical Assistance and Training Branch Head and NC DPH Deputy Director in consultation with local health directors identified through the NC Association of Health Directors to provide expertise in all phases of vaccination distribution.

Scope

This annex is relevant to all North Carolina LHDs to provide support with the responsibilities of building trust, developing proactive messaging, and performing outreach for both flu and COVID-19.

Situation Overview

LHDs should have mass vaccination sections included in their All-Hazard Emergency Operations Plans. LHDs serve all 100 counties in North Carolina and are in a unique position to administer and provide coordination for COVID-19 vaccination. LHDs are frequently involved in administering vaccines for children and adults and seasonal influenza vaccines, and frequently train in delivering mass vaccinations. LHDs are a trusted source of public health information in their communities. NC Division of Public Health (NCDPH), through working with LHDs, has the opportunity to build trust, develop proactive messaging, and perform outreach for both influenza and COVID-19 vaccinations.

Concept of Operations

A. Phase 0: Planning

- Identify at least two local health directors through the NC Association of Health Directors to provide expertise in all phases of vaccination distribution.

- Public Health Preparedness and Response (PHP&R) will identify existing vaccine-related communication best practices that align with established county All-Hazard Mass Vaccination Plans and are vetted by DHHS Communications.
- PHP&R will disseminate communication and outreach best practices via email and webinars.
- PHP&R will create an inventory survey that will be sent to LHDs to:
    - Identify public and private providers and/or employers that can vaccinate their patients/employees/residents (closed points of dispensing (PODs)) and where vaccinations can occur.
    - Identify which sites cannot conduct their own vaccinations in order for LHDs to assist with vaccinations.
    - Identify locations for open PODs, to include reaching HMPs.
    - Identify who has ultra-low temperature vaccine storage capability.
- NC DPH Immunization Branch will request that LHDs assist local providers (closed PODs) with enrollment in the vaccination software program.
- NC DPH will provide support for LHDs signing of provider agreements as described in Annex (B): Clinical Providers, Concept of Operations, Provider Enrollment Draft Process 1.f of this plan.
- NC DPH will provide expertise across various programs to maximize LHD support through multiple communications channels. This includes, but is not limited to, consultants in the following branches:
    - Communicable Disease
    - Local and Technical Assistance and Training
    - Child Health
    - Women's Health
    - Immunization
    - Chronic Disease and Injury
    - Preparedness and Response
- NC DPH will offer technical assistance for LHD-specific communications, including preparation of both internal and external frequently asked questions.
- NC DHHS will include members from LHD external relations into the Clinical/Prioritization sub-stream to ensure seamless communication of clinical guidelines to include:
    - Preparing for mass vaccination clinics
    - Tracking doses administered and other data
- NC DHHS will use weekly LHD calls to educate regarding the need for the signed agreement and related time requirements to ensure compliance prior to vaccine arrival.
- NC DHHS will provide continuous updates and education related to vaccine planning and implementation by presenting the most current vaccine information via the following avenues:

- Weekly LHD calls
- Weekly LHD executive leadership call
- NC Communicable Disease Manual updates
- Direct email (as needed)

B. Phase 1: Implementation

- NC DPH will conduct bidirectional feedback between LHDs and DHHS Communications to ensure the local perspective is incorporated by leveraging opportunities listed above.
- NC DPH will provide vetted DHHS Communications messaging to LHDs including:
  - Messages targeted to vulnerable and historically marginalized populations; sharing messaging among LHDs that have been favorably received locally by HMPs.
  - Alerts to LHD patients about flu and COVID-19 vaccine.
  - Messaging via trusted relationships between LHDs and K-12 public schools, institutes of higher education (IHEs), correctional facilities, agricultural and meat-packing businesses.
- DPH will provide technical assistance to LHDs, including but not limited to:
  - NC Immunization Registry (NCIR) tools.
  - Feasibility and utilization of the electronic health record (EHR) when possible.
  - Outlining optimal staffing operations and mass vaccination clinics.
  - Business plans and billing.
- LHDs will work with local emergency management to activate mass vaccination strategies throughout their jurisdictions according to their All-Hazard Plan (AHP). This should include not only clinic-based vaccination, but also community-based, mobile, and non-traditional vaccination sites.
- LHDs will support coordination with providers within a county that do not serve the number of people in a priority population required to meet direct shipment minimums (1,000 doses initially and 100 doses later on).
- NC DPH will provide LHDs with weekly county-level information on vaccination rates in the county to provide public-facing data to local officials and the public.
- NC DPH will provide weekly updates on statewide vaccination trends at the weekly LHD call.
- LHDs will prioritize staff based on the overall COVID-19 vaccination priority groups and make plans to vaccinate staff accordingly.
- Continue providing updates and education about vaccines via the avenues mentioned above in Phase 0: Planning.
- NC DPH will provide financial support for LHD to activate the AHP for mass vaccination efforts within their jurisdictions.

C. Phase 2: Adjustment

- NC DPH and LHDs will continue to communicate changes in vaccine prioritization, availability, and guidelines to all stakeholders via the avenues mentioned above.
- As more vaccine is available, LHDs will move from more targeted vaccination sites and expand to mobile, mass, and community-based vaccination sites.
- NC DPH will prioritize communication to LHDs preemptively announcing changes/adjustments in the plan for LHDs' feedback.

D. Phase 3: Transition

- NC DPH and LHDs will continue to communicate changes in vaccine prioritization, availability, and guidelines to all stakeholders via the avenues mentioned above.

Organization and Assignment of Responsibilities

A. General

At the local level, the organizations, relationships, communication, and responsibilities are specified in the LHD AHP General Operating Guidelines that cover Mass Vaccinations and Command and Control.

B. Organization

The NC DHHS Division of Public Health will leverage existing partnerships and develop new ones as needed to ensure the successful implementation of the state COVID-19 vaccination plan.

1. Key branches of the NC DHHS Division of Public Health will be responsible, including Public Health Pharmacist, Immunization Branch, Public Health Preparedness and Response Branch, Local Technical Assistance and Training Branch, Communicable Disease Branch.
    a. Serve as lead for this annex of the State of North Carolina COVID-19 Vaccination Plan.
    b. Serve as a conduit of information between NC DHHS and LHDs regarding vaccination planning and implementation.
    c. Assist with technical assistance from LHDs.
2. North Carolina Association of Local Health Directors
    a. Serve as a conduit between NC DHHS Division of Public Health and LHDs, appointing representatives to assist NC DHHS DPH as needed.
3. Local Health Department
    a. Activate their respective AHP and Mass Vaccination Plans, if needed.
    b. Serve as a conduit of information to their local stakeholders and community regarding vaccination planning and implementation.
    c. Assist with technical assistance from stakeholders within their county or

counties.

d. Serve as vaccination sites.
e. Provide information to NC DHHS DPH regarding populations served based on prioritization guidance.
f. Receive and store vaccine in accordance with federal/state guidelines.
g. Administer vaccine to employees and patients in accordance with federal/state prioritization guidelines.
h. Report vaccine inventory and use in accordance with state guidelines.
i. Stay current with the latest vaccine information.

C. Assignment of Responsibilities

North Carolina Division of Public Health will send a representative, as needed, to the SEOC during vaccination operation implementation and be the lead agency for LHD outreach. Other partners will be utilized as needed. Assignment of responsibilities and representatives within each LHD will be determined by each LHD or per respective All-Hazard Plans.

External Relations (LHD) SME – NC DPH Local Technical Assistance and Training Branch Head, NC DPH Deputy Director

Annex (A-4): External Relations (Public)

Purpose, Scope, and Situation Overview

Purpose

The purpose of this document is to define the actions and roles necessary to provide a coordinated response within the COVID-19 Vaccination Program Communication jurisdiction.

Scope

The COVID-19 Vaccination Program Communication jurisdiction supports the goals of the North Carolina COVID-19 Vaccination Plan and seeks to achieve the following outcomes to support vaccination use:

1. North Carolinians trust the information that they receive from NCDHHS and LHDs about COVID-19 vaccinations.
2. North Carolinians understand the benefits and risks of COVID-19 vaccinations.
3. North Carolinians make informed decisions about COVID-19 vaccinations.
4. North Carolinians know how and where to get a COVID-19 vaccinations.

Key audiences will include:

- Vaccine providers (medical assistants, nurses, doctors, pharmacists)
- Healthcare workers
- Critical populations (frontline workers, people at higher risk for adverse outcomes, and people 65 and older)
- Historically marginalized populations (Black/African American, Latinx/Hispanic, American Indian, immigrants/refugees, LGBTQ+, Asian Americans and persons with disabilities)
- People living in rural communities

Situation Overview

Polling in North Carolina shows significant concerns about a forthcoming COVID-19 vaccine. Only 23 percent of North Carolinians are willing to be vaccinated as soon as a COVID-19 vaccine is available, and only 9 percent of black North Carolinians and 17 percent of rural North Carolinians were ready to get the vaccine immediately, according to a September 2020 poll sponsored by WRAL.[1] Most people indicated they would likely get a vaccination after it had been out for a period of time. However, 22 percent indicated they would never get it. A

[1] SurveyUSA News Poll #25514. September 16, 2020. https://wwwcache.wral.com/asset/news/state/nccapitol/2020/09/16/19289941/PollPrint-DMID1-5o7mvpvg7.pdf.

national poll[2] by the Pew Research Center has similar findings. Black adults were much less likely to say they would get the vaccine. Concerns including side effects and uncertainty top the list of reasons. Black adults are less likely to trust medical scientists, no doubt the result of centuries of discrimination, unethical and abusive experimentation, and the structural racism built into the healthcare system, according to Pew research.[3]

In addition, while healthcare workers are prioritized in the vaccine plan, they may also be vaccine hesitant, as was the case for many during the 2009 H1N1 pandemic.

Early, transparent, intentional, consistent, and frequent communication to the public, particularly our key audiences, is an essential component to the strategy to ensure North Carolinians get vaccinated.

Concept of Operations

A. Phase 0: Planning

1. Form a communications advisory committee including marketing professionals from a variety of sectors to serve as a sounding board for strategy and activities and as dissemination partners.
   a. Tap into existing external partners to identify and invite 10 to 15 members to participate in the committee.
   b. Engage community health workers to reveal "ground truth" to vaccine resistance, and to develop/test messaging.

2. Use a facilitated meeting process to accomplish defined objectives that inform the development and implementation of the communication activities and articulate specific calls to action. Conduct research to identify the barriers, values, and motivations for key audiences to get vaccinated to inform effective messaging framework, messenger recruitment, and dissemination channels.
   a. Use focus groups, surveys, and others appropriate methods conducted in a linguistically and culturally appropriate manner.
   b. Create a method that allows for ongoing dialogue to continually reassess barriers and opportunities to 1) understand the impact of existing efforts,

[2] Tyson, A., Johnson, C., & Funk, C. (2020, September 18). U.S. Public Now Divided Over Whether To Get COVID-19 Vaccine. Retrieved October 14, 2020, from https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/.

[3] Gramlich, J., & Funk, C. (2020, August 27). Black Americans face higher COVID-19 risks, are more hesitant to trust medical scientists, get vaccinated. Retrieved October 14, 2020, from https://www.pewresearch.org/fact-tank/2020/06/04/black-americans-face-higher-covid-19-risks-are-more-hesitant-to-trust-medical-scientists-get-vaccinated/.

and 2) respond to changing attitudes over time based on collective experience with the vaccine.

c. Proactively share findings with healthcare, advocacy, and other organizations to assist them in their own outreach efforts. Host webinars and share fact sheets.
d. Establish methods to proactively monitor public reaction through traditional and social media analysis.

3. Create a message framework to serve as the foundation for communications outreach that builds on audience values and addresses the challenges and opportunities identified in the research. Develop an overarching, statewide narrative with targeted messaging for select critical populations and demographic groups.
   a. Hire an agency to support messaging creation, review, and update support outreach activities included in this plan.
   b. Create message framework document with written guide for partner agencies and organizations on how to use the document.
   c. Host webinars to share the message framework with partner organizations to build a consistent, research-based narrative.
   d. Update and continue sharing messaging framework document with partners to reflect findings from ongoing research.

4. Communicate early and often with the media and directly to North Carolinians through NCDHHS media channels (e.g., YouTube, Facebook, websites, etc.), including outlining the vaccine planning process and who is engaged, sharing the details of the plans as they are determined, educating the public on vaccines in general, providing facts about safety and efficacy, and quickly communicating about any adverse events.
   a. Review vaccine plans to identify core milestones in the planning and implementation process. Develop and distribute corresponding press releases and remarks for press briefings.
   b. Devote a portion of one press briefing per week to providing information on vaccines. Survey all workstreams to identify potential crises (e.g., over/under demand, adverse reactions, etc.) and put together a communications response playbook.
   c. Recruit a diverse team of social media influencers representing HMPs to counter misinformation, as described in Annex A-2.

5. Develop a defined set of communications actions and supporting templates (e.g., write op-eds, speak at community meetings, etc.) for advisory group members, particularly those representing HMP groups.

a. Work with the advisory group to identify a list of actions that members can take.
b. Survey members to catalog which actions each member is willing to implement.
c. Draft templates to support actions.
d. Track actions via surveys and one-on-one communication with team leads and report actions back to the group and NCDHHS leadership.

6. Publicly share vaccine data on the COVID-19 public dashboard.
   a. Meet with the epi-data team to identify available disaggregated data about vaccine.
   b. Provide input to the data office via joint meetings to establish data flow process and build a tableau dashboard.

7. Update dashboard daily by data office and Joint Information Center.
   Ensure vaccine providers are equipped to be vaccination ambassadors by sharing talking points and other resources with appropriate associations, such as the North Carolina Nurses Association, North Carolina Medical Society, Old North Medical Society, Federally Qualified Health Clinics, North Carolina Healthcare Association, North Carolina Association of Family Physicians, North Carolina Association of Pediatrics, North Carolina Board of Pharmacy and others.

8. Ensure there is a coordinated effort to mitigate vaccine hesitancy among healthcare workers.
   a. Host virtual meetings to share a call to action from Secretary for healthcare systems and associations to engage members/workforce regarding vaccine hesitancy through active dialogue.
   b. Survey organizations to assess planned activities and materials.
   c. Determine if gaps exist and address by creating supplemental collateral material.
   d. Add separate section discussing stories of early adopters, including among HMP trusted leaders and messengers.

9. Get started early with key messages developed and vetted by the External Advisory Committee. Initial communications products will include talking points for the Advisory Committee to use with their networks, a COVID-19 vaccine 101 deck that partners can use for presentations, and an infographic explaining the COVID-19 vaccine process. Messages will continue to be refined through additional input from the communications advisory committee and the targeted populations of vaccine providers, healthcare workers, critical populations, historically marginalized populations, and rural communities. Early key messages focus on building trust by:

a. Increasing knowledge about vaccines. Use the flu vaccine as a touchpoint to explain vaccines, being transparent about limitations. Vaccines work by triggering your body to produce protective antibodies that help prevent or reduce the severity of the disease.
b. Increasing understanding of the process to develop a COVID-19 vaccine. Most people do not know how vaccines are developed and approved. For COVID-19, they equate speed with shortcuts. Build confidence in the process to date as we currently understand it, while recognizing that there is more science to do. Vaccines are approved by the Food and Drug Administration and the FDA will need to demonstrate that they are safe and can work.
c. Set expectations on what will happen when a vaccine is developed. Most people think having a vaccine means it will be widely available for anyone to get. Once we have a vaccine or vaccines, it will still be some time before it is widely available to everyone.

B. Phase 1: Implementation

1. Continue activities (See Item D under Planning) to communicate with the media and directly to the public through NCDHHS media channels.

2. Keep stakeholders updated through regular email.
   a. Include vaccine information and updates in our existing semi-weekly stakeholder outreach email.

3. Create online toolkits to support local health departments, state and local government agencies, nonprofit organizations, businesses and individuals in amplifying messaging and reinforcing call to vaccinate.
   a. Design customizable social media graphics, sample messages, printed collateral, and PSAs and post online.
   b. Create presentation deck to review available tools and how to use them.
   c. Host webinars and participate in existing meetings to increase use of tools.
   d. Share vetted materials from around the state and nation.
   e. Create master list of priority organizations with greatest reach, particularly among prioritized and HMP populations.
   f. Contact priority organizations individually to encourage participation.

4. Hire an agency to create and launch a statewide paid advertising campaign.
   a. Work with a firm to develop creative concepts informed by our research.
   b. Conduct focus groups to test concept.
   c. Build media buy strategy to reach key audiences.
   d. Develop collateral.
   e. Negotiate for and purchase paid media.
   f. Present to and gather feedback from business coalitions to use collateral in

their own paid media campaigns.

5. Review incoming data from the vaccine workstream and epi-data team to determine coverage gaps for key audiences. Address gaps by engaging trusted partners and messengers.
   a. Work with community health workers (CHWs) to develop, vet, and refine messaging.
   b. Identify and work with micro and macro influencers to amplify vaccine messages on social media.
   c. Provide grants with accountability measures to organizations that reach key audiences to implement programs to share information about the vaccine. For example, if barbers are trusted messengers, partner with the North Carolina Barbers Association to equip barbers as spokespeople for their clients. Establish reporting mechanisms and collect feedback. Work with HMP-facing organizations and HMP-focused work group to develop and implement.
   d. Equip organizations that reach key audiences with turnkey communications toolkits and customizable materials to amplify messaging and reinforce the call to vaccinate.
   e. Communicate through trusted channels and methods identified in the research, including tactics like direct mail, Facebook Live events, and WhatsApp.

C. Phase 2: Adjustment

1. Promote vaccine events.
   a. Create customizable and downloadable toolkits for organizations to publicize community vaccine events. Use existing stakeholder dissemination tree to share.
   b. List events on COVID-19 ncdhhs.gov website.
2. Continue to meet with and review incoming data from the vaccine workstream and epi-data team to determine coverage gaps and adapt strategies, messages, and activities as needed, based on evaluation and metrics.

D. Phase 3: Transition

1. Create systems and processes throughout earlier phases to capture feedback from ongoing dialogue with internal/external DHHS partner to adapt strategies and continue implementation.

Organization and Assignment of Responsibilities

1. Assignment of Responsibilities

a. Governor and Secretary
    i. Spokespeople
b. Sr. Director of External Affairs
    i. Communications strategy lead
c. Office of Communications
    i. Messaging
    ii. Graphic design
    iii. Media relations
d. LatinX/Hispanic Engagement Director
    i. Member of vaccine communications team
    ii. Strategy development
    iii. Messaging
    iv. Outreach and dissemination
e. Vaccine Advisory Council
    i. Thought leadership
    ii. Outreach and dissemination
f. Historically Marginalized Population Workstream
    i. Strategic partner
g. Outreach and dissemination
    Office of Minority Health and Health Disparities
    i. Outreach and dissemination
h. Office of Rural Health
    i. Outreach and dissemination
i. Marketing and Communications Experts and Agency
    i. Communications strategy support
    ii. Research
    iii. Implementation
j. Media
    i. Messenger
k. Epi-Data Team
    i. Data analysis
    ii. Data source
l. Data Office
    i. Public dashboard
m. Local Health Departments
    i. Messengers
    ii. Outreach and dissemination
n. Healthcare Systems and Organizations
    i. Messengers
    ii. Outreach and dissemination
o. Vaccine Providers (medical assistants, nurses, doctors, pharmacists)

i. Messengers
ii. Outreach and dissemination

p. State and Local Government Agencies
i. Messengers
ii. Outreach and dissemination

q. State and Local Nonprofit Organizations
i. Messengers
ii. Outreach and dissemination

r. Business Community
i. Messengers
ii. Outreach and dissemination

s. Social Medial Influencers
i. Messengers
ii. Outreach and dissemination

t. Community and Advocacy Organizations/Trusted Messengers Key Audiences
i. Messengers
ii. Outreach and dissemination

u. 211
i. Information resource

External Relations (Public) SME – NC DHHS External Affairs

Annex (B): Clinical Providers

Purpose, Scope, and Situation Overview

Purpose

The purpose of the Clinical/Provider workstream is to maximize the impact of the U.S. government's COVID-19 vaccination program in North Carolina by identifying and enrolling as many eligible providers as possible and ensuring an equitable distribution of vaccine that includes critical and priority populations early in vaccination efforts. Crucial components to the success of this workstream include clear, targeted, and effective communication surrounding the COVID-19 vaccine and the system identified to collect and report COVID-19 vaccine administration data into the Immunization Information System (IIS) Vaccine Administration Management System (VAMS) or the state's alternative.

Scope

Describe the anticipated plans to effectively identify providers for enrollment in the COVID-19 vaccination program in North Carolina and provide the necessary education and training to administer COVID-19 vaccine, increase coverage, and ensure accurate reporting of data to the chosen reporting system.

Situation Overview

This interim plan is written based on initial critical and priority populations identified and with the assumption that the U.S. Centers for Disease Control and Prevention may be providing detailed additional guidance on the targeted priority populations during each phase of this vaccination campaign.

Concept of Operations

A. Phase 0: Planning

The COVID-19 vaccination program provider enrollment process will follow the steps as outlined below. Additional details on each step are provided in sections A1 and A2.

Provider Enrollment – Draft Process

1. Enrollment identification and outreach for potential COVID-19 vaccination provider enrollment (including those not currently utilizing the North Carolina Immunization Registry) with priority given to those serving critical populations and priority groups.
    a. The first provider groups to be targeted for enrollment include local health departments and hospitals.
    b. Pending additional CDC guidance, long-term care (LTC) facilities are also critical partners and will be included in the first round of provider enrollments. Considerations of LTC facility enrollments and vaccinations are noted here and remain ongoing.
        i. Pending additional CDC guidance, CDC is planning to coordinate vaccination efforts at the federal level between LTC facilities and pharmacies.
        ii. Pending additional CDC guidance, North Carolina will participate in this federal program that is expected to cover 95% of LTC sites. Non-covered sites will be addressed at the state level in coordination with the state, the Division of Health Service Regulation, and LTC sites and pharmacies.
        iii. Pending additional CDC guidance, vaccine allocations will be reported to the state for this federal program, and reporting to the state will be required as a part of the program.
    c. The next set of providers will be those who have the most reach to critical populations, including Federally Qualified Health Centers, corrections facility health providers, and employee healthcare providers that serve frontline workers with high risk of exposure.

d. In addition, North Carolina will pursue contracting directly with a vendor or vendors who provide direct vaccine administration services to deploy as needed for surge vaccination efforts in priority populations. This would be similar to state contracts for surge testing capability.
e. Providers identified above and by the External Relations workstream and the External Advisory Committee will be sent a letter explaining the enrollment process along with the COVID-19 Vaccination Provider Program Agreement and Provider Profile to be submitted to the Immunization Branch within 10 days of receipt.
f. Initial distribution and collection of agreements for local health departments and hospitals/health systems will occur using REDCap (Research Electronic Data Capture) survey tools. A letter containing a link to Provider Enrollment system in REDCap and instructions for completion will be distributed to all LHDs and hospitals/health systems. The Provider Enrollment system allows for providers to complete the CDC COVID-19 Vaccination Program Provider Agreement, Provider Profile, and CDC Supplemental COVID-19 Redistribution Agreement (if applicable) entirely electronically to streamline the enrollment process. Data from Provider Enrollment system will be used for licensure verification and storage and handling assessments prior to approving a provider for enrollment. Automated approval and denial letters will be sent to providers as applicable via the Provider Enrollment system. Additional enhancements are planned to the Provider Enrollment system to improve the provider experience for subsequent provider enrollments.
g. Each provider agreement (Section A) and associated provider profiles (Section B) will be reviewed for completeness. For each prescriber listed in Section B, the Immunization Branch (IB) will verify the professional licensure information utilizing North Carolina Board of Medicine, North Carolina Board of Pharmacy, and North Carolina Board of Nursing databases. The IB will also ensure appropriate storage equipment is listed within the provider profile section of the agreement.
h. Incomplete agreements, facilities with inactive/suspended prescribers, and those with inappropriate storage units will not be approved for enrollment. A form letter indicating an inability to currently enroll the facility and any applicable steps to remedy the exclusion will be sent to the organization's email address as specified in Section A of the provider agreement.
i. Facilities approved to proceed with enrollment will be sent a toolkit with resources and educational requirements developed by the CDC. The organization's identified primary and back-up COVID-19 vaccine coordinators will be required to complete specific training module(s) and submit documentation of training completion. Required training will cover the following areas as directed by the CDC:

- COVID-19 vaccine administration (Advisory Committee on Immunization Practices (ACIP) recommendations, specific product indications (related to age, contraindications, and dosage), site, route, needle length, use of adjuvants/reconstitution requirements, administration documentation, etc.).
- Second-dose reminders (requirements for using same product; strategies for recall, use of COVID-19 vaccination record cards, etc.).
- Emergency Use Authorization (EUA) fact sheets for providers and vaccine recipients or vaccine information sheets (VISs), as applicable (i.e., where to locate such documents and the requirement to provide to patients prior to vaccine administration).
- Vaccine Adverse Event Reporting System (VAERS) requirements and process.
- Storage and handling requirements (how to maintain the proper cold chain from receipt of shipment to vaccine administration (or transfer to another location approved via the IB), transport requirements, managing temperature excursions, etc.).
- Ordering and inventory controls (how to order and receive vaccine; how to report vaccine administration, inventory counts, wastage, and spoilage to the IB; and how to manage product expiration dates, including how to identify expiration dates by vaccine lots via the US Department of Health and Human Services' website (will insert link as it becomes available) and understanding beyond use date (BUD) tracking labels and manufactured dates versus expiration dates).
- CDC's Vaccine Finder (how to submit facility information for COVID-19 vaccination clinics).
- Billing restrictions or allowances (e.g., administration fees).

Training will occur using a variety of tools (e.g., self-paced web-based training modules, job aids, etc.) as described in section 2a. Completion of provider training (for the organization's identified primary and back-up COVID-19 vaccine coordinators) will be tracked by the IB. Tracking tools (e.g., Excel, electronic databases, etc.) are TBD.

On-call nursing staff will also be available to answer vaccine questions (both clinical/administration and storage/handling related) as needed.

a. NC DPH will issue single memo as cover letter to send with the provider agreement to describe processes for completion of the agreements, profiles, and educational trainings.

2. Ordering and Clinical/Programmatic Guidance:
    a. The following items being currently developed/updated by the CDC will form the basis of a provider toolkit. Such guidance will be reviewed by the IB to identify any potential training gaps and the need for additional educational tool development. Additional tool development includes (but is not limited to) the minimum storage and handling guidance document, North Carolina-specific requirements, and reporting and ordering systems (e.g., VAMS/IIS), as specified by CDC. Step-by-step ordering instructions will be added upon receipt of VAMS information from CDC.

PRODUCT	NEW/UPDATE	ADDITIONAL INFORMATION
Storage and handling toolkit	Update	An addendum with general COVID-19 vaccine storage, handling, and transport information will be added, and the addendum will be updated as COVID-19 vaccine products are approved. A fully updated toolkit, incorporating COVID-19 information into the actual toolkit, will not be issued until 2022.
COVID-19 training module	New	Under development is a web-based module. Topics will include storage/handing, vaccine indications, contraindications/precautions, administration, and documentation. It will not have CE and will be amended as new COVID-19 vaccine products are introduced.
Vaccine product summary sheets	New	Fact sheets with storage, handling, preparation, indications, contraindications/precautions, and administration will be developed for each vaccine.
Additional immunization guidance materials	New	More extensive information related to storage, handling,

PRODUCT	NEW/UPDATE	ADDITIONAL INFORMATION
		preparation, administration, shipping, packaging, and transport will be provided as necessary (not all vaccines will need additional guidance).
Comprehensive table of vaccine products	New	A table of COVID-19 vaccine products with key information will be updated as vaccines are approved.
Beyond-use dates and expiration-date tracking tools	New	A resource will be provided to track BUD and expiration dates, for use early in vaccine distribution process.
Advisory Committee on Immunization Practices recommendation summary information	New	Conduct webinar and slide deck for use by awardees and other partners.
You Call the Shots web-based training	Update	Updates to the You Call the Shots Vaccine Administration and Storage and Handling modules to refer users to appropriate COVID-19 vaccine websites. Information will be updated more extensively in early 2021 based on continuing education timelines.
Healthcare personnel FAQs	New	Web-based FAQ document.
Providing vaccinations safely during a pandemic	Update	CDC has developed this website to provide guidance about safely providing vaccines during COVID 19. The website will be updated as appropriate. A .png file (horizontal) has been developed for awardees to use for presentations, and a .pdf (vertical) for print will be posted to the website above.

PRODUCT	NEW/UPDATE	ADDITIONAL INFORMATION
Vaccine Administration Management System (VAMS) Guide	New	CDC will be releasing resources on the utilization of VAMS.

B. Phase 1: Implementation

Enrollment/Ordering/Clinical Guidance

Implementation of the above plans will be ongoing throughout the vaccination response. Enrollment will continue to expand as vaccine supplies increase. Communication resources will be updated and distributed as needed, including the release of new clinical guidelines and vaccine safety concerns. As stated in the Communications Section below, the IB will utilize the email address indicated on the COVID-19 Provider Agreement to communicate and distribute new resources and guidance. Additional contacts included in the communications matrix will also be utilized to aid in the distribution of materials.

C. Phase 2: Adjustment

Adjustments will be made based on updated guidance from the CDC's Immunization Services Division. Any recommendations for changes to the plan will be communicated to the Immunization Branch's assigned CDC project officer for approval.

D. Phase 3: Transition

Transition of COVID-19 vaccination efforts from an emergency response operation to incorporation of the vaccine into routine operations via the Immunization Branch (e.g., Vaccines for Children and/or 317 funded vaccine programs) is yet to be determined. Transition plans will be guided by directives from the CDC's Immunization Services Division.

Organization and Assignment of Responsibilities

1. General

The North Carolina Immunization Program will leverage existing partnerships and develop new connections as needed to ensure successful implementation of the COVID-19 vaccination efforts. Most departments/agencies of government have emergency functions in addition to their normal day-to-day duties. These emergency functions usually parallel or complement normal functions. Each department/agency is responsible for developing and maintaining its own emergency management procedures.

2. Organization(s)

- CDC (programmatic guidance, funding, approval of plans).

- North Carolina DHHS Office of Communications (assistance with job aid/webinar development, outreach as needed).
- Vaccinating providers (responsible for following requirements as outlined in the COVID-19 Vaccination Program Provider Agreement).
- North Carolina local health departments (assistance with identifying critical populations and providers serving such groups, responsible for following requirements as outlined in the COVID-19 Vaccination Program Provider Agreement, lead agencies for vaccination efforts/coordination for their respective counties).
- North Carolina Immunization Branch (lead agency for activities noted within this annex).
- COVID-19 External Advisory Committee (refining priority populations, enhancing reach of activities, engaging providers, providing communications).
- North Carolina Immunization Coalition (assistance with provider communications and development of training tools as needed).
- North Carolina Immunization Advisory Committee (assistance with provider communications, guidance for program considerations).
- Immunization Action Coalition (vaccine-related health education tools/templates).
- Association of Immunization Managers (to identify best practices being utilized by other awardees as needed).

3. Assignment of Responsibilities

The Immunization Branch will be the lead agency for provider, enrollment, and training. Other partners will be utilized as needed (see section B above for organization listing).

Communications

Communications with enrolled providers will be addressed through the above-stated training/outreach plans. Internal communications between applicable staff will occur daily with reporting to other state officials based on need. Information pertaining specifically to enrolled COVID-19 vaccinators, including programmatic updates, will be sent via the Immunization Branch, using each organization's specified email address with supplemental outlets (e.g., mail, fax, etc.) utilized as needed. Broader dissemination of more generalized information as needed, including expansion of COVID-19 vaccination provider enrollments, will occur via the outlets identified in the communication annex.

References

A. Federal

1. Centers for Disease Control and Prevention. (2020, September 14). CDC COVID-19 Vaccination. Program provider agreement, pp. 1-8.

2. Centers for Disease Control and Prevention. (2020, September 14). CDC supplemental COVID-19. Vaccine redistribution agreement, pp. 1-2.
3. Centers for Disease Control and Prevention. (2020, September 16). COVID-19 Vaccination Program. Interim playbook for jurisdiction operations. Version 1.0, pp. 1-57.

Clinical Providers SME – NC DHHS Immunization Branch

Annex (C): Prioritization of Critical Populations

Purpose, Scope, and Situation Overview

Purpose

Candidate vaccines against COVID-19 are being developed under the auspices of Operation Warp Speed and are likely to obtain Emergency Use Authorization by the end of 2020 and perhaps under a full Biologics License Application Approval later in 2021. However, the expectation is that initial vaccine supplies will only be sufficient to cover a small portion of the population. North Carolina has been asked by the U.S. Department of Health and Human Services (HHS) to develop a plan describing how the state will prioritize populations to be vaccinated as supplies of vaccine become available in the state.

Scope

The scope of this section is to describe North Carolina's plan for prioritizing populations for COVID-19 vaccination, as well as the process used to develop it. North Carolina will leverage all available guidance from the federal government, NAM, and ACIP to identify critical populations for vaccination. Where federal guidance lacks specificity or allows for state-specific tailoring, this interim plan will further prioritize populations to vaccinate.

Situation Overview

Process for development of a prioritization approach: The CDC COVID-19 Vaccination Program Interim Playbook for Jurisdictional Operations calls for states to identify critical populations that should be prioritized for vaccination during early phases when only limited amounts of vaccine are available. Vaccination will be an ongoing process likely extending through 2021 and beyond, and may require repeated prioritization efforts as conditions change; this document reflects the prioritization process that North Carolina conducted from September to mid-October 2020, in anticipation of the initial vaccine release expected to occur sometime between late 2020 and early 2021.

North Carolina considered a number of external sources in developing its prioritization approach. In particular, North Carolina considered guidance from the CDC's Advisory Committee on Immunization Practices (ACIP)[1] and the National Academy of Medicine (NAM)[2] because of the role of these entities in advising the federal response. In addition, North Carolina considered guidance developed by Johns Hopkins University[3] and the World Health Organization.[4]

After reviewing relevant materials, North Carolina leadership drafted a proposed prioritization, and the North Carolina Institute of Medicine convened its COVID-19 External Advisory Committee, as described earlier in this document, to refine the prioritization plan. In three two-hour meetings and via written feedback, the group reviewed, commented, and provided

input on North Carolina's proposed framework for developing its prioritization (i.e., the intended process in developing the framework and the values it aimed to emphasize), as well as on the prioritization plan itself.

Over the course of these meetings, the COVID-19 External Advisory Committee (hereafter referred to as the Advisory Committee) expressed agreement with the general principles and values underlying the development of the framework and proposed reordering several groups based on their detailed knowledge of North Carolina populations. North Carolina leadership reviewed feedback from the Advisory Committee and incorporated it wherever feasible and consistent with their understanding of projected vaccine availability and best practices.

Principles underlying development of a prioritization approach:

The guiding principles for allocation proposed by ACIP:

- Distribute vaccines efficiently and equitably
- Avoid exacerbating inequities and disparities

The guiding principles for prioritization by NAM:

- Maximization of benefits
- Equal regard
- Mitigation of health inequities
- Fairness
- Evidence-based
- Transparency

Based on external references and Advisory Committee feedback, North Carolina elected to build its prioritization approach based on principles reflecting a blend of those recommended by NAM and ACIP and to emphasize guiding principles that consider the practical and ethical implications for allocating and distributing vaccine across the state.

The guiding principles selected by North Carolina:

- Equity (considered by both North Carolina leadership and the Advisory Committee to be crucial)
- Maximization of benefits
- Transparency
- Operational feasibility
- Reliance on a strong evidence base
- "Do no harm" (added in recognition of the vital importance of maintaining public confidence in science-based vaccination and that experience with this specific vaccine could be limited at the time of its initial release)

Further, there was a recognition that plans would need to be flexible and adjusted depending on current situations, deployment would happen through established and new channels to maximize access, and clear and consistent communication was key to a successful vaccination campaign. Members of the Advisory Committee concurred with these principles.

Prioritization scenarios considered: In developing a prioritization approach, North Carolina considered a range of scenarios recommended by the CDC, including release in limited quantities of a vaccine requiring ultra-cold chain storage; release in more substantial quantities of a vaccine requiring standard storage; and a scenario where quantities of both vaccines are released at once. The prioritization framework described below primarily reflects the scenario involving a limited release of a vaccine requiring ultra-cold chain storage and larger allocations per facility (100-1,000 doses). However, it can be adapted to the other two scenarios, each of which offers greater flexibility because they involve larger amounts of vaccine that can be delivered to a wider variety of sites. In the event that more vaccine becomes available, North Carolina can extend vaccinations to additional priority groups more rapidly than currently anticipated.

DHHS describes its prioritization plan in this document; however, this prioritization is subject to change based on:

- Recommendations or additional guidance to be provided by ACIP
- The populations with Phase III clinical trial safety and efficacy data at the time of initial allocation
- The populations the EUA will permit to receive the vaccine at the time of initial allocation

Concept of Operations Planning

North Carolina, in consultation with the COVID-19 External Advisory Committee, has developed a prioritization that overall follows the NAM and ACIP/CDC approaches. Both recommend dividing populations into phased groups ranked by priority. In cases where the two approaches conflict, North Carolina has generally elected to follow NAM more closely because NAM's approach allows for smaller priority groupings, which will be important in the event of a very limited initial allocation.[5] North Carolina developed a four-phase plan, with the first phase divided into an initial phase (1a) and a subsequent phase (1b); Phase 1 is meant to stabilize healthcare delivery and protect those at highest risk for mortality should they be infected with COVID-19.

Phase 1a of vaccine dissemination will include healthcare workers and medical first responders who are at high risk of exposure based on work duties or who are vital to the initial COVID-19 vaccine distribution. High risk of exposure is defined as those caring for COVID-19 patients, cleaning areas where COVID-19 patients were admitted, performing procedures at high risk of aerosolization (e.g., intubation, bronchoscopy, suctioning, invasive dental procedures, invasive

specimen collection, CPR), handling of decedents with COVID-19, and administering vaccine in initial closed or targeted vaccine clinics. Phase 1a will also include staff in long-term care settings. **Phase 1a will likely involve vaccinating approximately 140,000 to 161,000 individuals.**

Both NAM and CDC also begin with healthcare workers and first responders at high risk for COVID exposure. This prioritization offers several benefits beyond the primary goal of stabilizing the healthcare delivery system. Healthcare workers, especially long-term care staff, can expose high-risk patients to the virus. Healthcare workers, including those who deliver vaccines, can be important advocates for vaccination, and may be better positioned as vaccine champions if they themselves have been vaccinated. Initially, vaccine may be easier to deliver in a centralized way in healthcare settings due to expected storage and minimum ordering requirements.

Phase 1b of vaccine dissemination will include residents in long-term care settings, including nursing homes, adult care homes, family care homes, group homes, and homes serving individuals with intellectual and developmental disabilities; people who have two or more of the chronic conditions identified by ACIP/CDC as increased risk of COVID disease severity;[6] people over 65 years who live in congregate settings (i.e., migrant farm camps, prisons/jails, homeless shelters); and staff of congregate living settings. **Phase 1b will involve vaccinating approximately 727,000–951,000 individuals.** In accordance with the NAM approach, this phase emphasizes vaccinating those at significantly higher risk of COVID-19 morbidity and mortality, rather than seeking primarily to block transmission. Chronic conditions currently defined by the CDC as increased risk for COVID-19 are cancer, chronic kidney disease, COPD, immunosuppression due to organ transplant, obesity, serious heart condition, sickle cell disease, and Type 2 diabetes. If and when these conditions change based on CDC definition, prioritization criteria will be updated accordingly.

Based on input from and consultation with the Advisory Committee, priority groups in Phase 1b are similar to, but not identical to, groups prioritized by NAM. North Carolina considered the NAM recommendation of only including residents in long-term care facilities with underlying conditions that put them at significantly higher risk or who are 65 or older, but recognized several challenges with this approach. First, it may be impractical to identify and vaccinate only those with certain chronic conditions within long-term care facilities, rather than vaccinating all members of the group. Second, long-term care settings have high risk of spread throughout the facilities and have high rates of co-morbidity among their residents. For this reason, North Carolina has proposed to prioritize all residents of long-term care facilities, rather than only vaccinating older residents.

North Carolina has incorporated NAM's additional recommendation to prioritize adults living in other crowded or congregate settings (e.g., migrant farm camps, homeless shelters, jails, and prisons) who are 65 years and older in addition to those who have two or more chronic conditions. In addition, given that many people in congregate settings may decide against being

vaccinated in early phases, North Carolina will also prioritize staff in congregate or crowded settings (jails, prison, homeless shelters) to increase protections for those high-risk individuals.

As North Carolina operationalizes vaccine deployment in phase 1b, the state will prioritize outreach, enrollment and allocation to providers and agencies who serve the highest risk populations within the phase 1b group. These include congregate livings settings (migrant farm camps, prisons and jails, and homeless shelters) and frontline workers with a high risk of exposure.

Phase 2, which is analogous to NAM Phase 2 and CDC Playbook Phase 1B, will focus on reductions in transmission by prioritizing those at high risk of exposure and transmission to others. Phase 2 of vaccine dissemination will include people in congregate living settings (migrant farm camps, prison/jails, homeless shelters) who are younger than 65 or have one or no chronic conditions; frontline workers at high or moderate risk of exposure who have one or no chronic conditions; healthcare workers not included in Phases 1a or 1b; adults with one chronic condition identified by CDC/ACIP as increased risk of COVID disease severity;[6] and people who are 65 or older with one or no chronic conditions. **Phase 2 will involve vaccinating up to 1.18–1.57 million individuals.**

As noted in prior sections of the plan, historically marginalized populations have been disproportionately impacted by this pandemic. Although we do not list race or ethnicity groups as the sole criteria for prioritization, prioritizing groups for outreach by risk of exposure and chronic conditions in Phase 1 and 2 promotes equity. Historically marginalized populations are disproportionately represented among the high-risk populations, frontline and high-density occupational setting workforce, and congregate living settings. For example, nationally African Americans and Latinx people comprise 40+% of long-term care workers. In North Carolina, 51% of homeless people and 52% of incarcerated people are African American. Further, prioritizing essential workers for outreach promotes equity. A national survey by Kaiser Family Foundation found higher proportions of African American and LatinX populations are essential workers as compared to white populations.[7]

Phase 3 includes remaining frontline workers and workers in industries critical to societal functioning who are at higher risk of exposure and who have not been vaccinated in previous phases, as well as K-12 and college students. North Carolina's prioritization approach assumes that by the time North Carolina has reached Phase 3, sufficient data will be available to determine vaccines' safety and efficacy in children and guide use in pediatric populations. **Phase 3 will likely involve vaccinating approximately 574,000–767,000 individuals.**

Phase 4 includes the remaining population of North Carolina, and will likely involve vaccinating approximately 3.6–4 million individuals.

Details of North Carolina's approach can be found in tables below, which provide a range of estimates for the size of each phase, reflecting higher and lower rates of vaccine uptake (ranging from 30% to 65%, based on a review of survey data [5]).

4-Phase Prioritization Framework

Phase 1	Phase 2	Phase 3	Phase 4
Estimated 727,000 – 951,000 individuals	***Estimated 1.18 M – 1.57 M individuals***	***Estimated 574,000 – 767,000 individuals***	***Estimated 3.60 M – 4.00 M individuals***

Phase 1a: ~ 140,000 – 161,000 (see below for subgroup estimates)
• Health care workers and COVID responders at high risk for exposure based on work duties or vital to the initial COVID vaccine response
  ○ High risk of exposure is defined as those caring for COVID-19 patients, cleaning areas where COVID-19 patients are admitted, performing procedures at high risk of aerosolization (e.g., intubation, bronchoscopy, suctioning, invasive dental procedures, invasive specimen collection, CPR), handling decedents with COVID, administering vaccine in initial closed or targeted vaccination clinics.
  ○ Population includes: nurses, physicians, respiratory techs, dentists, hygienists, nursing assistants, environmental services staff, EMT/paramedics, home health workers, personal care aides, community health workers**,** morticians/funeral home staff, pharmacists, public health nurses, public health and emergency preparedness workers who meet the above definition of "high risk of exposure."
• LTC staff (SNFs, adult care homes, family care homes, group homes, and ICF-IDDs)
Phase 1b: ~ 587,000 – 790,000 (see below for subgroup estimates)
• LTC residents (SNFs, adult care homes, family care homes, group homes, and ICF-IDDs)
• Staff of congregate living settings.
• Adults with high risk of complications per CDC
Operationally prioritize settings based on risk of exposure:
	• Migrant Farm/fishery workers in congregate living without 2+ Chronic Conditions
	• Incarcerated individuals without 2+ Chronic Conditions
	• Homeless shelter residents without 2+ Chronic Conditions
	• Frontline workers at high or moderate risk of exposure without 2+ Chronic Conditions
	• All other Health Care Workers not included in Phase 1A or 1B
	• Teachers and school staff
	• Other adults age 18-64 with one chronic condition
	• 65+ year olds with one or no chronic conditions
		• Workers in industries critical to the functioning of society and at increased risk of exposure who are not included in Phase 1 or Phase 2
		• K-12, college students
			• Remaining population

Phase 1	Phase 2	Phase 3	Phase 4
Estimated 727,000 – 951,000 individuals	***Estimated 1.18 M – 1.57 M individuals***	***Estimated 574,000 – 767,000 individuals***	***Estimated 3.60 M – 4.00 M individuals***
○ Migrant farm and fisheries workers in congregate housing with 2+ Chronic Conditions* or ≥ age 65 ○ Incarcerated individuals with 2+ Chronic Conditions* or ≥ age 65 and jail and prison staff ○ Homeless shelter residents with 2+ Chronic Conditions* ≥ 65 and homeless shelter staff ○ Health care workers not included in Phase 1A with 2+ Chronic Conditions ○ Frontline workers with 2+ Chronic Conditions at high risk of exposure (firefighters, police, workers in meat packing plants, seafood and poultry not in congregate housing, food processing, preparation workers and servers, manufacturing, construction, funeral attendants and undertakers not included in Phase 1A, transportation workers, retail workers (including grocery store workers), membership associations/org staff (e.g., religious orgs), child care workers, and workers in government, public health, emergency management and public safety whose functioning is imperative to the COVID-19 response) ○ Other Adults with 2+ Chronic Conditions*: *For all populations 2+ Chronic conditions means those defined by CDC as increased risk for COVID (Cancer, Chronic kidney disease, COPD, Immunosuppressed from organ transplant, Obesity, Serious heart condition, Sickle Cell disease, Type 2 Diabetes)			

Phase 1 Prioritization Framework

Phase	Population	Population Range	Population Details	Identification Approach
1A	Healthcare workers and COVID-19 responders *at high risk for exposure or are vital to the COVID response*	102,000 – 117,000	• "High risk of exposure/vital to initial COVID-19 vaccine distribution" is defined as those caring for COVID-19 patients, cleaning areas where COVID-19 patients are 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, administering vaccine in initial closed or targeted vaccination clinics. The population includes nurses, home health workers, personal care aides, physicians, respiratory techs, dentists, hygienists, nursing assistants, environmental services staff, EMT/paramedics, community health workers, pharmacists, public health nurses, public health and emergency preparedness workers, and morticians/funeral home staff who meet the above definition of "high risk of exposure."	• List generated by employer based on classifications
	LTC staff	38,000 – 44,000	• Staff in skilled nursing facilities, adult care homes, family care homes, group homes, and intermediate care facilities for individuals with IDD (ICF-DD).	• List generated by facilities
	Subtotal for Phase 1A	**140,000 – 161,000**		
1B	LTC residents	67,000 – 77,000	• Residents in skilled nursing facilities, adult care homes, family care homes, group homes, and ICF-IDDs.	• List generated by facilities
	Adults with high risk of complications per CDC and staff of congregate living settings. Operationally prioritize settings based on risk of exposure.			
	Migrant farm/ fisheries workers in *congregate housing with 2+ chronic conditions* or ≥ age 65*	5,000 – 6,000	• Migrant farm and fisheries workers *in congregate living settings with 2+ chronic conditions* or ≥ 65 listed below*. (Note that migrant farm workers will enter NC on a staggered schedule based on the harvesting calendar, with only a small portion likely present in November and December.)	• Self-identification
	Incarcerated individuals *with 2+ chronic conditions**	19,000 – 22,000	• Incarcerated individuals in jails, prisons, and immigration detention centers *with 2+ chronic conditions*or ≥* age 65 and all jail, prison, and detention center staff.	• List generated by facilities

Phase	Population	Population Range	Population Details	Identification Approach
	or ≥ age 65 and jail/prison staff			
	Homeless shelter residents *with 2+ chronic conditions* or* ≥ age 65 and homeless shelter staff	2,000 – 3,000	• Homeless individuals (based on average number of homeless individuals in shelters per night) *with 2+ chronic conditions* or* ≥ age 65 and all homeless shelter staff.	• List generated by facilities
	Healthcare workers with 2+ chronic conditions and not included in Phase 1A	*45,000 – 52,000*	• Healthcare workers with 2+ chronic conditions* who are not in Phase 1A. • Population includes inpatient and outpatient staff who are not directly caring for COVID-19 patients.	• List generated by employer based on classifications
	Other frontline workers with high risk of exposure and 2+ chronic conditions	*88,000 – 116,000*	• Firefighters, police, meat packing plant workers, seafood/poultry workers not in congregate housing, food processing workers, preparation workers and servers, manufacturing workers, construction workers, funeral attendants and undertakers not included in Phase 1A, transportation workers, retail workers (including grocery store workers), membership associations/organization staff (e.g., religious organizations),childcare workers, and workers in government, public health, emergency management, and public safety whose functioning is imperative to the COVID-19 response with 2+ chronic conditions.*	• Self-identification
	Other individuals *with 2+ chronic conditions**	362,000 – 513,000	• Other adults with two or more chronic condition who are not otherwise captured in Phase 1 or the other categories in Phase 2.	• Self-identification
	Subtotal for Phase 1B	**587,000 – 790,000**	*For all populations, 2+ chronic conditions means those defined by CDC as increased risk for COVID-19 (cancer, chronic kidney disease, COPD, immunosuppression doue t organ transplant, obesity, serious heart condition, sickle cell disease, type 2 diabetes).	

Phase	Population	Population Range	Population Details	Identification Approach
	Phase 2 Total	**727,000 – 951,000**		

Draft Prioritization Framework – Phase 2

Phase	Population	Population Range	Population Details	Identification Approach
2	Migrant farm/fishery workers in congregate living *without 2+ chronic conditions and under 65*	13,000 – 18,000	• Migrant farm and seafood workers *without 2+ chronic conditions and under 65*. *(See comment on previous slide about migrant farm worker arrival dates.)*	• Self-identification
	Incarcerated individuals *without 2+ chronic conditions and under 65*	13,000 – 15,000	• Incarcerated individuals in jails and prisons or immigration detention centers *without 2+ chronic conditions and under 65*.	• List generated by facilities
	Homeless shelter residents *without 2+ chronic conditions and under 65*	1,600 – 2,200	• Homeless individuals (based on average number of homeless individuals in shelters per night) *without 2+ chronic conditions and under 65*.	• List generated by facilities

	Frontline workers in essential industries *at moderate risk of exposure without 2+ chronic conditions*	202,000 – 266,000	• **Population includes the following individuals *without 2+ chronic conditions*:**
			  • Firefighters and police
			  • Meat packing workers
			  • Food processing, preparation workers, and servers
			  • Manufacturing workers
			  • Construction workers
			  • Funeral attendants and undertakers not included in Phase 1A
				• Self-identification

Phase	Population	Population Range	Population Details	Identification Approach
			• Transportation workers • Some retail workers (including grocery store workers) • Some membership associations/organization staff (e.g., religious organizations) • Childcare workers • Workers in government, public health, emergency management, and public safety whose functioning is imperative to the COVID-19 response	
	All other healthcare workers *not included in Phase 1A or 1B*	145,000 – 168,000	• All other healthcare workers who were not identified as at high risk of exposure for Phase 1A or included in Phase 1B due to having 2+ chronic conditions. • Population includes inpatient and outpatient staff who are not directly caring for COVID patients.	• List generated by employer based on classifications
	Education workers	44,000 – 59,000	• Population includes K-12 and university staff.	• Identification by schools • Self-identification
	Adults age 18-64 *with 1 chronic condition who are not included in other categories*	557,000 – 775,000	• All adults age 18-64 with exactly one chronic condition. • Excludes individuals captured in other categories in Phases 1 and 2.	• Self-identification
	Adults age 65+ *with 1 or 0 chronic conditions who are not included in other categories*	200,000 – 270,000	• All adults age 65 or older with 1 or 0 chronic conditions. • Excludes individuals captured in other categories in Phases 1 and 2.	• Self-identification
	Phase 2 Total	**1.18 M to 1.57 M**		

Draft Prioritization Framework – Phase 3

Phase	Population	Population Range	Population Details	Identification Approach

3	Workers in industries critical to the functioning of society and at increased risk of exposure who are not included in Phase 1 or Phase 2	34,000 – 46,000	• **Population includes:**
			  • Energy and telecom workers
			  • Water, energy, and waste operators
			  • Retail workers (including grocery store workers) not included in Phase 2
			  • Membership association/organizations not included in Phase 2
				• Self-identification

	Students	619,000 – 826,000	• **Population includes:**
			  • K-12 students (if there is evidence for children from studies)
			  • University students (undergraduate and graduate)
				• Identification by schools
				• Self-identification

	Phase 3 Total	**574,000 – 767,000**		

Draft Prioritization Framework – Phase 4

Phase	Population	Population Range	Population Details	Identification Approach
4	Remaining population not in Phases 1-3	3.60 M – 4.00 M individuals	Remaining population for whom the vaccine is recommended by ACIP and for whom there is sufficient safety and efficacy data	Self-identification
	Phase 4 Total	**3.60 M – 4.00 M**		

Implementation

To identify individuals eligible for vaccination in Phases 1a and 1b, North Carolina will rely on a combination of employer participation and self-report. North Carolina DHHS will rely on employers to identify healthcare workers who are at high risk of exposure due to the nature of their work or who work in long-term care settings in Phase 1a. In Phase 1b, congregate facilities will identify their residents and staff, and employers will be asked to identify workers

at risk based on their job responsibilities. Individuals in congregate living settings other than long-term care settings and frontline workers with high risk of exposure will need to be prioritized further for assignment to phase 1b. Employers and facilities may have the information needed to identify individuals who are 65 or older or who have 2 or more chronic conditions. Other settings (e.g., migrant farm camps, frontline workers) may not. North Carolina will allow individuals with two or more designated chronic conditions to identify themselves (or be identified by their guardians, if applicable). Self-identification based on individuals' recall, or the recall of their designated proxies or guardians, may allow some individuals to request vaccine inappropriately. However, requiring individuals to seek documentation from a medical provider may be burdensome for individuals and providers alike, and could reinforce inequities by privileging those who have ready access to medical care.

North Carolina will engage with local health departments and other stakeholders in an extensive public education campaign (described previously in this document) to inform providers and residents about vaccination and the prioritization framework. DHHS will work with a wide range of healthcare providers, including primary care and safety-net providers among others, to identify individuals with high-risk comorbidities. Out-patient and community-based providers will also be asked to identify their high-risk patients and can give information to those patients about community-based vaccination clinics. People will be able to self-identify as being in a prioritized risk category for community-based vaccination.

In subsequent phases, employers, facilities, and schools will identify individuals at risk based on their role or living conditions, and individuals will continue to be able to self-identify.

Adjustment

North Carolina expects that its allotment and prioritization approach will require updating over time. The allotment and prioritization approach may be affected by:

- The number of vaccines that gain FDA authorization or approval
- The number of doses of each vaccine allocated to North Carolina
- The logistics required to distribute each vaccine
- New data from clinical trials around safety and efficacy for populations
- Populations included in FDA authorization or approvals
- Post-market information on safety and efficacy
- Recommendations for use from Advisory Committee on Immunization Practice
- North Carolinians' interest in vaccination over time as initial phases are successfully completed and confidence grows in the vaccine's safety

North Carolina expects multiple reassessment points per the evolving information above when the prioritization approach can be revisited and adjusted, if needed. These adjustment points will also provide opportunities to reconsider prioritization for children and pregnant women, which have currently been deferred due to lack of vaccine trial data for these populations.

Transition

The duration of vaccine-induced immune response is unknown, but it is possible that individuals could require frequent (for example, annual) revaccination to maintain immunity. The initial round of vaccination will likely extend into 2021, after which North Carolina will transition its prioritization approach to one that can inform an ongoing vaccination effort similar to, and potentially coordinated with, influenza vaccination.

Organization and Assignment of Responsibilities

NC DHHS will oversee the implementation and maintenance of its vaccine prioritization approach based on vaccines allocated by HHS. This will include overseeing outreach to healthcare providers and facilities to identify critical populations; developing messaging to inform vaccine providers and North Carolinians likely to be eligible in Phase 1b and 2 about high-risk comorbidities and encouraging self-identification where appropriate; and reconvening the Advisory Committee through the NC Institute of Medicine as needed to advise on reprioritization. North Carolina will also continue to monitor emerging literature and data around vaccine safety and efficacy in pediatric and other populations, as well as vaccine uptake, to assess coverage in prioritized populations and make short-term adjustments as needed.

North Carolina's COVID-19 Vaccine Advisory Committee will continue to consult on vaccine prioritization process and supports efforts to engage with key populations.

Federal groups, including the Advisory Committee for Immunization Practices provide additional guidance, prioritization framework, and recommendations for priority groups.

Details of North Carolina's approach can be found in tables below, which provide overall population estimate ranges reflecting higher and lower rates of vaccine uptake (ranging from 30% to 65%, based on a review of survey data[5]). Certain populations (e.g., healthcare workers) are further stratified into different phases.

North Carolina Bureau of Labor Statistics (BLS) Categories Used to Estimate Key Populations for COVID-19 Vaccine Allocation Framework

DHHS used North Carolina Bureau of Labor Statistics data from 2020 to identify a number of key employment categories, as outlined in the table below. In cases where BLS data was not available, DHHS leveraged a number of other data sources, including CDC Behavioral Risk Factor Surveillance System (BRFSS) data (2018); NC DHHS estimates of LTC licensed facilities staff and occupancy rates (2020); United States Interagency Council on Homelessness statistics (2019); North Carolina Department of Public Safety Statistics (2020); employment data on migrant farmworkers, seasonal farmworkers, and seafood workers from the North Carolina Department of Commerce, North Carolina Growers Association (NCGA), Legal Aid of North Carolina, and North Carolina Agromedicine Institute (2019).

Population/BLS Category	Size
Firefighters, Police & Sheriff's Patrol Officers	
Firefighters	15,200
Police and Sheriff's Patrol Officers	21,750
Total	**36,950**
Food Preparation and Serving	
Chefs and Head Cooks	2,600
First-Line Supervisors of Food Preparation and Serving Workers	37,850
Cooks, Fast Food	22,720
Cooks, Institution and Cafeteria	10,960
Cooks, Restaurant	50,070
Cooks, Short Order	2,930
Cooks, All Other	210
Food Preparation Workers	20,270
Bartenders	13,670
Fast Food and Counter Workers	136,970
Waiters and Waitresses	82,340
Food Servers, Non-restaurant	8,320
Dining Room and Cafeteria Attendants and Bartender Helpers	8,680
Dishwashers	13,340
Hosts and Hostesses, Restaurant, Lounge, and Coffee Shop	17,500
Food Preparation and Serving-Related Workers, All Other	1,480
Total	**429,910**
Jail and Prison Staff	
Correctional Officers and Jailers	15,450
Total	**15,450**
Healthcare Workers	
Chiropractors	880
Dentists, General	3,440
Orthodontists	150
Dentists, All Other Specialists	90
Dietitians and Nutritionists	2,160
Optometrists	1,020
Pharmacists	10,020
Physician Assistants	5,440
Podiatrists	200
Occupational Therapists	3,530
Physical Therapists	6,310
Radiation Therapists	590
Recreational Therapists	410
Respiratory Therapists	4,240
Speech-Language Pathologists	4,450
Exercise Physiologists	280

Population/BLS Category	Size
Therapists, All Other	160
Veterinarians	2,910
Registered Nurses	99,960
Nurse Anesthetists	3,190
Nurse Midwives	180
Nurse Practitioners	5,540
Audiologists	450
Anesthesiologists	670
Family Medicine Physicians	1,270
General Internal Medicine Physicians	280
Obstetricians and Gynecologists	400
Pediatricians, General	800
Psychiatrists	430
Physicians, All Other; and Ophthalmologists, Except Pediatric	14,080
Surgeons, Except Ophthalmologists	600
Dental Hygienists	7,090
Acupuncturists and Healthcare Diagnosing or Treating Practitioners, All Other	890
Clinical Laboratory Technologists and Technicians	12,030
Cardiovascular Technologists and Technicians	1,090
Diagnostic Medical Sonographers	2,330
Nuclear Medicine Technologists	540
Radiologic Technologists and Technicians	7,180
Magnetic Resonance Imaging Technologists	920
Emergency Medical Technicians and Paramedics	10,680
Dietetic Technicians	270
Pharmacy Technicians	13,560
Surgical Technologists	3,450
Veterinary Technologists and Technicians	3,600
Ophthalmic Medical Technicians	2,590
Licensed Practical and Licensed Vocational Nurses	16,910
Opticians, Dispensing	1,730
Orthotists and Prosthetists	350
Hearing Aid Specialists	230
Medical Dosimetrists, Medical Records Specialists, and Health Technologists and Technicians, All Other	11,860
Athletic Trainers	950
Genetic Counselors	130
Health Information Technologists, Medical Registrars, Surgical Assistants, and Healthcare Practitioners and Technical Workers, All Other	750
Home Health and Personal Care Aides	62,310
Nursing Assistants	56,780
Orderlies	960

Population/BLS Category	Size
Occupational Therapy Assistants	1,390
Occupational Therapy Aides	90
Physical Therapist Assistants	2,820
Physical Therapist Aides	790
Massage Therapists	2,980
Dental Assistants	9,510
Medical Assistants	19,640
Medical Equipment Preparers	2,040
Medical Transcriptionists	1,340
Pharmacy Aides	270
Veterinary Assistants and Laboratory Animal Caretakers	4,290
Phlebotomists	5,960
Community Health Workers	860
Healthcare Support Workers, All Other	3,650
Total	**448,940**
Construction Workers	
Construction Managers	13,500
First-Line Supervisors of Construction Trades and Extraction Workers	29,260
Boilermakers	240
Brickmasons and Blockmasons	2,540
Stonemasons	90
Carpenters	17,880
Carpet Installers	340
Floor Layers, Except Carpet, Wood, and Hard Tiles	740
Floor Sanders and Finishers	270
Tile and Stone Setters	800
Cement Masons and Concrete Finishers	4,880
Construction Laborers	26,110
Paving, Surfacing, and Tamping Equipment Operators	1,330
Pile Driver Operators	100
Operating Engineers and Other Construction Equipment Operators	13,640
Drywall and Ceiling Tile Installers	2,020
Electricians	19,320
Glaziers	1,550
Insulation Workers, Floor, Ceiling, and Wall	1,160
Insulation Workers, Mechanical	1,080
Painters, Construction and Maintenance	3,590
Paperhangers	180
Pipelayers	3,160
Plumbers, Pipefitters, and Steamfitters	12,820
Reinforcing Iron and Rebar Workers	410
Roofers	3,000

Population/BLS Category	Size
Sheet Metal Workers	3,530
Helpers--Brickmasons, Blockmasons, Stonemasons, and Tile and Marble Setters	970
Helpers--Carpenters	1,300
Helpers--Electricians	5,710
Helpers--Painters, Paperhangers, Plasterers, and Stucco Masons	120
Helpers--Pipelayers, Plumbers, Pipefitters, and Steamfitters	3,790
Helpers--Roofers	380
Helpers, Construction Trades, All Other	940
Construction and Building Inspectors	4,720
Elevator and Escalator Installers and Repairers	160
Fence Erectors	440
Hazardous Materials Removal Workers	1,440
Highway Maintenance Workers	3,860
Rail-Track Laying and Maintenance Equipment Operators	100
Septic Tank Servicers and Sewer Pipe Cleaners	1,160
Miscellaneous Construction and Related Workers	1,080
Total	**189,710**
Manufacturing Workers	
Structural Iron and Steel Workers	1,570
Solar Photovoltaic Installers	670
First-Line Supervisors of Production and Operating Workers	21,530
Aircraft Structure, Surfaces, Rigging, and Systems Assemblers	350
Coil Winders, Tapers, and Finishers	680
Electrical, Electronic, and Electromechanical Assemblers, Except Coil Winders, Tapers, and Finishers	8,620
Engine and Other Machine Assemblers	860
Structural Metal Fabricators and Fitters	1,650
Fiberglass Laminators and Fabricators	730
Miscellaneous Assemblers and Fabricators	55,030
Extruding and Drawing Machine Setters, Operators, and Tenders, Metal and Plastic	4,540
Forging Machine Setters, Operators, and Tenders, Metal and Plastic	350
Rolling Machine Setters, Operators, and Tenders, Metal and Plastic	630
Cutting, Punching, and Press Machine Setters, Operators, and Tenders, Metal and Plastic	5,970
Drilling and Boring Machine Tool Setters, Operators, and Tenders, Metal and Plastic	140
Grinding, Lapping, Polishing, and Buffing Machine Tool Setters, Operators, and Tenders, Metal and Plastic	2,420
Lathe and Turning Machine Tool Setters, Operators, and Tenders, Metal and Plastic	690
Milling and Planning Machine Setters, Operators, and Tenders, Metal and Plastic	220
Machinists	11,900
Metal-Refining Furnace Operators and Tenders	500
Pourers and Casters, Metal	130

Population/BLS Category	Size
Model Makers, Metal and Plastic	90
Patternmakers, Metal and Plastic	80
Foundry Mold and Coremakers	170
Molding, Coremaking, and Casting Machine Setters, Operators, and Tenders, Metal and Plastic	7,130
Multiple Machine Tool Setters, Operators, and Tenders, Metal and Plastic	2,340
Tool and Die Makers	1,290
Welders, Cutters, Solderers, and Brazers	11,740
Welding, Soldering, and Brazing Machine Setters, Operators, and Tenders	880
Heat Treating Equipment Setters, Operators, and Tenders, Metal and Plastic	530
Layout Workers, Metal and Plastic	40
Plating Machine Setters, Operators, and Tenders, Metal and Plastic	1,100
Tool Grinders, Filers, and Sharpeners	90
Metal Workers and Plastic Workers, All Other	500
Tire Builders	1,610
Helpers--Production Workers	13,430
Production Workers, All Other	3,560
Total	**163,760**
Transportation	
Bus Drivers, Transit and Intercity	3,330
Passenger Vehicle Drivers, Except Bus Drivers, Transit and Intercity	18,280
Motor Vehicle Operators, All Other	3,690
Total	**25,300**
Funeral Workers	
Funeral Attendants	1,540
Morticians, Undertakers, and Funeral Arrangers	1,040
Total	**2,580**
Meat Packers, Fish and Seafood Workers	
Meat, Poultry, and Fish Cutters and Trimmers	13,320
Slaughterers and Meat Packers	5,910
	19,230
Retail trade (e.g., grocery stores, retail stores)	
Retail Salespersons	143,830
Total	**143,830**
Childcare workers	
Childcare workers	19,780
Total	**19,780**
Energy/telecom repairs	
Electrical Power-Line Installers and Repairers	4,020
Telecommunications Line Installers and Repairers	2,900
Total	**6,920**
Water/Energy/Wastewater Operators	

Population/BLS Category	Size
Nuclear Power Reactor Operators	360
Power Plant Operators	580
Stationary Engineers and Boiler Operators	360
Water and Wastewater Treatment Plant and System Operators	3,460
Chemical Plant and System Operators	730
Gas Plant Operators	140
Petroleum Pump System Operators, Refinery Operators, and Gaugers	250
Plant and System Operators, All Other	110
Total	**5,990**

[1] ACIP, "ACIP Presentation Slides: August 2020 Meeting," August 26, 2020. Available at: https://www.cdc.gov/vaccines/acip/meetings/slides-2020-08.html.

[2] National Academies of Sciences, Engineering, and Medicine, "Framework for Equitable Allocation of COVID-19 Vaccine," October 2020. Available at: http://nap.edu/25917.

[3] Johns Hopkins University, "Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States," August 2020. Available at: https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2020/200819-vaccine-allocation.pdf.

[4] World Health Organization, "A global framework to ensure equitable and fair allocation of COVID-19 products: And potential implications for COVID-19 vaccines," WHO Member States briefing, June 18, 2020. Available at: https://apps.who.int/gb/COVID-19/pdf_files/18_06/Global%20Allocation%20Framework.pdf Accessed 2020-06-23.

[5] A. Malik, S. McFadden, J. Elharakea, S. Omer, "Determinants of COVID-19 vaccine acceptance in the US," EClinicalMedicine, August 12, 2020. Available at: http://https//www.journals.elsevier.com/eclinicalmedicine. S. M. O'Keefe, "One in Three Americans Would Not Get COVID-19 Vaccine," Gallup, August 7, 2020. Available at: https://news.gallup.com/poll/317018/one-three-americans-not-covid-vaccine.aspx. K. Fisher et al., "Attitudes Toward a Potential SARS-CoV-2 Vaccine: A Survey of U.S. Adults," Annals of Internal Medicine, September 4, 2020. Available at: https://www.acpjournals.org/doi/10.7326/M20-3569. L. Neergaard and H. Fingerhut, "AP-NORC poll: Half of Americans would get a COVID-19 vaccine," Associated Press, May 27, 2020. Available at: https://apnews.com/article/dacdc8bc428dd4df6511bfa259cfec44. Morning Consult and Politico, "National Tracking Poll #200797," July 24-26, 2020. Available at: https://www.politico.com/f/?id=00000173-987a-d36e-abff-fdfa6c1b0000.

[6] Diagnoses include: Cancer, chronic kidney disease, chronic obstructive pulmonary disease, immunocompromised state from solid organ transplant, obesity (BMI >=30), serious heart conditions, sickle cell disease, and Type II diabetes. Source: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-08/COVID-05-McLung.pdf (p. 37)

[7] Source: https://www.kff.org/policy-watch/taking-stock-of-essential-workers/

Prioritization of Critical Populations SME – NC DHHS COVID-19 Planning Team Leads

Annex (D): Allocation/Distribution

Purpose, Scope, and Situation Overview

Purpose

The purpose of this annex is to detail how allocation, ordering, and distribution will take place.

Scope

Define the conceptual plan for COVID-19 vaccine allocation, ordering, and distribution in North Carolina as it relates to all providers enrolled in the COVID-19 Vaccination Provider Program.

Situation Overview

Vaccine allocation, ordering, and distribution will be integral to getting people vaccinated. Allocation is the process of determining the amount of vaccine sent to individual provider sites out of the total amount allotted to North Carolina. Ordering is the process by which amounts of vaccine will be communicated to CDC for sending to providers. Distribution is the process by which vaccine will move from the manufacturer to the site where the vaccine will be administered.

Concept of Operations

A. Phase 0: Planning/Allocation

1. Prior to receiving an initial vaccine supply, North Carolina will determine target and priority groups based on CDC, ACIP, and NAM recommendations. North Carolina's specific needs based on the North Carolina population will also be factored in. See Annex C for details.
2. Providers will be enrolled based on action in the Clinical/Prioritization portion of this plan. Provider types are noted in Appendix 4, Communications Matrix.
3. Providers will identify the populations they serve and the amounts of those populations.
    1. For employer or facility-based vaccination clinics, facilities can use these lists to contact employees and plan for vaccination clinics.
    2. For community-based clinics, for example vaccination clinics by LHDs for people with chronic conditions, providers can use their list to send a note to high-risk patients to inform them of an upcoming vaccination event.
    3. In the initial phases, healthcare systems, local health departments, and other facilities will be encouraged to pre-register people who are interested in vaccination. They can use these lists and pre-registration for vaccination clinics to inform vaccine needed at clinics for administration. This will reduce waste of vaccine by allocating amounts needed for people who plan to receive the vaccine.

B. Phase I: Implementation

1. The Immunization Branch will be notified of an amount of vaccine allotted to North Carolina by the federal government for distribution to COVID-19 enrolled providers.

2. Additional sub-allocations of vaccine will be distributed to providers serving the open priority group(s).
    i. Allotments of doses to vaccination providers will be based on:
        1. Priority group(s) served
        2. Number of doses allocated to North Carolina
        3. Vaccine product provided in the allocation
        4. Vaccination site on-hand vaccination inventory and type
        5. Number of people within a priority group that a provider serves
            a. Minimum shipment amounts will be increments of 100
        6. Storage and handling capacity at the vaccine provider site
        7. Minimizing the potential for wastage of vaccine, constituent products, and ancillary supplies
    ii. The pandemic module of NCIR will compute allocations. HHS Tiberius can also be used for this process.
    iii. Allocations will be reviewed by the COVID-19 vaccination team at the state level.
    iv. Providers will have the option to request to skip a round of allocation if they feel their supply is adequate.

3. No doses will be held back at the jurisdiction or provider level. The federal government will hold back product initially to ensure second doses are available. North Carolina should allocate the doses they have available to them at the dose level.

4. Once amounts are allocated to individual providers, reviewed and approved by state staff, those amounts will be loaded from NCIR to VTrckS.

5. Once approved, CDC will transmit the information as orders to McKesson (or the vaccine manufacturer if an ultra-cold stored vaccine).
    i. When the vaccine supply begins to meet demand, and the amount of vaccine allotted to the state begins to meet administration needs, the model for allocation will transition more to that of provider-initiated requests/orders that are then approved by the state and transmitted via VTrckS.

6. Once an order is approved for shipment by CDC, distribution will begin.

7. Manufacturers' and ancillary supplies are being collected at the CDC central

distributor McKesson with backup from Cardinal and Amerisource Bergen Company.

8. Vaccine (and adjuvant, if required) will be shipped to provider sites pending further information from CDC. Timing of shipments may be altered based on vaccine-specific cold chain requirements that limit local storage capability.
    i. CDC has advised jurisdictions not to purchase ultra-cold storage equipment at this time; ultra-cold vaccine may be shipped from the manufacturer in coolers that are packed with dry ice, can store vaccine for an extended period of time, and can be repacked for longer use. CDC will provide additional detail as it becomes available.

9. Ancillary supply kits and diluent (if required) will ship separately from the vaccine due to different cold chain requirements, but shipments will be timed from the centralized distributor to arrive with or before the vaccine.
    i. Ancillary supply kits 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. Each kit will include supplies needed to administer 100 doses of vaccine.
    ii. For COVID-19 vaccines that require reconstitution with diluent or mixing adjuvant at the point of administration, these ancillary supply kits will include additional necessary syringes, needles, and other supplies for this purpose.
    iii. Sharps containers, gloves, bandages, and other supplies will not be included.

10. Per CDC, the state anticipates that selected retail pharmacy partners will receive direct federal allocations to conduct on-site vaccination clinics for residents and staff in long-term care facilities (LTCF). LTCFs that choose to administer within the facility or administer vaccine by another provider of their choice will receive vaccine from the state allocation.

11. The state will monitor Vaccine Adverse Events Reporting (VAERS) reports.

C. Phase 2: Adjustment

1. Many COVID-19 vaccine candidates are in development, and clinical trials are being conducted simultaneously with large-scale manufacturing. It is not known which vaccines will be approved or when they'll be approved. COVID-19 vaccination program plans must be flexible and accommodate multiple scenarios. It is expected that demand will exceed supply, and therefore planning is based on use of the priority group system. The following points will trigger plan adjustments and movement through the opening of access to priority

groups:

i. Change in vaccine product provided to state or removal of a vaccine product from approved/authorized status
ii. Supply exceeds demand of the open priority groups
iii. Supply exceeds demand overall

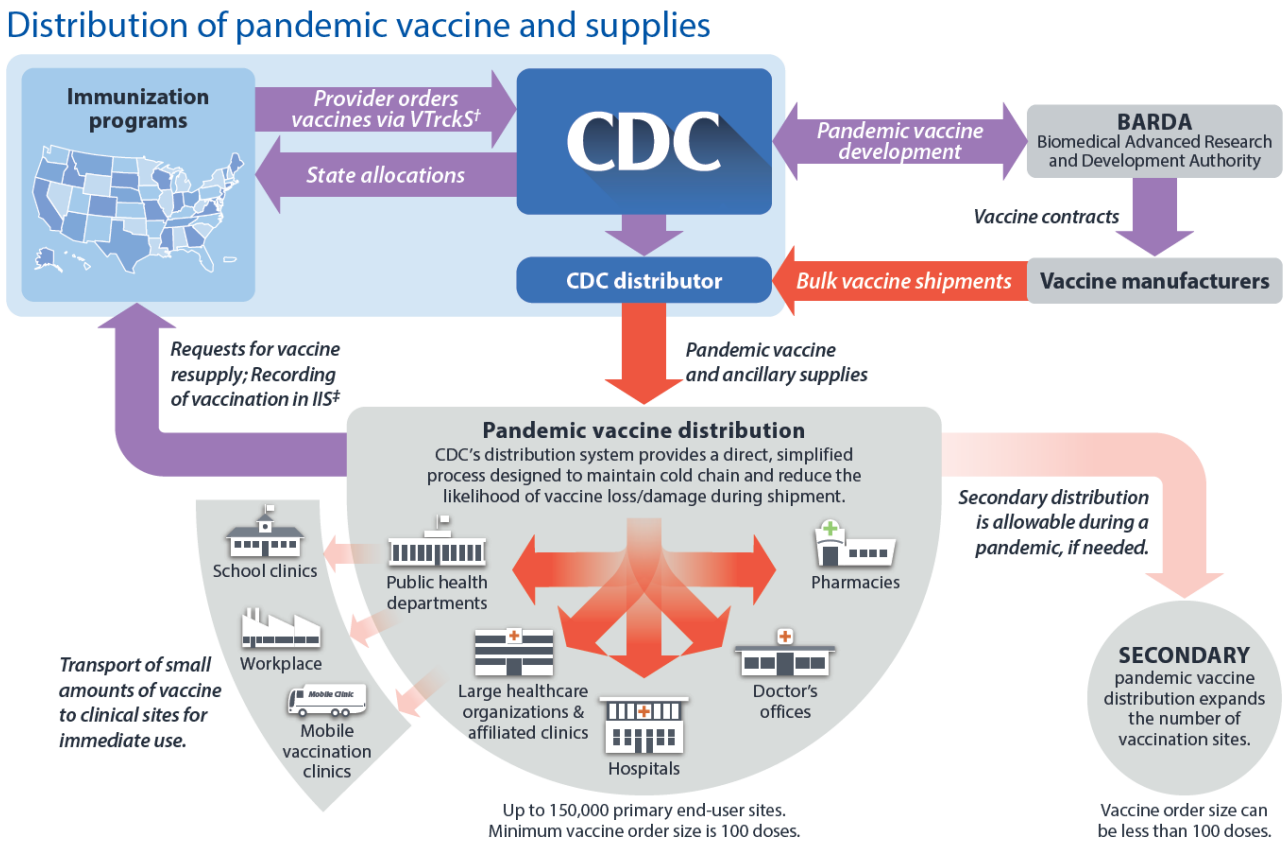
D. Phase 3: Transition

During this phase, continued vaccination strategies will focus on open vaccination to maintain high coverage levels. Vaccines will be distributed primarily to commercial and private section partners, and public partner sites as needed. When vaccine supply is available for expanded groups among the general population, a listing of COVID-19 vaccinating provider sites will be available on a national, public-facing website called Vaccine Finder.

Organization and Assignment of Responsibilities

A. Allocation
    a. CDC – provides allotted amounts to state
    b. State – provides allocation to provider
    c. Provider – ensures administration occurs based on priority groups
B. Distribution
    a. CDC – oversees central distribution contracts
    b. State – ensures accurate delivery information provided for each provider and timely entry of orders
    c. Contract distributor – ensures vaccine and ancillary supplies are delivered in a timely, temperature-controlled, efficient manner

The following figure from the CDC references the vaccine distribution concept described above.



Allocation/Distribution SME – NC DHHS Immunization Branch

Annex (E): Supply Chain/Storage

Purpose, Scope, and Situation

Purpose

The purpose of this annex is to identify the actions and roles involved with ensuring supply chain and storage requirements are adhered to from receipt to vaccine administration in North Carolina. These include the coordination of sufficient vaccine quantities to meet priority group planning/public demand, to include corresponding ancillary supplies and second doses of series. Additionally, vaccine temperature control/ cold-chain storage requirements will need to be strictly followed to ensure vaccine efficacy, while limiting vaccine wasting. This annex provides implementation guidance to partners involved with mass vaccination coordination at the state level, as well as provides planning guidance to local jurisdictions, including health departments, medical providers, and other healthcare entities. The Medical Countermeasures (MCM) Unit of Public Health Preparedness & Response Branch (PHP&R), within the NC Division of Public Health (DPH), is responsible for ensuring the content of this annex is supported by current guidance, including from Operation Warp Speed (OWS), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), vaccine manufacturers, and North Carolina state health officials.

Scope

This annex applies to all vaccine providers and coordinating state agencies, including IB, PHP&R, HPP, and NCEM, who will be involved with coordinating and implementing vaccine supply chain and storage requirements. This annex will coordinate closely with Annex D: Allocation/Distribution. PHP&R, along with the Immunization Branch within the Division of Public Health, will act as subject matter experts and provide technical assistance, as needed, throughout the planning, implementation, adjustment, and transition phases.

Situation Overview

This annex includes strategies based upon current CDC recommendations pertaining to supply chain and storage requirements, for potential vaccine candidates “A” and “B.” Both vaccines require two doses, separated by ≥21 or >28 days, and both doses will need to be of the same candidate. Storage and preparation requirements range from refrigeration (2°C to 8°C), freezing (-20°C), to ultra-low cold chain (-80°C to -60°C). CDC has advised that temperature control requirements of both vaccines are subject to change, and storage procedures may need to be adapted as additional data from vaccine clinical trials is forthcoming.

Current guidance on vaccine planning scenarios indicates state and local plans should address three scenarios of supply chain and storage: receipt of vaccine “A,” receipt of vaccine “B,” or receipt of both vaccines “A” and “B.” Ancillary supplies will also accompany vaccine but will be

shipped separately. The selection of a final scenario will depend upon the outcomes of vaccine clinical trials.

Vaccine distribution will currently be managed centrally through McKesson, and several other backup distributors. Expansion to additional healthcare organizations, commercial scale and community pharmacies, and non-traditional/mobile administration locations for targeted groups is being investigated. Final distribution strategies decided at the federal level and by state health officials will also impact the supply chain and storage requirements included in this annex.

Concept of Operations

A. Phase 0: Planning

- Address leaders' guidance directives applicable to supply chain and storage
    - Vision of success goals pertaining to transparency and stewardship.
    - Support key tasks, including:
        - Establish continual quality improvement processes to identify and address gaps in preparedness, planning, and execution.
        - Drafting an FAQ document. For more information, see Annex (A-3): External Relations (LHD).
        - Remaining up to date with current OWS, CDC, FDA, and vaccine manufacturer documentation.
- In partnership with the OEMS HPP Program, assess vaccine storage capacity at healthcare sites. For more information, see Annex (A-3): External Relations (Healthcare).
- Using the provider enrollment form, assess each local health department/vaccination provider's storage capacity by volume, to determine the amount of vaccine that can be stored at routine refrigerated (2° to 8°C), frozen (-20°C), and ultra-cold (-80° to -60°C) temperatures.
- IB to communicate with CDC immunization project officer to assess the impact of storage of additional flu vaccine along with COVID-19 vaccine on existing vaccine infrastructure in North Carolina (contingent on vaccine North Carolina receives and storage requirements).
- Industrial Hygiene Unit within PHP&R will draft safety instructions for the safety, handling, and storage of dry ice, including transport, handling with cryogenic PPE, and disposal.
- Identify and develop a timeline for needed temperature-controlled storage based upon available guidance from CDC and vaccine clinical trials. Use existing state contracts and policies, when possible, to source temperature-controlled storage locations/equipment/dry ice/data monitoring devices for refrigerated, frozen, and ultra-low cold chain vaccine to augment existing storage. This task will exclude

sourcing the ultra-low temperature freezers, on the continued recommendation from CDC.

- Collaborate, inform, and educate local health departments/commercial pharmacies/vaccine providers about supply chain and storage planning and state-level activities in this annex. For additional information, refer to Annex (B): Clinical Prioritization.
- Coordinate with IB through established weekly touchpoint call to assess vaccine provider mass vaccination capacity, and leverage other plans, including H1N1 Pandemic Influenza and MCM plans, and use of local health departments and local receiving sites and mobile dispensing sites, as needed. This call occurs weekly on Thursdays at 1 p.m.
- Support and coordinate with IB as needed, and also during established weekly touchpoint call, to assess and plan for gaps in vaccine storage and handling once enrolled providers and vaccination sites receive vaccine.
- Identify whether any wasted/unused vaccine and/or storage equipment (vaccine coolers, etc.) need to be recovered/returned to federal partners, via the Q&A sessions of the weekly CDC Vaccine Coordination Call. If this information is not communicated, inquire with CDC Immunization Project Officer assigned to North Carolina Vaccine Workgroup.

B. Phase 1: Implementation

- Continue activities on planning phase.
- Monitor CDC guidance via email and webinars to determine final vaccine planning scenario and storage requirements from receipt to end user.
- Collaborate with IB and HMP workstream via established weekly touchpoint call on final storage and supply chain procedures to ensure vaccine provider gaps are appropriately addressed.
- Collaborate, inform, and educate local health departments/vaccine providers about updates to supply chain and storage operations. Additional details can be found in Annex (B): Clinical Prioritization.
- Maintain end-to-end visibility on supply chain to ensure second doses of series are available. More information to be available in Annex (F): Data, Reporting and Performance Tracking.
- Maintain a reliable inventory management system/procedure capable of tracking vaccine by QR barcode located on vaccine cartons (vial codes being investigated), to be compatible with identified Vaccine Tracking Platform(s), to ensure accurate inventory reporting when requested. More information forthcoming in the Vaccine Interim Playbook and Storage and Handling Toolkit from CDC.

- PHP&R, along with IB, will assess need to activate existing mass vaccination, medical countermeasure, and distribution plans for the state and local health departments based on pre-established triggers.
- Determine whether orders of 100-1,000 vials will need to be repackaged for smaller providers. For additional details see Annex (B): Clinical Prioritization.
- Source ancillary supplies not being provided by CDC (e.g., sharps containers). Exploring purchasing options currently between DHHS and North Carolina Emergency Management (NCEM).
- Coordinate/monitor return of ultra-low temperature shipping containers to CDC designated location. Further details pending the release of the updated COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations.
- Assess state and local medical waste disposal contracts for increased capacity due to COVID-19 waste, including sharps containers, PPE, and wasted/unused vaccine, if vaccine is to not be returned per CDC. Investigate adding addendums to existing state contracts through state-run facilities.
    - Waste disposal contracts will likely exclude dry ice, as it can be disposed of via sublimation in accordance with safety protocols. See Appendix 7: Safety Data Sheet - Dry Ice and Appendix 8: Dry Ice Safety Instructions.

C. Phase 2: Adjustment

- Continue activities of implementation phase.
- PHP&R will coordinate with IB and HMP workstream through weekly touchpoint call to maintain vaccine supply to everyone, as supply meets or exceeds demand.
- Collaborate and inform local health departments of operational elements of the adjustment phase via established weekly call.
- Monitor ordering trends of vaccine and activate or demobilize non-traditional vaccination sites as needed based on local health department MCM plans.

D. Phase 3: Transition

- Continue activities of implementation phase.
- Demobilization and recovery: Close locations such as mobile vaccination sites, state-run depots identified by IB and North Carolina PHP&R, and return any equipment used to maintain/monitor storage and handling of vaccine. Receive and return wasted/unused vaccine, and equipment or storage containers needing to be returned to federal partners, according to the procedures detailed in the State MCM Plan and Vaccine for Children (VFC) Program.
- Vaccine recovery: additional details of COVID-19 vaccine recovery are still being finalized and will be communicated once available.

Organization and Assignment of Responsibilities

The following agencies have assigned roles and responsibilities supporting vaccine supply chain and storage requirements.

A. Organization

1. NC PHP&R
2. IB
3. OEMS HPP
4. NCEM
5. Local health departments/vaccine providers
6. Healthcare systems and providers
7. Community pharmacies

B. Assignment of Responsibilities

PHP&R

- North Carolina PHP&R will serve as the lead of this annex.
- Monitor guidance released from OWS, CDC, FDA, etc. regarding storage parameters of vaccine(s).
- Provide updates weekly through Intergovernmental Affairs Calls, CDC Vaccine Coordination webinars, etc.
- Update guidance as applicable.
- Ensure supply chain and storage procedures support equitable access to vaccine(s), as widespread vaccine becomes increasingly available.
- Track maps of vaccine orders/distribution using CDCs VAMS, Tiberias, and other platforms as they are identified.

Immunization Branch

- Provide subject matter expertise on existing vaccine requirements, vaccine tracking platforms/databases, and legal requirements as they apply to supply chain and storage procedures, on weekly touchpoint call.

North Carolina Emergency Management (NCEM)

- Assist with identifying and procuring alternatives to vaccine storage capacity and resources (example: dry ice).

OEMS HPP

- Communicate with IB, PHP&R to assess vaccine storage capacity by volume, at hospitals, in the three temperature ranges. PHP&R MCM assignee to HPP (OEMS) will facilitate this communication. More information available in External Relations Annex A-1: Healthcare.

Local Health Departments/ Vaccine Providers

- Identify storage capacity by volume at routine refrigerated (2°C to 8°C), frozen (-20°C), and ultra-cold (-60° to -80°C) temperatures, and communicate with IB through the provider agreement/other query means. Immunization providers in local health department(s) should follow provider agreement to notify IB if and when changes to storage capacity by volume occur.

References

A. Federal

1. Vaccine Planning Scenarios. COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. September 16, 2020.
2. COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. September 16, 2020.
3. Vaccine Storage and Handling Toolkit, January 2020.
4. CDC COVID-19 Vaccination Program Provider Agreement.

B. State

1. North Carolina PHP&R Medical Countermeasures Plan, June 2017; Annex of the North Carolina Emergency Operations Plan.
2. North Carolina Pandemic Influenza Plan; Part C. Medical Countermeasures: Vaccine Preparedness and Response. November 2011.
3. Leaders Guidance Document. August 2020.

Supply Chain/Storage SME – NC DHHS Immunization Branch, NC PHP&R (MCM)

Annex (F): Data, Reporting, and Performance Tracking

Purpose, Scope, and Situation Overview

Purpose

The purpose of the Data, Reporting, and Performance Tracking workstream is to ensure the design, deployment, and validation of the end-to-end data management system for tracking data related to COVID-19 vaccination, including provider enrollment, vaccine dose administration, patient scheduling, vaccine ordering, and reports and dashboards for heterogeneous internal and external audiences.

Because each of these systems is distinct and owned by different entities, the interfaces among these components, as well as with existing systems such as electronic health records, are of critical importance.

The full data, reporting, and performance tracking ecosystem under development includes integration of North Carolina's COVID-19 vaccine IT systems, including but not limited to immunization information systems (IIS), referred to as the North Carolina Immunization Registry (NCIR), with the CDC's Vaccine Administration Management System (VAMS) modules, Immunization (IZ) Gateway, Vaccine Tracking System (VTrckS), a potential alternative system, and other COVID-19 data exchanges. As part of this work, data dashboards will be deployed for both internal and external dashboards for analysis and reporting purposes. The dashboards will provide transparent reporting on who is receiving the vaccine, vaccination availability phases, demographics, and more.

Scope

The Data, Reporting & Performance Tracking workstream will define and implement the processes and requirements for the documentation, collection, exchange, and reporting of COVID-19 vaccine data. The data architecture diagram for COVID-19 immunization provided by CDC and the North Carolina COVID-19 data and information flow diagram are included at the end of this section.

Situation Overview

The following outlines North Carolina's COVID-19 vaccine data, reporting, and performance tracking requirements that must be addressed within the information technology system architecture. The North Carolina Immunization Registry (NCIR), North Carolina's Immunization Information System (IIS), is based on the Wisconsin Immunization Registry platform and is maintained by Gainwell Technologies. NCIR does not include all of the required functionality for mass vaccine management. In addition, NCIR may not be stable with the increased provider load and increased functionality use expected as part of the COVID-19 vaccination effort. Due to system limitations, vaccination management will not be done primarily through NCIR.

However, the immunization data on residents of North Carolina will ultimately need to be deposited in NCIR for long-term storage and longitudinal tracking.

The plan below describes how:

1. Providers will be enrolled by the state
2. Providers will interact with the CDC's VAMS for vaccine management, patient scheduling, dose administration, etc.
3. North Carolina will exchange data through the CDC's IZ Gateway
4. Vaccine inventory will be ordered from VTrckS via NCIR
5. North Carolina vaccination data will be reported to stakeholders

Based on the CDC guidance to ensure an adequate infrastructure to support the COVID-19 Vaccination Program during all pandemic operations phases I-III, a decision was made to explore the use of the CDC's Vaccine Administration Management System (VAMS), that supports all CDC data collection requirements and supports end-to-end operations from the time vaccine leaves the distributor until the time the vaccine is administered and documented to meet defined standards. An analysis has also been done to determine the best alternative option to VAMS for end-to-end functionality in the event North Carolina chooses to not utilize VAMS.

The web-based VAMS application enables jurisdictions and clinics to support vaccination operations for critical populations. VAMS is a clinical system that records vaccination administration events. VAMS will send data to IZ Clearinghouse and from there to the IIS (NCIR) through the IZ Gateway, fulfilling all state and federal data, reporting, and storage requirements. Providers can then query the IIS (NCIR) to update the patient record in their EHR system.

VAMS is being built with end users in mind. The CDC's planned go-live for the VAMS system is October 26, 2020. The proposed functionality allows for tracking and monitoring by promoting real-time awareness of inventory on hand, doses administered, and patient-level data. The application is meant to be easy to use and will have different modules for different user groups (jurisdictions, clinics, employers, and recipients) with customizable features designed for each user group. If designed and implemented as planned, VAMS will make setting and keeping track of vaccination appointments simple.

VAMS can be used in a variety of scenarios including:

- Non-traditional vaccine providers critical to reaching priority populations
- Mobile COVID-19 vaccination clinics
- Providers who do not have electronic health systems
- Nursing homes, correctional facilities, and other providers that need a reporting solution

Within VAMS:

- Jurisdictions can
    - Identify employers with employees who need to be vaccinated
    - Identify sites for mass vaccination clinics
    - Access data for analysis and reporting

- Employers/organizations can
    - Use one common link to send to employees/individuals to allow them to register to receive a vaccination
    - Identify essential and high-priority workers who need to receive vaccine when it first becomes available and send second dose reminder
    - Upload lists of these workers in a bulk format

- Clinicians can
    - Scan vaccine barcodes
    - Manage recipient administration workflow
    - Set up customized vaccination schedules
    - Submit order requests and track vaccine inventory including wastage and administration

- Vaccine recipients can
    - Answer eligibility screening questions
    - Make vaccination appointments
    - Get a reminder about returning for a second dose if required
    - Receive a vaccination certificate

Additional language support for recipients is planned after initial launch

Currently, VAMS only supports data tracking and vaccination activities of individuals once their employer or an organization identifies them as a vaccine recipient.

The scenario described below describes a possible vaccination encounter for the initial dose of COVID-19 vaccine using VAMS, during phases II-III when vaccine will be delivered in a less targeted, more open way and through multiple community sites. A person seeking a COVID-19 vaccine will search for an available vaccination site clinic using Vaccine Finder (https://vaccinefinder.org/). The person will complete a pre-visit eligibility screening questionnaire and will receive a QR code on their mobile device if the appointment is confirmed.

On the visit day, the vaccination site will scan the person's QR code and confirm the person's identity for check-in. The person will be taken to the vaccination area, where the vaccinating provider will review the pre-visit screening questionnaire and check for contraindications, explain the risk and benefits of the vaccine, provide an Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as applicable, for the patient to review, and

obtain consent to administer the vaccine. Once the person has given consent, the provider will order the vaccine, prepare the vaccine for administration, and administer to the person. The person will be asked to wait for the duration of the observation period to observe for adverse reactions. At the end of the observation period, the person will be assessed for readiness to discharge. The provider will then review the instructions on reporting adverse side effects and provide a vaccine administration record (i.e., printed copy or handheld card) with the earliest date the second dose can be given, using the minimum interval of 21 or 28 days, depending on the vaccine product administered. The immunization information will be sent to the COVID-19 clearing house via the IZ Gateway for exchanging data with and/or querying to obtain a consolidated vaccination record; using systems designed to support satellite, temporary, or off-site vaccination clinics; and generating coverage reports for use within the jurisdiction. This data exchange functionality will be used for sending second-dose reminders for vaccine recipients – a task that will be critical to ensure recipients complete the COVID-19 vaccine series.

Administration of the second dose within the vaccine series will follow the same steps listed above, with the addition of verification of the previous dose to ensure the correct match of COVID-19 vaccine products and dosing intervals.

The specifications to support the data extracts will be provided by the CDC to ensure data submissions align with the format required for submission to the COVID-19 clearing house. Jurisdictions must use a system that supports dose-level accountability—from the time vaccine leaves the distributor until the vaccine is administered or unused vaccine is returned—and provides data to the CDC that meet defined standards. Jurisdictions will need to have a solution (either leveraging existing or new) for extracting required data from their IIS as a contingency for network outages. The specifications to support the data extracts will be provided by the CDC to ensure data submissions align with the format required for submission to the COVID-19 clearing house. Planning activities will include executing needed Data Use Agreements (DUAs); establishing mechanisms for ordering; maintaining visibility on doses administered by priority group and location as well as on-hand inventory levels; proactively reporting data on the public dashboard; and addressing any legal considerations related to sharing protected data.

The Immunization (IZ) Gateway is a centralized technical infrastructure that facilitates the flow of immunization data through an intelligent message router. The IZ Gateway is sponsored by the CDC and led by the U.S. Department of Health and Human Services (HHS) Office of the Chief Technology Officer. The IZ Gateway is securely hosted on Amazon Web Services (AWS) through the Association of Public Health Laboratories (APHL) and does not save information centrally, but will route data securely among provider sites and immunization information systems (IIS).

Utilizing IZ Gateway functionality to relay vaccination information from one sending system to multiple IISs presents unique opportunities for data sharing as well as data exchange challenges. IISs are built to support the HL7 Version 2.5.1 standard. However, each jurisdiction's system has requirements that may vary slightly for HL7 field content and mapping, while still

meeting standard requirements. Entity resolution will also need to be addressed, e.g., determining whether Michael Smith at one clinic is the same person as Mike Smith who was vaccinated at a different clinic.

Providers will use VAMS to enter COVID vaccine doses. These doses will be transmitted as HL7 messages through the IZ Gateway, relaying vaccination information from VAMS to the CDC Clearinghouse and Data Lake and routed to the NCIR. Once this dose is in the NCIR, it will become part of the patient's medical record. Providers who have existing connections through their electronic health records (EHRs) will be able to query these doses through standard messaging and receive complete vaccination histories which will include COVID-19 vaccine. For more detailed technical specifications and the VAMS web-based system functionality, see Appendix 4.

Additional factors that will need to be tracked include demographics of doses administered and high-priority population status.

North Carolina is exploring the use of an alternative end-to-end system, and work flows may be different if a different system is chosen.

Concept of Operations

A. Phase 0: Planning

1. NCIR

a. Determine the baseline immunization registry capacity and evaluate upgrades for a substantial increase in users, and functionality needs. These include, pending additional CDC guidance, clinic registration and scheduling, documenting vaccine administration in near real time, dose-level accountability, ordering, inventory management, and reporting CDC-defined core data elements.

b. Connect the NCIR with the IZ Gateway to increase the availability and volume of complete and accurate immunization data stored within the NCIR. Review and sign DUA with APHL to participate in IZ Gateway "Connect" functionality. Address legal challenges to participating in IZ Gateway "Share" functionality and review and sign MOU with APHL to participate in "Share."

c. Evaluate CDC recommendations including upgrading to cloud hosting and data storage to ensure adequate database capacity as well as working toward reviewing the findings of the American Immunization Registry Association's (AIRA) measurement and improvement initiative.

d. Prioritize bug fixes, address system security risks, and implement enhancements important for COVID-19 vaccine readiness.

e. Assess and address data quality issues, especially issues related to patient matching and deduplication.

f. Add COVID-19 vaccine, schedule, and interoperability codes to NCIR, once released.

2. Enrollment

a. Use prioritization of critical populations to identify providers who will administer vaccine to those priority populations. Methods of communicating with providers to let them know how to enroll are listed in the communications matrix of this plan.

b. Vaccines For Children (VFC) providers are potential vaccinators and each VFC provider's vaccination capacity can be determined by reviewing patient population size and vaccine administration data from the peak week of the 2019-2020 influenza season.

   i. Use Business Objects to generate a query of public doses administered entered in the NCIR by VFC providers to compare to reported population enrollment data to determine vaccination capacity. This will be used to determine high volume providers.

c. Vaccination providers, including existing VFC providers, must enroll in the COVID-19 vaccination program by signing and agreeing to conditions outlined in the CDC COVID-19 Vaccination Program Provider Agreement, which will be distributed to all providers.

d. Providers not already using NCIR will need to sign an NCIR agreement and confidentiality agreement specifically for COVID-19.

e. Providers identified as COVID-19 vaccination providers will be enrolled using an electronic system, the Provider Enrollment system, – initially the Provider Enrollment system will utilize REDCap for the first set of providers with addition enhancements using advance automation tools to improve the provider experience. The Provider agreements and links will be distributed via networks outlined in the Communications Matrix. Instructions will be sent in a cover letter with copies of the provider agreement, profile and redistribution agreement as needed.

f. Twice per week, information on each enrolled vaccination provider/site, including provider type and setting, patient population (i.e., number and type of patients served), refrigerated/frozen/ultra-cold temperature storage capacity, and logistical information for receiving COVID-19 vaccine shipments, including ship-to site information for each enrolled provider will be sent to the CDC in the CDC-provided format. It is anticipated that the information will be collected and stored within a combination of Provider Enrollment system and the NCDHHS Business Intelligence Data Platform (BIDP).

g. Provider organizations and jurisdictions will be required to sign a Data Use Agreement (DUA) to use VAMS, which will be coordinated through a third-party concierge service.

h. Registration and site approval within VAMS is a requirement to use the system.

3. Ordering

a. Enter the provider organization/site information in NCIR and VTrckS.
    1. Receive provider agreement from provider.
    2. Review application for completeness.
    3. Ensure all associated clinicians are eligible for participation.
        i. Clinicians will be checked against appropriate credentialing board.
    4. Assign a pin based on county if provider does not already have one.
b. Create organization information in NCIR.
c. Create site information in NCIR.
d. Click manage orders to ensure the org/site are set up correctly.
e. Click on manage organization screen to enable the physical inventory count.
f. During the daily order export process, the master data file will be exported and uploaded into VTrckS, which will create the newly created organizations in VTrckS.
g. Orders will be created through the NCIR. This may be a manual process until additional enhancements have been completed in the NCIR. Current processes allow for provider-initiated ordering; however, this will not be allowed until vaccine quantities are sufficient. Initially, supplies will be allocated at the state level. Orders will be uploaded pending additional CDC guidance, once per week.
h. Orders are then decremented against North Carolina's existing COVID allocation and transmitted to the distribution system to process and prepare for shipping. Pending additional CDC guidance, once the exact allotment/allocation process comes from CDC, specific steps will be added.

4. Reporting

a. North Carolina providers will use, pending additional CDC guidance, CDC's VAMS as the doses administered tool for all COVID-19 doses, throughout all phases of the mass vaccination effort. VAMS will allow for reliable, rapid data collection in a consistent manner across all jurisdictions and avoid potentially complicated variations in data quality and availability.
b. In North Carolina, G.S. 130A-153 grants the NC Commission for Public Health to grant additional access to immunization information. Due to the new requirement to send identifiable information to the CDC, North Carolina is evaluating current rules in the North Carolina Administrative Code and proceeding with the emergency rule-making process to be able to comply with CDC requirements.
c. It is anticipated one agreement will be signed between the state of North Carolina and VAMS.
d. It is anticipated that North Carolina will have access to data through CDC's Immunization (IZ) Data Lake. The Immunization Data Lake is a cloud-hosted data repository to receive, store, manage, and analyze COVID-19 vaccination data.

CDC, awardees, federal agencies, and pharmacy partners will use the IZ Data Lake to store and process administration, coverage, logistics, inventory, ordering, distribution, and provider data. VAMS, IIS, pharmacies, VTrckS, and VaccineFinder.org will provide data for the IZ Data Lake.

e. Update reminder/recall functionality to allow for brand specificity.
f. Create a COVID page on the Immunization Branch website.
g. CDC will notify jurisdictions in the event maintenance is scheduled on the VAMS system. Workflows, including announcements posted to NCIR (capable of emailing primary contact) and the Immunization Branch COVID webpage, have been created to notify providers in advance of planned outages.
h. Ensure providers understand the need for and have contingency plans for unexpected outages. Business processes have been developed for offline use since we are using an internet-based tool (e.g., we have developed hard copies of forms) so doses may be entered at a later time. This information will be included in the communications toolkit.
i. Pending additional CDC guidance, data will be received from the IZ Data Clearinghouse.
j. Pending additional CDC guidance, the NCDHHS BIDP (Business Intelligence Data Platform) and NCIR (IIS) will be utilized to provide internal and external performance tracking, reporting, and dashboards.

B. Phase 1: Implementation

1. NCIR

a. Evaluation of an interface with the IZ Gateway Share component ("Connect" and "Share") during a second phase of system connectivity is ongoing. IZ Gateway "Share" allows the exchange of immunization information across IIS jurisdictions by automating messages to an IIS for patients immunized outside of their jurisdiction.
b. Enhance announcement functionality to be able to provide more targeted notifications to providers.
c. As security risks and changes are constant, they will be evaluated and addressed throughout each phase of the response.

2. Enrollment

a. Selection of providers to receive vaccine shipments is detailed in the Allocation and Distribution Annex plan.
b. Signed agreements and VAMS registration will be required by all providers regardless of the phase in which they begin administering COVID-19 vaccine.
c. Providers must be set up in NCIR and VTrckS.

3. Ordering

a. Ordering will be allocated at the state level during the Implementation Phase. It is anticipated that during Phase 1, a limited supply of vaccine will be available. Using existing interoperable uploads of vaccine orders into the CDC's Vaccine Order Tracking System (VTrckS) and Tiberius; a seamless, secure, and access-controlled collaboration across all government agencies and teams relevant to the Operation Warp Speed (OWS) COVID-19 vaccine effort, including federal agencies and state health departments, will be used to estimate vaccine allocation. The Tiberius platform integrates data concerning COVID-19 vaccine clinical trial operations, manufacturing, allocation, ordering, distribution, inventory, and population-level administration to provide OWS with a real-time understanding of the effort. Tiberius allows users to better understand and support exploring and analyzing key COVID-19 metrics and forecasts from multiple government and academic modeling groups to support bespoke federal government workflows.
b. Pending additional CDC guidance, refrigerated vaccine transfers must follow existing Immunization Branch policies and require prior approval before the transfer of vaccine.

4. Reporting

a. When vaccine supply is available for expanded groups among the general population, a national COVID-19 vaccine finder will be available on the public-facing Vaccine Finder website. All vaccination providers may be required to report and maintain their COVID-19 vaccination information on the CDC's Vaccine Finder.
b. Internal dashboards will be created to monitor information on provider enrollment, vaccine wastage, vaccine transferred between providers, and providers who are not reporting doses administered.
c. A public-facing dashboard will include information on doses administered, demographics of people receiving vaccine, and 1- and 2-dose COVID-19 vaccination coverage (e.g., coverage reports). The exact location of the dashboard is still TBD.
d. The state will monitor the CDC COVID-19 Vaccination Response Dashboard for:
    1. Data for planning (e.g., estimates of critical population categories, number and attributes of healthcare providers and facilities)
    2. Implementation data (e.g., number of enrolled COVID-19 vaccination providers, COVID-19 vaccine supply and distribution, COVID-19 vaccine administration locations)
    3. COVID-19 vaccine administration data

It is extremely important to understand the requirement for COVID-registered vaccine providers to report adverse events. All providers signing the CDC COVID-19 Vaccination Program Provider Agreement must report adverse events to the Vaccine Adverse Event

Reporting System (VAERS). The immunization program must educate to ensure that providers understand the procedures on reporting adverse events to VAERS. Before administering COVID-19 vaccine, the organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. The organization must also report moderate and severe adverse events following vaccination to VAERS. Training of COVID-19 vaccination providers is vital to ensure the success of the COVID-19 vaccination program. This includes procedures for reporting moderate and severe events as well as vaccine administration errors to VAERS. The CDC continuously monitors the safety of vaccines given to children and adults in the United States. VAERS, co-administered by the CDC and the FDA, is the national frontline monitoring system for vaccine safety. More information on VAERS is available at https://vaers.hhs.gov/reportevent.html The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving "willful misconduct" as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

C. Phase 2: Adjustment

1. NCIR

a. As security risks and changes are constant, they will be evaluated and addressed throughout each phase of the response.

2. Enrollment

a. Selection of providers to receive vaccine shipments is detailed in the Allocation and Distribution Annex plan.
b. Signed agreements and VAMS registration will be required by all providers regardless of the phase in which they begin administering COVID-19 vaccine.
c. Providers must be set up in NCIR and VTrckS.

3. Ordering

a. Ordering will still be allocated at the state level during the adjustment phase.

4. Reporting

a. Reporting will evolve as data needs/requests change.
b. The state will continuously monitor available dashboard reports for situational awareness throughout the COVID-19 vaccination program response.
c. The state will continue to monitor CDC's Weekly Flu Vaccination Dashboard.
d. The state will continue to monitor the CDC COVID-19 Vaccination Response Dashboard.

D. Phase 3: Transition

1. NCIR

a. As security risks and changes are constant, they will be evaluated and addressed throughout each phase of the response.

2. Enrollment

a. After the adjustment phase, the Immunization Branch will resume normal operations for enrolling providers, which may include receipt of COVID vaccine if applicable.
b. Signed agreements and VAMS registration will be required by all providers regardless of the phase in which they begin administering COVID-19 vaccine.
c. Providers must be set up in NCIR and VTrckS.

3. Ordering

a. The NCIR may be used for provider-initiated COVID-19 vaccine ordering, but this is still to be determined depending on supply availability.

4. Reporting

At the time of transition to routine vaccinations, reporting will also transition to a routine basis.

Organization and Assignment of Responsibilities

A. General

1. Centers for Disease Control and Prevention (CDC)
2. North Carolina Immunization Branch
3. Information Technology Division (ITD)
4. ITD Technology Office and Data Office
5. Gainwell Technologies (formerly DXC MS LLC)
6. Vaccine Distributors – TBD

B. Organization

1. Local health departments
2. Private providers
3. Federally qualified health centers/rural health centers
4. Hospitals
5. Pharmacies

C. Assignment of Responsibilities

CDC

- Provide support to North Carolina as necessary

Immunization Branch

- Employer outreach and onboarding
- Clinic outreach and onboarding
- Administration of provider enrollment process
- Upload of provider data into CDC systems
- Management of vaccine inventory and orders
- Oversight of VAMS use/process
- Provide support for clinics/employees for use of VAMS
- Reporting and analytics
- Provide ordering and reporting mechanism
- Maintain a connection with the IZ Gateway to deliver complete COVID-19 vaccination records to providers in a timely manner

Information Technology Division (ITD)

- Assist with technical details of enrollment process
- Assist with capacity planning for NCIR
- Ongoing monitoring of NCIR system capacity
- Assist with technical planning for NCIR
- Maintain a connection with the IZ Gateway to deliver complete COVID-19 vaccination records to providers in a timely manner
- Assistance with requirements and development of performance monitoring, reports, and dashboards

ITD Technology Office and Data Office

- Oversight of public-facing dashboards
- Maintain data connections between IZ Data Lake and dashboards
- Develop and maintain required NCDHHS BIDP connection with the IZ Gateway and NCIR to deliver COVID-19 vaccine performance monitoring, reporting, and dashboards

Gainwell Technologies

- Implement changes/enhancements to NCIR
- Maintain a connection with the IZ Gateway to deliver complete COVID-19 vaccination records to providers in a timely manner

Vaccine Manufacturers

- Vaccine development, manufacturing, packaging

Local Health Departments

- Employer outreach and onboarding
- Clinic outreach and onboarding
- Inventory management

- Vaccine administration
- Reporting
- Dose tracking, including reminder/recall

Private Providers

- Employer outreach and onboarding
- Clinic outreach and onboarding
- Inventory management
- Vaccine administration
- Reporting
- Dose tracking, including reminder/recall

Federally Qualified Health Centers/Rural Health Centers

- Employer outreach and onboarding
- Clinic outreach and onboarding
- Inventory management
- Vaccine administration
- Reporting
- Dose tracking, including reminder/recall

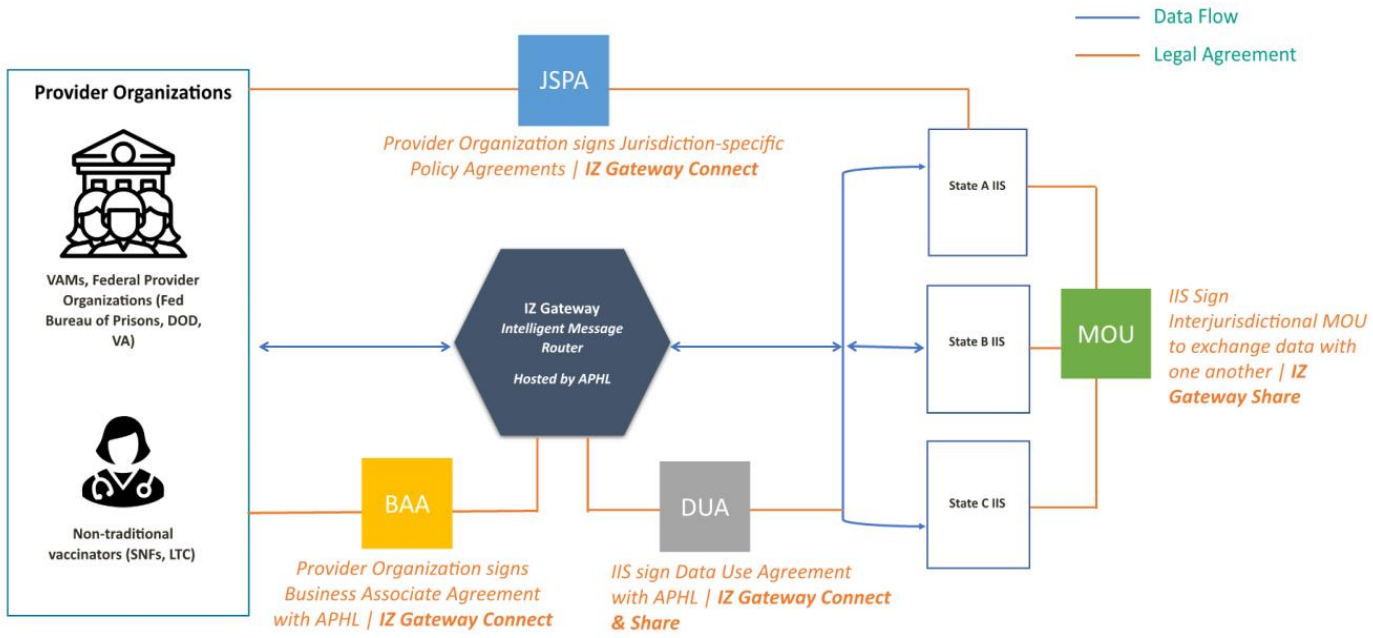
Hospitals

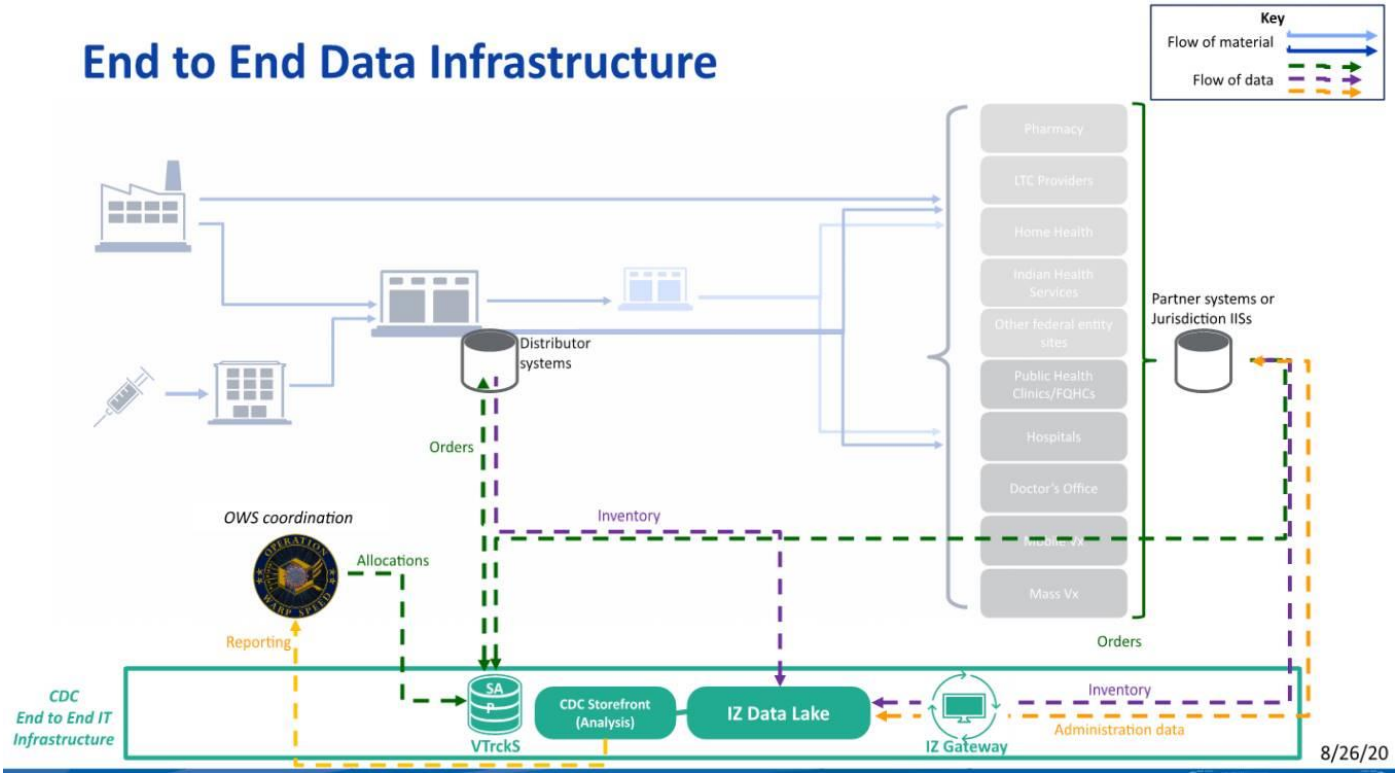
- Employer outreach and onboarding
- Clinic outreach and onboarding
- Inventory management
- Vaccine administration
- Reporting
- Dose tracking, including reminder/recall

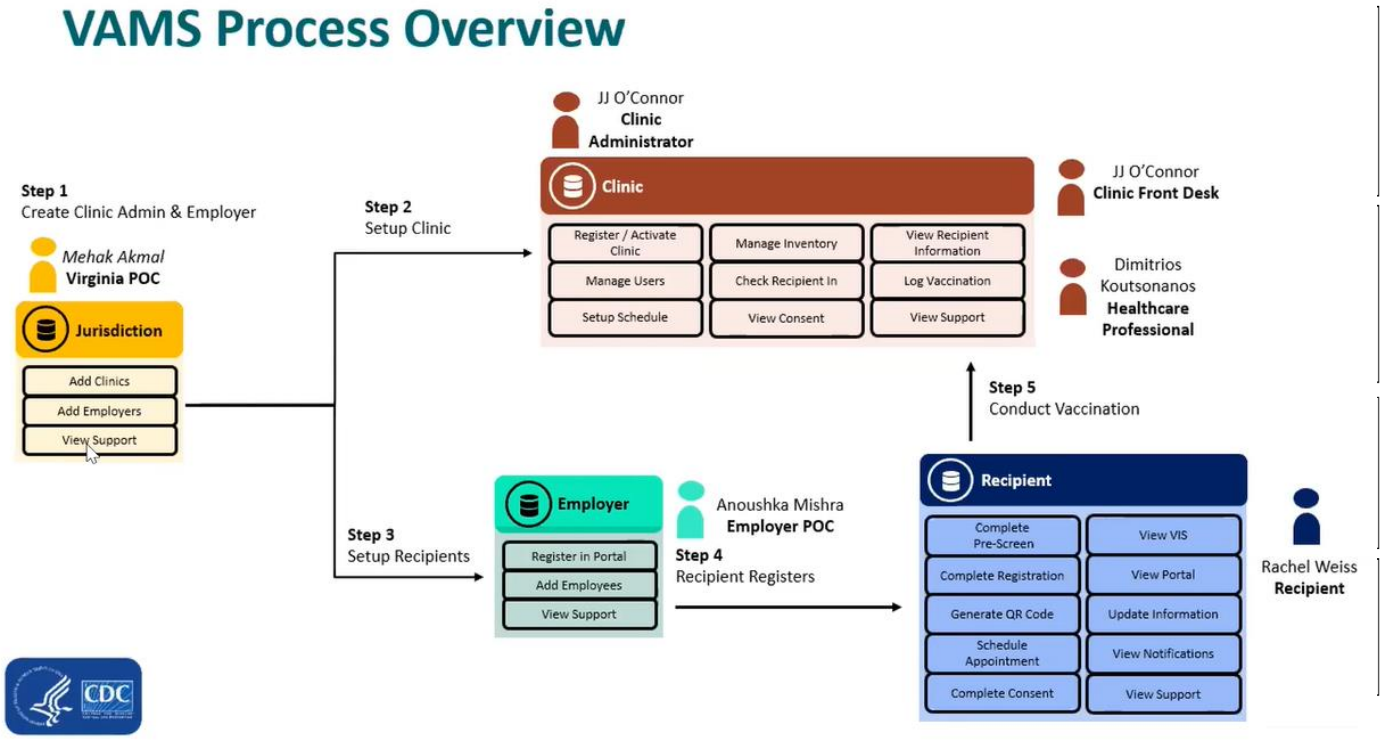
Pharmacies

- Employer outreach and onboarding
- Clinic outreach and onboarding
- Inventory management
- Vaccine administration
- Reporting
- Dose tracking, including reminder/recall

IZ Gateway Connect & Share Legal Agreements







COVID-19 Vaccine Provider Enrollment Process

Data, Reporting, and Performance Tracking SME – NC DHHS Immunization Branch, Division of Information Technology

APPENDICES

Appendix 1: COVID-19 Vaccination Plan List of Acronyms

ACIP- Advisory Community of Immunization Practices

AHP- All-Hazard Plan

AIRA- American Immunization Registry Association

AMEXCAN- Association of Mexicans

APHL- Association of Public Health Laboratories

ASPR- Assistant Secretary for Preparedness and Response

AWS- Amazon Web Services

BIDP- Business Intelligence Data Platform

BLS - Bureau of Labor Statistics

BUD- Beyond Use Date

CHAMP – Community (testing in) High-priority And Marginalized Populations

CBO- Community Based Organization

CDC- Centers for Disease Control and Prevention

CPG- Comprehensive Preparedness Guide

CPH – Commission for Public Health, the public health rulemaking body

DHHS – NC Department of Health and Human Services

DUA- Data Use Agreements

EMAC-Emergency Management Assistance Compact

EMS- Emergency Medical Services

EUA- Emergency Use Authorization

FBO- Faith-Based Organization

FDA- Food and Drug Administration

FQHC- Federally Qualified Health Centers

EHR- Electronic Health Record

HHS- U.S. Health and Human Services

HIPAA- Health Insurance Portability and Accountability Act

HMP- Historically Marginalized Populations

HPP- Healthcare Preparedness Program

HSEEP-Homeland Security Exercise and Evaluation Program

IB- Immunization Branch

IIS- Immunization Information System

ITD- Information Technology Division

IZ Gateway- Immunization Gateway

IZIG- IZ Gateway implementation Guide

LGBTQ+- Lesbian, Gay, Bisexual, Transgender, Queer

LHD- Local Health Department

LTCF- Long-Term Care Facility

MCM- Medical Countermeasures

MRN- Medical Record Number

NAACP- National Association for the Advancement of Colored People

NAM- National Academy of Medicine

NBC Agents – Nuclear, Biological, or Chemical Agents

NCAAT- North Carolina Asian Americans Together

NCALHD- North Carolina Association of Local Health Directors

NCDHHS – North Carolina Department of Health and Human Services

NCDPH – North Carolina Division of Public Health

NCEM – North Carolina Emergency Management

NCIR- North Carolina Immunization Registry

NIMS- National Incident Management System

NIS- National Immunization Survey

OEMS- Office of Emergency Services

OWS- Operation Warp Speed

PHP&R- Public Health Preparedness and Response

POD- Points of Dispensing

PPE- Personal Protective Equipment

PREP Act- Public Readiness and Emergency Preparedness Act

PSA- Public Service Announcement

Secretary – Secretary of NCDHHS

SEOC – State Emergency Operations Center

SERT- State Emergency Response Team

VAERS- Vaccine Adverse Event Reporting System

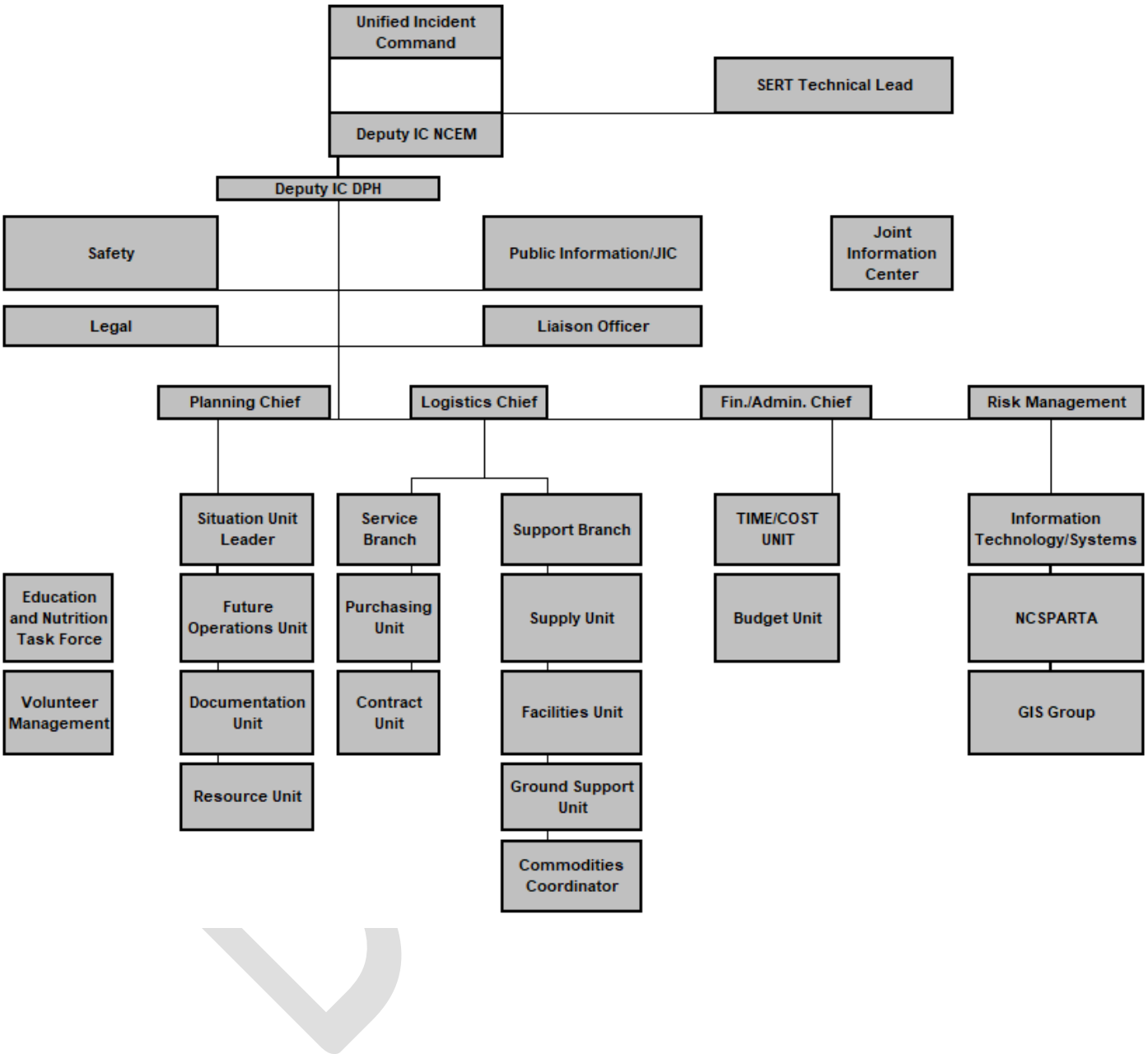
VAMS-Vaccine Administration Management System

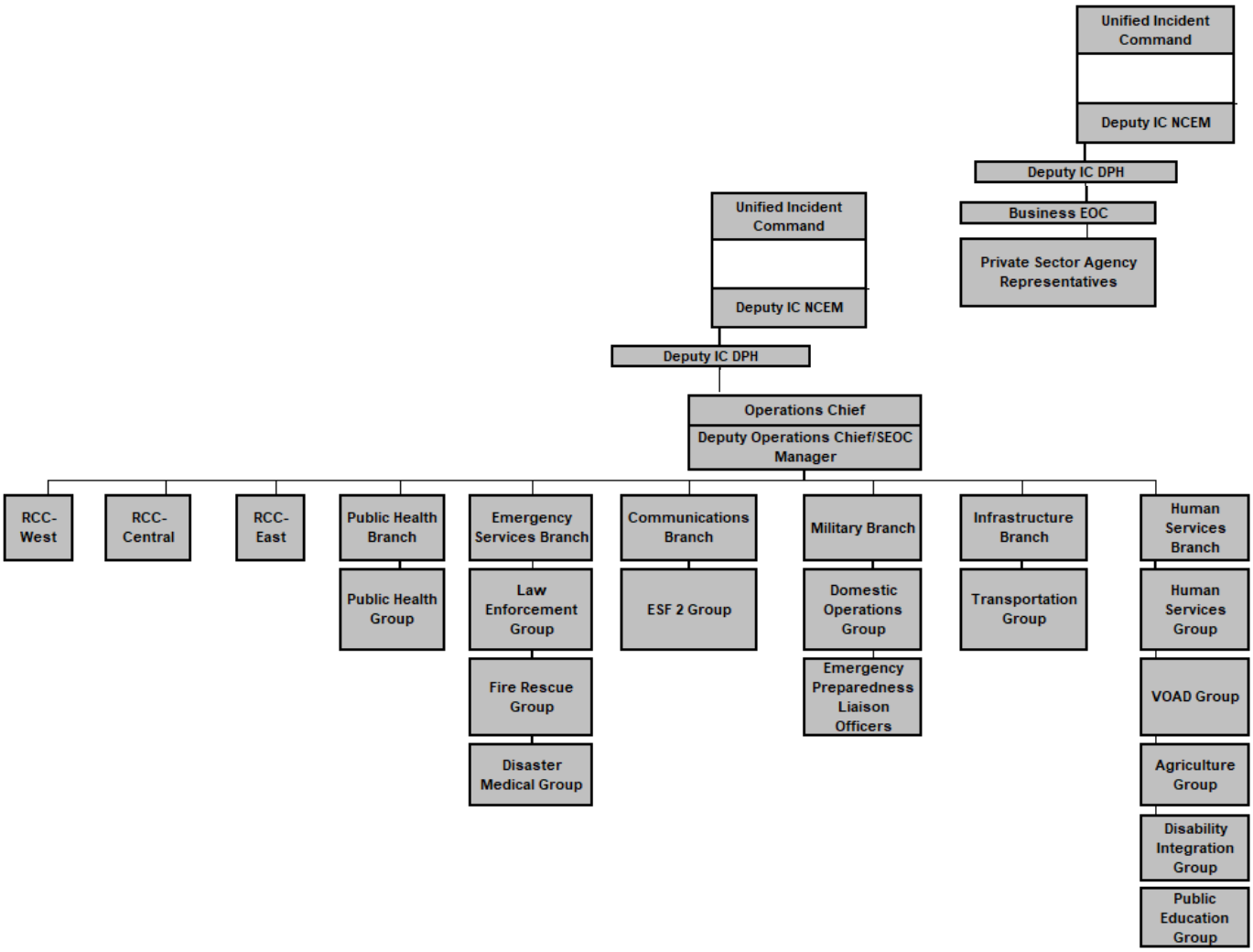
VFC- Vaccine for Children

VIS- Vaccine Information Sheets

VTrckS- Vaccine System

Appendix 2: COVID-19 SERT Organizational Structure




Unified Incident Command
Deputy IC NCEM
Deputy IC DPH
Business EOC
Private Sector Agency Representatives
Unified Incident Command
Deputy IC NCEM
Deputy IC DPH
Operations Chief
Deputy Operations Chief/SEOC Manager
RCC-West
RCC-Central
RCC-East
Public Health Branch
Public Health Group
Emergency Services Branch
Law Enforcement Group
Fire Rescue Group
Disaster Medical Group
Communications Branch
ESF 2 Group
Military Branch
Domestic Operations Group
Emergency Preparedness Liaison Officers
Infrastructure Branch
Transportation Group
Human Services Branch
Human Services Group
VOAD Group
Agriculture Group
Disability Integration Group
Public Education Group

Appendix 3: North Carolina Legal Authority to Address COVID-19 Pandemic

I. IMPORTANT DEFINITIONS AND ACRONYMS

A. DEFINITIONS (set out in G.S. 130A-2)

1. **Communicable disease** is defined as "an illness due to an infectious agent or its toxic products which is transmitted directly or indirectly to a person from an infected person or animal through the agency of an intermediate animal, host, or vector, or through the inanimate environment." This definition is the basis for many of the communicable disease statutes used to prevent the spread of disease in the event of a pandemic.

2. **Communicable condition** is defined as "the state of being infected with a communicable agent but without symptoms." These individuals may spread disease unknowingly and be less likely to be identified by healthcare providers.

3. **Isolation authority** is defined as "the authority to issue an order to limit the freedom of movement or action of persons or animals that are infected or reasonably suspected to be infected with a communicable disease or communicable condition for the period of communicability to prevent the direct or indirect conveyance of the infectious agent from the person or animal to other persons or animals who are susceptible or who may spread the agent to others."

4. **Quarantine authority** is defined as "the authority to issue an order to limit the freedom of movement or action of persons or animals which have been exposed to or are reasonably suspected of having been exposed to a communicable disease or communicable condition for a period of time as may be necessary to prevent the spread of that disease. Quarantine authority also means the authority to issue an order to limit access by any person or animal to an area or facility that may be contaminated with an infectious agent. The term also means the authority to issue an order to limit the freedom of movement or action of persons who have not received immunizations against a communicable disease when the State Health Director or a local health director determines that the immunizations are required to control an outbreak of that disease."

B. ACRONYMS

1. NCDHHS – North Carolina Department of Health and Human Services
2. Secretary – Secretary of NCDHHS
3. CPH – Commission for Public Health, the public health rulemaking body
4. NBC agents – nuclear, biological or chemical agents

II. PUBLIC HEALTH STATUTES AND RULES

North Carolina has a strong public health system involving both state agencies and local health departments that provide the foundation for responding to a pandemic. North Carolina has a core set of statutes dealing with communicable disease surveillance, investigation, and control that are essential tools in identifying and responding to the pandemic.

A. MANDATORY REPORTING AND SURVEILLANCE

1. G.S. 130A-134 grants CPH rulemaking authority to create a list of communicable diseases and conditions to be reported. Reportable diseases and conditions are listed in 10A NCAC 41A .0101.
2. G.S. 130A-135 – 130A-141.1 establish reporting requirements for physicians, laboratories, and others. Reports are required when a condition or disease listed in rule is reasonably suspected. G.S. 130A-142 provides immunity for persons making reports.
3. G.S. 130A-141.1 grants the State Health Director authority to issue a temporary order requiring the reporting of information that may indicate the existence of a communicable disease or condition that presents a danger to the public health. The order shall be effective for no more than 90 days. CPH has the authority to continue the reporting requirement by rule, including, where appropriate, through emergency and temporary rulemaking.
4. G.S. 130A-480 establishes a mandatory syndromic surveillance program to review electronic hospital emergency department data to detect and investigate public health threats.

B. INVESTIGATION AND CONTROL

1. Under G.S. 130A-144 (investigation and control measures):
    i. The state health director and local health directors have a right to examine/review/obtain relevant medical or other records that pertain to investigating/controlling communicable disease.
    ii. Attending physicians are required to give control measures prescribed by CPH in rule. The local health director is responsible for ensuring that prescribed control measures are given.
    iii. All persons are required to comply with control measures.
2. Control measures promulgated by CPH are found at 10A NCAC Subchapter 41A.
    i. There are specific control measures set out in rule for a few diseases and conditions (e.g., HIV, Hep B, TB). For other communicable diseases and conditions, the general control measure rule applies (10A NCAC 41A .0201).
        1. This rule aligns control measures with “guidelines and recommended actions” published by the CDC and, if none, with the “Control of Communicable Diseases Manual” published by APHA (both of which are incorporated by reference in the rule).

2. The state health director has authority to devise control measures for outbreaks of communicable diseases and conditions for which a specific control measure is not provided by rule.
3. In implementing or devising control measures, the control measure utilized must be "reasonably expected to decrease the risk of transmission" and "consistent with recent scientific and public health information."

ii. Isolation and quarantine are control measures. The state health director and local health directors have specific isolation and quarantine authority under G.S. 130A-145.
1. This authority is to be exercised only "when and for so long as the public health is endangered, all other reasonable means for correcting the problem have been exhausted, and *no less restrictive alternative exists*."
2. There is due process (judicial review) afforded under G.S. 130A-145(d).

iii. Local health directors are charged with enforcing control measures.

3. G.S. 130A-146 sets out special requirements for transportation of the bodies of persons who have died from communicable diseases. Control measures for handling and transportation of the bodies of persons who have died from certain communicable diseases are set out in 10A NCAC 41A .0212.
4. G.S. 130A-147 provides additional authority for CPH to adopt rules for the detection, control, and prevention of communicable diseases.

C. CONFIDENTIALITY

1. Under G.S. 130A-143, all information and records (public and private) that identify a person who has or may have a communicable disease or condition required to be reported is confidential. There is a narrow list of exceptions, including disclosure to other public health agencies and disclosure that is necessary to protect the public health that is made pursuant to control measures.

D. PUBLIC HEALTH REMEDIES

1. G.S. 130A-17 provides the Secretary or a local health director a right of entry to enforce G.S. Chapter 130A and rules adopted by CPH or a local board of health.
2. G.S. 130A-18 allows the Secretary or a local health director to pursue injunctive relief in superior court for violation of Chapter 130A or rules adopted by CPH or a local board of health.
3. G.S. 130A-20 allows the Secretary or a local health director to order abatement of an imminent hazard or to enter property and abate the imminent hazard. Imminent hazard is defined in G.S. 130A-2(3).
4. G.S. 130A-25 makes a violation of G.S. Chapter 130A or rules adopted pursuant to Chapter 130A a misdemeanor. Paragraph (b) is particularly important because it

provides for specific sentencing outside of the Structured Sentencing Act for persons violating control measures (G.S. 130A-144(f)) or isolation or quarantine orders (G.S. 130A-145). Persons convicted under this section can be sentenced for up to two years in designated prisons with the ability to properly manage prisoners with communicable diseases.

E. POSSIBLE TERRORIST INCIDENT

1. G.S. 130A-475 through 130A-479 set out additional authorities around public health threats that may have been caused by a terrorist incident using NBC agents.
2. While not likely to apply in the most probable scenarios of transmission, the consideration of the state's powers to address a possible terrorist incident using some form of coronavirus as a biological agent is included in the cited statutes.

F. VACCINATION PROGRAM

1. G.S. 130A-485 establishes a vaccination program for first responders who may have been exposed to infectious diseases when deployed to disaster areas.

2. G.S. § 130A-153 includes reporting by local health departments and access to immunization information in patient records, and grants the Commission for Public Health rulemaking authority to grant additional access to immunization information as described in 10A NCAC 41A .0406.

III. EMERGENCY MANAGEMENT/PUBLIC HEALTH COORDINATION

A. G.S. Chapter 166A, Article 1A sets out the North Carolina Emergency Management Act.

B. Under G.S. 166A-19.3, "emergency" is defined to include public health causes. The full definition is: "**An occurrence or imminent threat of widespread or severe damage, injury, or loss of life or property resulting from any natural or man-made** accidental, military, paramilitary, terrorism, weather-related, **public health**, explosion-related, riot-related **cause**, or technological failure or accident, including, but not limited to, a cyber incident, an explosion, a transportation accident, a radiological accident, or a chemical or other hazardous material incident."

C. G.S. 166A-19.12 provides for coordination between the Department of Public Safety, Division of Emergency Management and the State Health Director to amend or revise the North Carolina Emergency Operations Plan regarding public health matters. The plan shall provide for: (a) the epidemiologic investigation of a known or suspected threat caused by NBC agents; (b) the examination and testing of persons and animals that may have been exposed to a NBC agent; (c) the procurement and allocation of immunizing agents and prophylactic antibiotics; (d) the allocation of the Strategic National Stockpile; (e) the appropriate conditions for quarantine and isolation in order to prevent further transmission of disease; (f) immunization procedures; and (g) the issuance of guidelines for prophylaxis and treatment of exposed and affected persons.

D. Under G.S. 166A-19.20, a state of emergency may be declared by the governor or by a resolution of the General Assembly, if either finds that an emergency exists.
E. G.S. 166A-19.30 sets out additional gubernatorial powers during a state of emergency.
F. Under G.S. 166A-19.22, a state of emergency may be declared by the governing body of a municipality or county, if either finds that an emergency exists. This authority may be delegated to the mayor or chair of the board of county commissioners. There are certain requirements for determining an emergency area. The governing body of a county or municipality that has declared an emergency has additional powers under G.S. 166A-31(b) and may seek mutual aid from other counties to assist with the emergency through the state-wide Mutual Aid Agreement.
G. The governor may also seek out mutual aid from other states to deal with an emergency under the Emergency Management Assistance Compact (EMAC) under G.S. 166A-19.72, G.S. 166A-19.10, and Article 4 of the North Carolina Emergency Management Act G.S. 166A-40 to 53.
H. G.S. 166A-19.60 and 166A-19.61 provide for certain immunity and exemptions from liability.

IV. CRIMINAL ACTS AND CRIMINAL PROCEDURE

A. CRIMINAL ACTS

See G.S. 130A-25 in II. D. 4. above.

B. CRIMINAL PROCEDURE

1. G.S. 15A-401(b)(4) allows a law enforcement officer to detain a person violating an order restricting the freedom of movement of a person or access to a person issued by the state or local health director at a place designated by the health director until the person's initial appearance before a magistrate or judge. This provision is intended to prevent the spread of the disease to others in the courts or jails as part of the normal processing of someone on criminal charges.

2. G.S. 15A-534.5 allows the judge or magistrate at an initial appearance to deny pretrial release if the judge or magistrate determines that a person arrested for violation of a state or local health director's order restricting the person's freedom of movement or access poses a threat to the health and safety of others. It also allows the judge or magistrate to confine the person to a designated area or facility after receiving recommendations from the state or local health director.

Appendix 4: VAMS Overview, Specifications for North Carolina Immunization Registry (NCIR) and VAMS Connectivity, and Vaccine Data Architecture

VAMS Overview:

The CDC Vaccine Administration Management System (VAMS) is an online tool to manage vaccine administration from the time the vaccine arrives at a clinic to when it is administered to a recipient. VAMS is free for public-health-approved clinics, and can be used on computers, tablets, and other mobile devices. It is not a smartphone app, and no installation or download is required for this web-based platform. It provides vaccine administration functionality through four user modules: Jurisdictions, Employers/Organizations, Clinics, and Recipients.

For the state of NC, VAMS will interact with the existing Immunization Information System (IIS), North Carolina Immunization Registry (NCIR), through HL7 messages sent through the IZ Gateway and IZ Clearing House (see architecture diagram).

Currently, VAMS is not available for public use. A Jurisdiction ("state") user creates Provider Organization ("Clinic") and Employer accounts in VAMS. The Employer enters employee ("Recipient") information. Those employees identified would receive notification to access the Recipient Portal to register and schedule their appointments.

The VAMS clinic module provides a web-based application for clinics to access and support scheduling, immunization tracking, and inventory management. The VAMS Vaccine Employers/Organization Module provides a web-based application for employers to access and upload employee information for potential vaccination administration. The Jurisdiction ("state") is responsible for the identification of the organization and will notify them via email that they have been identified to participate in the COVID-19 vaccination. Vaccine Recipient Module provides a web-based application for individuals to locate and schedule immunization appointments. The applications will be mobile responsive.

The following describes some of the main functions related to clinic users and the VAMS clinic module.

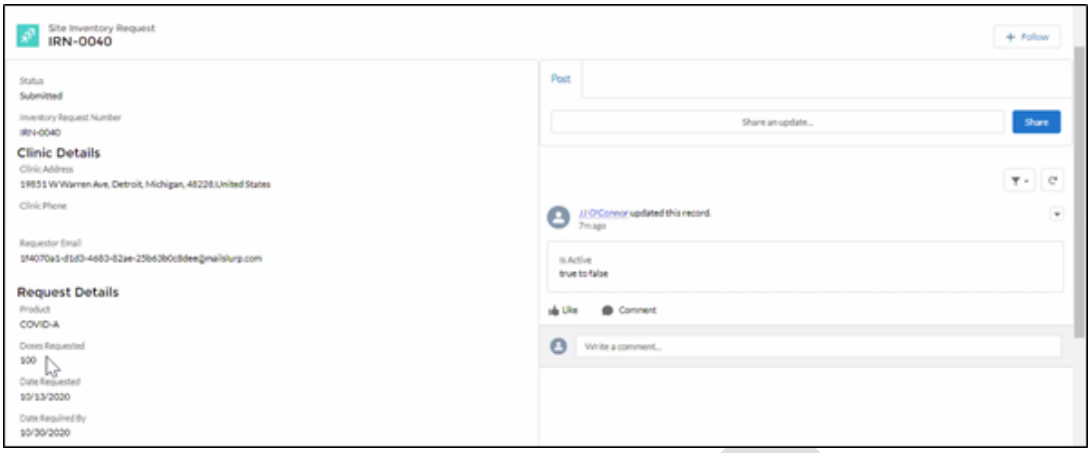
Clinic Administration:

1. Jurisdiction ("state") user accesses VAMS Jurisdiction Portal and adds Provider Organization ("Clinic") based on information provided in the COVID-19 Vaccination Provider enrollment process.
    a. Enters clinic point of contact, clinic name and type, provider VTrckS PIN, IIS facility ID used for routing inventory requests, operating and shipping address, etc.

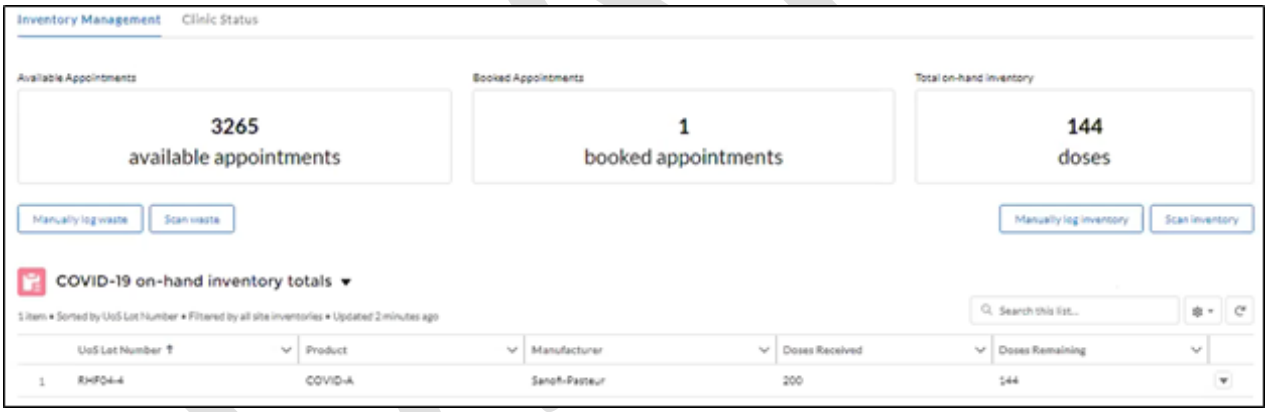
2. Clinic point of contact receives link to complete registration in VAMS.
    a. Creates username and password. The username is defaulted to the clinic point of contact's email address and the clinic point of contact is prompted to enter their new password during the initial registration.
    b. Enters additional users, hours of operation, providers/clinicians, location of vaccination administration, etc.

Inventory Management:

1. Clinic user accesses VAMS Clinic Portal and places order request (vaccine type, vials requested, etc.).
2. State user monitors inventory request dashboard in Jurisdiction portal to review new orders
    a. Can change status
    b. Can communicate with clinic regarding order request



3. State user consolidates orders from all clinics and generates a .csv file for export to NCIR (IIS).
4. State user imports order request file into NCIR.
5. State user generates file from NCIR to upload into VTrckS to place the orders.
6. Clinic user receives ordered vaccinations and accesses Clinic Portal - Inventory Management.
    a. Uses a barcode scanner to scan the vials or enters them manually



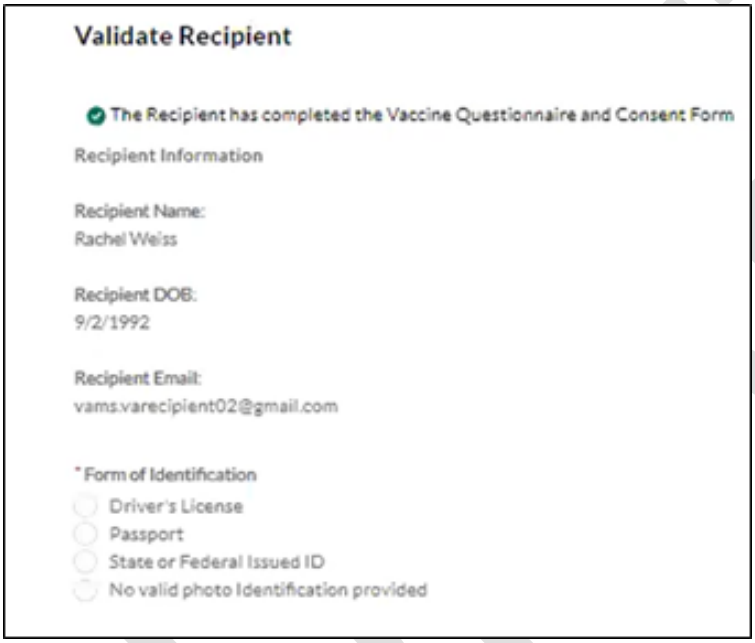
7. Clinic user can also log waste during inventory receipt.
    a. Uses a barcode scanner to scan the vials or enters the waste manually

Within Inventory Management, clinic users can monitor inventory levels and doses administered. VAMS does not support transfer of inventory to other clinics.

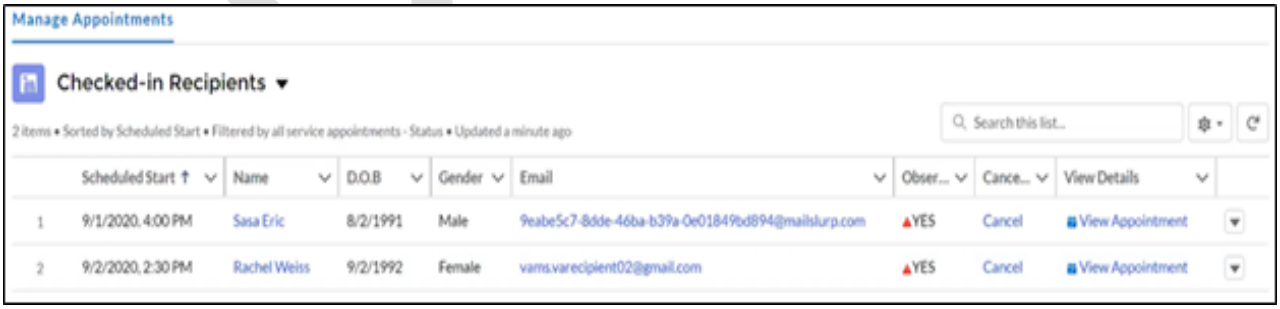
Vaccine Administration:

Recipient completes vaccination questionnaire and consent form, and schedules appointment.

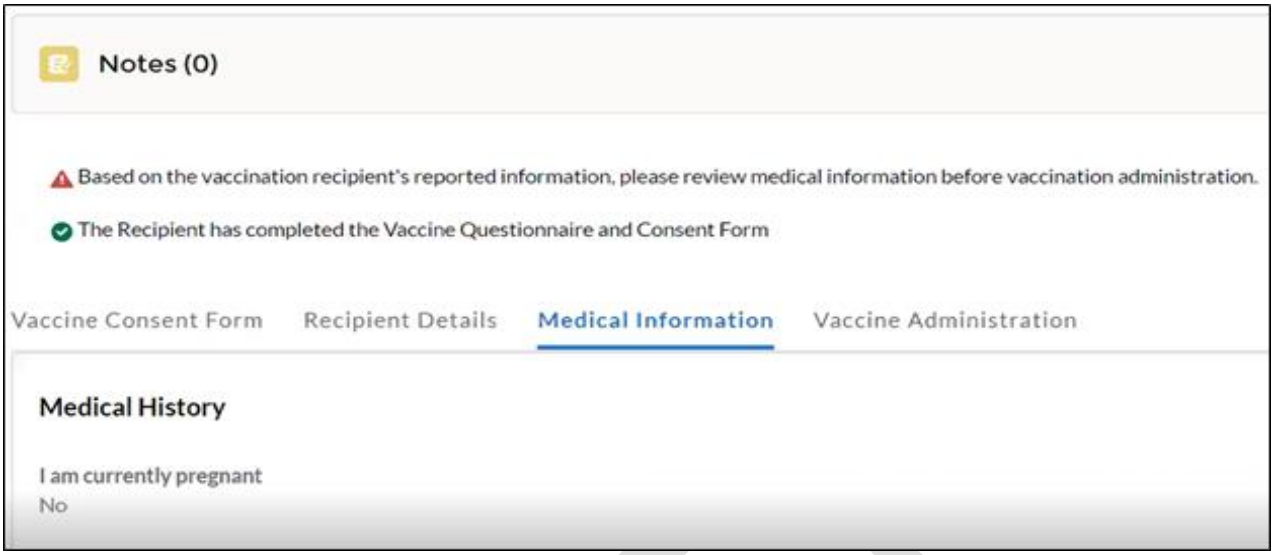
1. Recipient presents at clinic.
    a. Provided a QR code via email or SMS during time of scheduling
2. Clinic user accesses clinic portal to view the scheduled appointments or create a new one.
    a. No public walk-ins are accepted— only employees (recipients) who have been identified by employers registered in VAMS
3. Clinic user scans QR code or searches for the recipient.
4. When the recipient is located, clinic user performs check-in by validating the recipient has completed the vaccine questionnaire and consent form and verifying their identity.



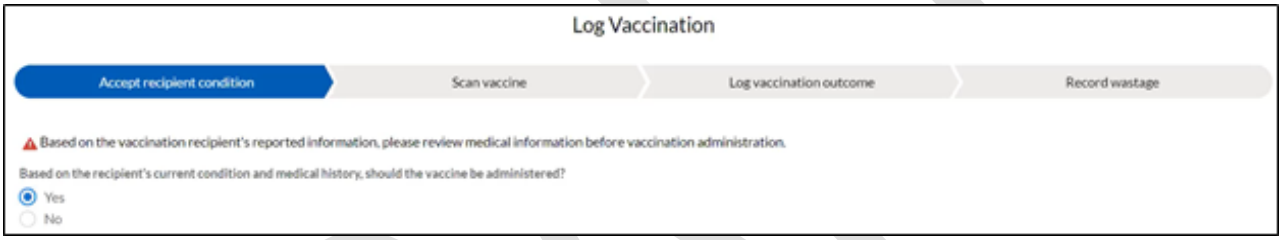
5. Vaccinating clinician accesses the Clinic Portal - Manage Appointments to view the recipients who are checked in and selects next recipient.



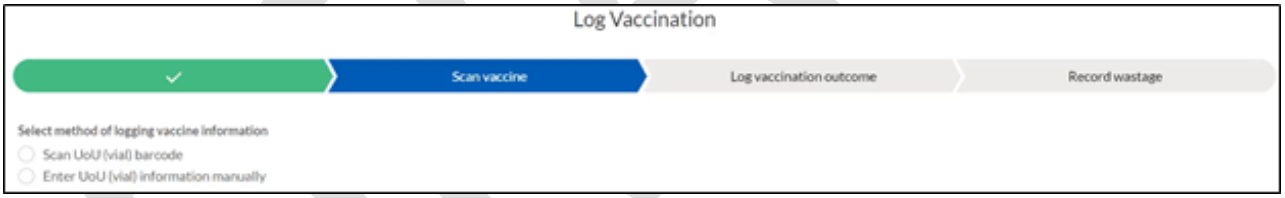
6. Recipient presents to vaccinating clinician.
7. Clinician again verifies identity of recipient and reviews medical information that was entered by the recipient in the recipient module prior to scheduling the appointment.



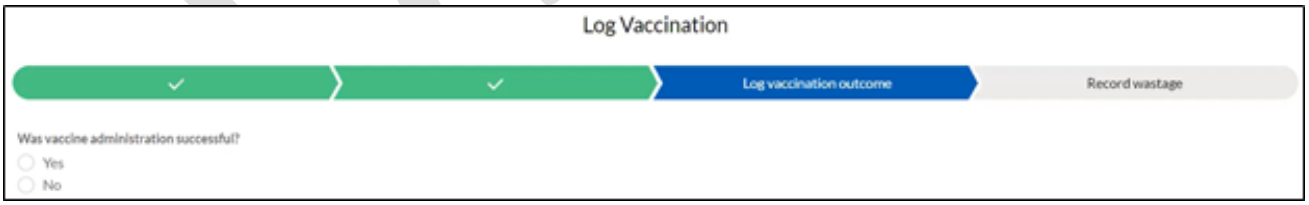
8. Clinician begins the "Log Vaccination" process.



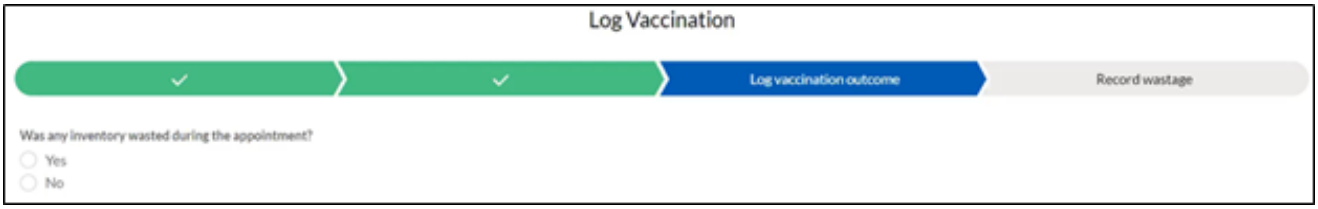
a. Scan barcode or enter manually



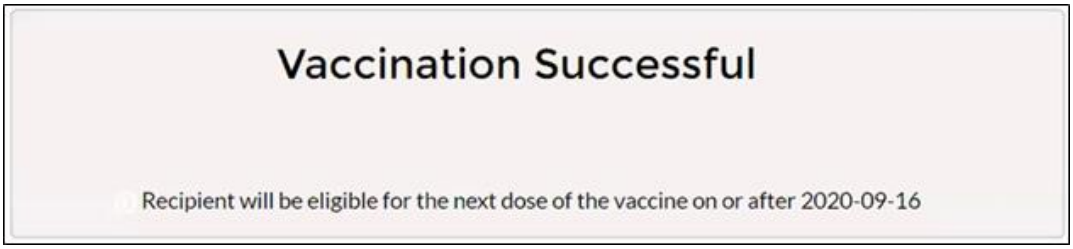
b. Administer vaccine to recipient
c. Log vaccination outcome



d. Record any wastage



e. Complete vaccination logging



9. Recipient receives a vaccination certificate (digital and/or physical).
10. Recipient receives reminder notification to schedule second dose.

The recipient can schedule the second dose at any available clinic and is not restricted to the one where the initial dose was administered. To obtain initial vaccination information, clinic users can query NCIR or search for recipient information using the vaccination certificate. The VAMS system also provides the CDC and jurisdictions ("state") access for supporting and monitoring performance of clinics within their states/jurisdictions. This will include ongoing management of the organizations within the state/jurisdiction and allows the CDC to see and perform analysis on unidentifiable information across the states/jurisdictions.

Technical planning and considerations:

NCIR will connect to VAMS through IZ Gateway. Messaging is based on the CDC's HL7 Version 2.5.1 Implementation Guide for Immunization Messaging Release 1.5 and transmitted via a Simple Object Access Protocol (SOAP) web service interface. NCIR will be using the existing Web Service Definition Language (WSDL) to establish connection with IZ Gateway Connect. The connectivity was established successfully in a test region September 18, 2020. The production connectivity will be established once a Data Use Agreement (DUA) between NCIR and the Association of Public Health Laboratories, Inc. (APHL) is approved and signed.

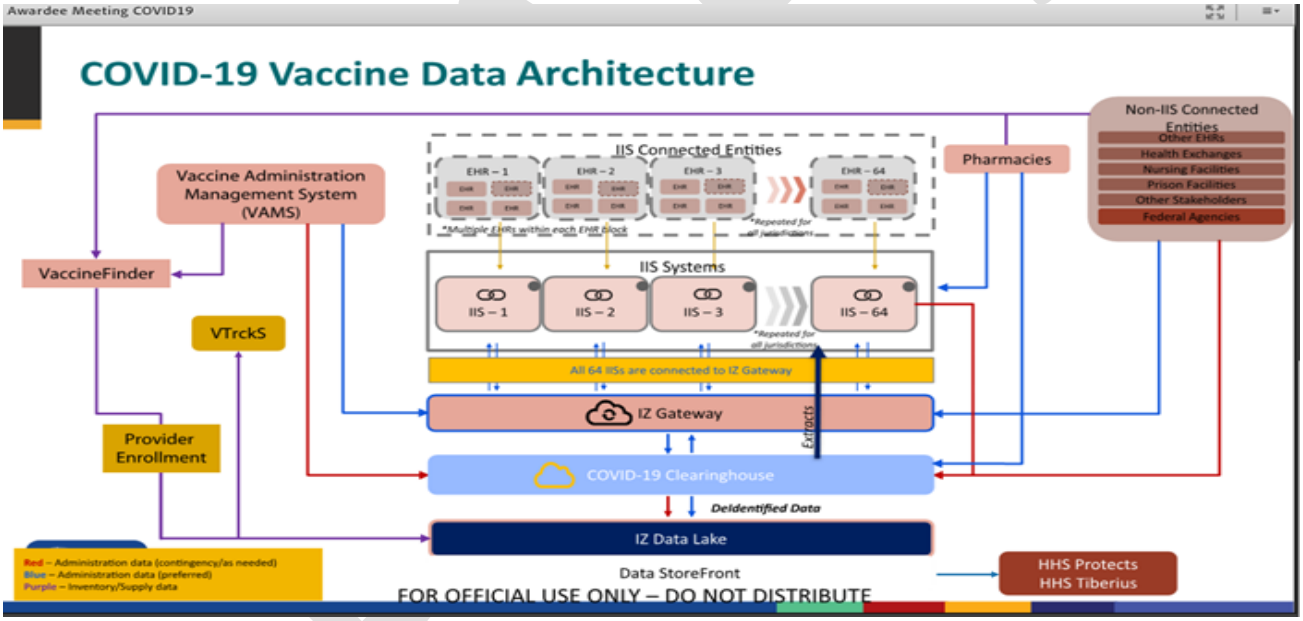
The American Immunization Registry Association (AIRA) released the IZ Gateway Implementation Guide (IZIG) on September 24, 2020. The IZIG provides HL7 message content guidelines for successful processing through the IZ Gateway. Per AIRA, all requirements and field-specific guidance in the document conform to CDC "HL7 Version 2.5.1: Implementation Guide for Immunization Messaging," Release 1.5 and Addendum. Where applicable, the IZIG applies additional segment and field comments, constraints, and guidance to ensure consistent and successful message processing between submitters and receivers through the IZ Gateway. The IZIG document provides the further details on the testing that IIS-specific requirements that may need to be accommodated by the sending system at the time of exchange in order for messages to process successfully. The IZ Gateway Onboarding Team will support evaluation and communication of IIS-specific requirements as needed. Jurisdiction-specific testing between provider sites and their associated IIS will still be needed and may necessitate further modifications.

The IZIG serves as a living document and will be updated monthly as data exchange through the IZ Gateway is operationalized and evaluated. The core requirements and structure of the HL7 fields will not change; certain content expectations may be updated to support IZ Gateway and COVID-19 data exchange

The assumption is that NCIR will receive identified data via the IZ gateway for those COVID-19 vaccines administered and entered in the VAMS system by the providers in North Carolina.

The vaccination data entered in the VAMS will be sent to the NCIR via the IZ Gateway batch process. The data entered in the VAMS will be sent to IZ Data Clearing House/Data Lake frequently, and depending on the load on the server, the transaction will be sent to the NCIR in batches.

NCIR will receive the patient's medical record number (MRN) in the HL7 message sent from VAMS. The MRN is the unique identifier for the patient at the submitting facility. The NCIR application will use both MRN and patient demographic data for the deduplication process. The existing RunMatch algorithm will be used for the deduplication process.



IZ Gateway:

The Immunization Gateway (IZ Gateway) facilitates electronic messaging of vaccination records in a secure infrastructure allowing IIS systems across the nation to share vaccine administration data not only between jurisdictions, but also with provider organizations.

IZ Data Lake

The Immunization Data Lake is a cloud-hosted data repository to receive, store, and manage COVID-19 vaccination data for doses administered, vaccination coverage, ordering, inventory, and distribution. The Data Lake will provide a catalogue of different COVID-19 vaccine-related data sources that can be used to aid in monitoring COVID-19 vaccine ordering, distribution, coverage, and uptake. Data streams currently being onboarded to the Data Lake include provider enrollment data, VTrckS, and Vaccine Finder.

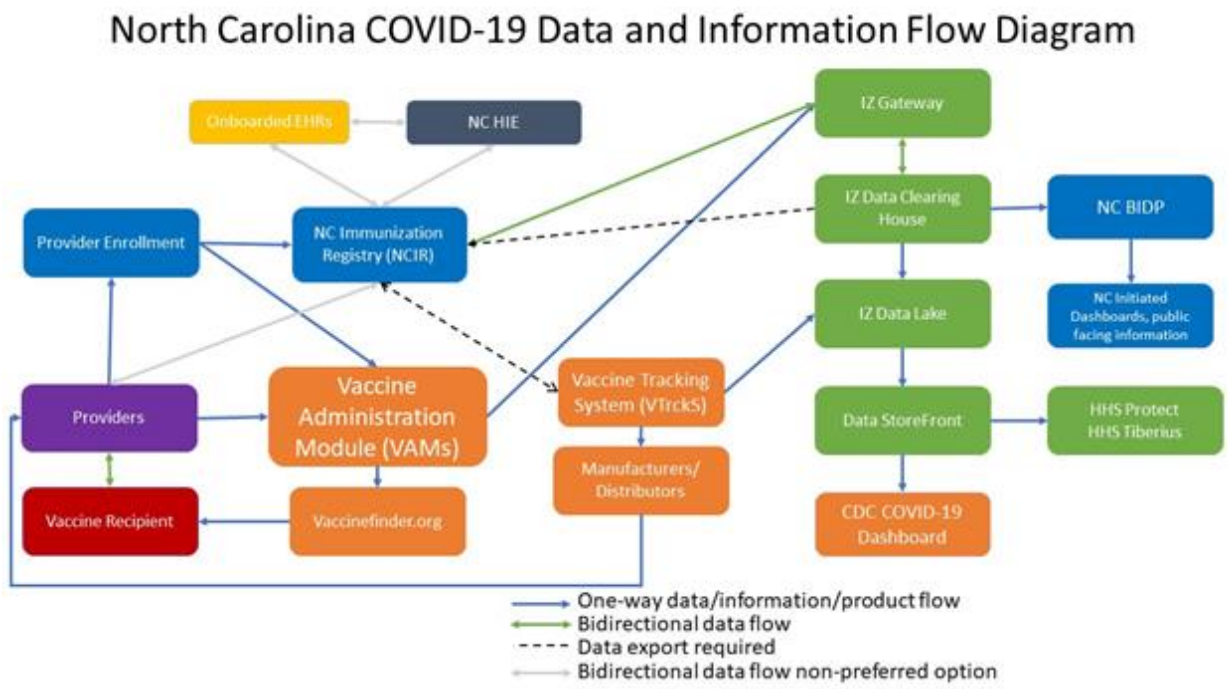
There are multiple ways to onboard to the IZ Gateway, including Connect and Share.

Connect enables large national and non-traditional vaccination systems for satellite/temporary/off-site clinic settings to report and query immunization data with IISs, using the gateway's centralized data exchange, avoiding multiple individuals, and point-to-point connections.

Share allows exchange of immunization data between IIS jurisdictions by automating message triggers through the IIS for patients immunized outside of their jurisdiction, to route messages to the patient's state of residence through the IZ Gateway.

IZ Data Clearinghouse

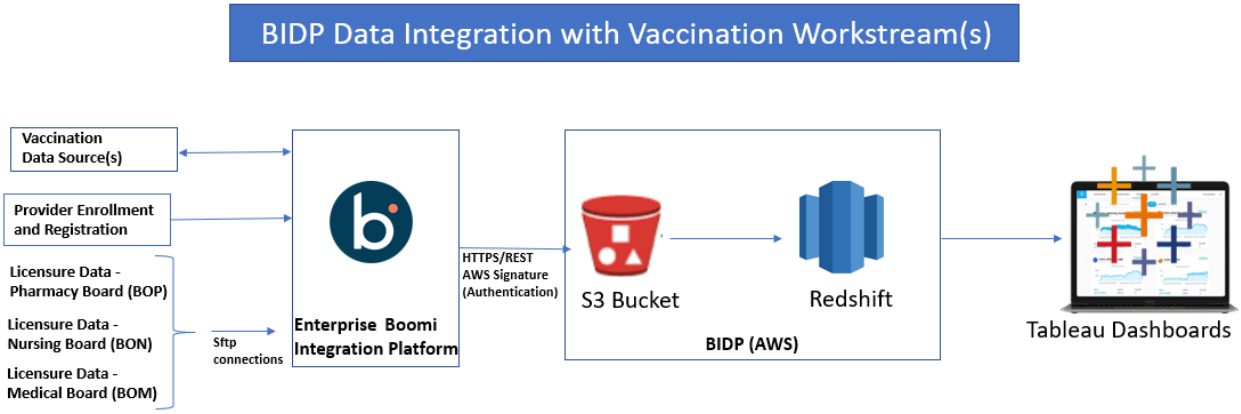
The IZ Data Clearinghouse is a comprehensive data system for COVID-19 vaccine administration data. It encrypts and stores personally identifiable information including vaccine administration data, provides secure bidirectional interfaces for electronic data exchange, allows secure role-based access for authorized data users/system, supports multijurisdictional lookup/queries by the providers for validating vaccine type and manufacturer for administration of a second dose, provides real-time operational metrics to trading partners on data submission and processing, and sends pseudonymized, de-identified vaccine administration data to the IZ Data Lake for CDC and HHS use.



Data Architecture for ingesting data into NCDHHS Business Intelligence Data Platform (BIDP) from Vaccination Workstreams

NCDHHS BIDP is a HIPAA-compliant cloud-based business intelligence data platform to integrate data from multiple internal (North Carolina government agencies) and external (hospitals, labs, federal systems, other partners not on the state network) sources, and in different data formats (databases and flat files). It provides a single unified view to analysts and tableau developers for analysis, reporting, and creation of COVID-19 dashboards for DHHS internal programs, other North Carolina agencies, and the public.

For this effort the NCDHHS BIDP platform will be utilized to integrate data from different systems, e.g., COVID-19 vaccine provider enrollment, NCIR, CDC VAMS, CDC IZ Data Clearing House, North Carolina Medical Board, North Carolina Board of Nursing, North Carolina Board of Pharmacy, etc. The CDC IZ Gateway will be used as needed to connect to vaccine data for state data reporting purposes. The data will be used for analysis, performance monitoring, reporting, and visualization through tableau dashboards on who is receiving the vaccine, vaccination availability phases, demographics, and more.



Key Planning Actions

1. Identify complete list of data elements to be ingested from the IZ Data Clearinghouse and NCIR.
2. Pending additional CDC guidance, identify the source system connection(s) requirements and establish connectivity.
3. Pending additional CDC guidance, create data pipeline to orchestrate data movement from the source system(s) to NCDHHS BIDP.
4. Pending additional CDC guidance, validate the data by business.
5. Pending additional CDC guidance, design, deploy, and test reports and tableau dashboards
6. Pending additional CDC guidance, create custom data extracts (views) for tableau users and/or third parties (if needed).
7. Pending additional CDC guidance, provide Redshift table(s) access to tableau developers.
8. Pending additional CDC guidance, identify internal and outside third parties who need access to vaccination data or reports.

Appendix 5: Communications Matrix

The following communications matrix identifies key stakeholder for external relations, the lead agency and person responsible for communication with that stakeholder group, the main methods of communication used to reach that stakeholder, and any third parties or secondary agencies that may assist in reaching that stakeholder. The comments/strategies include any specific outreach efforts for provider enrollment.

Stakeholder Group	State Lead	Methods of Communication and Frequency	Partners Available to Assist
Healthcare Coalitions	HPP	Direct Email to HCC Lead Weekly HCC lead calls Quarterly Regional HCC meetings	PHP&R Regional Pharmacists
Hospitals/Health Systems	HPP	Direct Email to POCs Monthly Hospital/EMS Webinar Monthly ORH/HCC Webinar Quarterly Regional HCC Meetings	NC Healthcare Assoc. Regional HCCs Duke Margolis Round Table
Fire/EMS Agencies	HPP	Direct Email to POCs Monthly Hospital/EMS webinar Monthly ORH/HCC Webinar Quarterly Regional HCC meetings	Regional HCCs NC OEMS Local Health Departments OSFM LEMAs
Skilled Nursing Facilities/Assisted Living	HPP	Direct Email to POCs Quarterly Regional HCC meetings	Regional HCCs NC Healthcare Facilities Assoc. NC Senior Living Assoc. Local Health Departments
Adult Care Homes/ Group Homes/ICFs	ACLS	Direct Email to POCs	NC Healthcare Facilities Assoc. NC Senior Living Assoc.
Home Health and Hospice Agencies	HPP	Direct Email Quarterly Regional HCC meetings	Association for Home & Hospice Care NC Association for Home Health & Hospice Local Health Departments

Stakeholder Group	State Lead	Methods of Communication and Frequency	Partners Available to Assist
State Operated Facilities	MCM Pharmacist Lead	Direct Email	HPP
Dialysis Centers	HPP	Direct Email Quarterly Regional HCC meetings	Regional HCCs ESRD Network 6
FQHCs Rural Clinics Free & Charitable Clinics	ORH	Direct Email	North Carolina Association of Community Health Centers Association of Free and Charitable Clinics
State Law Enforcement	MCM Pharmacist Lead	Direct Email	NCEM
Local Health Departments	LHD workstream	Direct Email Weekly LHD COVID-19 Call Monthly regional PC Meetings	PHP&R regional Pharmacists NC Immunization Branch
Pharmacies	PHP&R MCM Pharmacists	Direct Email	NC Board of Pharmacy NC Retail Merchants Association
Providers/Physician Assistants	NCDPH state Epi	email	NC Medical Board NC Medical Society NC Peds Society NC Academy of Family Physicians Health Insurance Plans/Payers/NC Medicaid NC Academy of Physician Assistants Old North State Medical Society Durham Academy of Medicine
Nurses/NPs	NC DPH Chief Nurse/NC DPH School Curse Contact	email	NC Board of Nursing Black Nurses Association NC Nurses Association

Stakeholder Group	State Lead	Methods of Communication and Frequency	Partners Available to Assist
Urgent Care Centers	Urgent Care Association	email	NC Medical Board NC Board of Nursing NC Medical Society
Dentists/Dental Clinics	To be determined	email	NC State Board of Dental Examiners
Contracted Mobile Providers	To be determined	email	To be determined
Respiratory Technicians	To be determined	email	To be determined
School-Based Health Centers (K-12)	NCDPH School Health Unit	School-Based Health Center Alliance (quarterly meetings) Direct communication with SBHC Alliance as needed	NC DHHS Policy; Department of Public Instruction
Student Health (Colleges/ Universities)	NC DHHS Policy	email	NC DPI
Occupational Health Clinics	To be determined	email	To be determined
Travel Clinics	To be determined	email	To be determined
Department of Defense	EM Rep to Vaccine Workstream	email	NCEM, Emergency Preparedness Liaison Officers
Department of Public Safety	EM Rep to Vaccine Workstream	email	NCEM
Veterans Affairs	EM Rep to Vaccine Workstream; HPP Rep	email	NCEM
Local EMA	EM Rep to Vaccine Workstream	email	NCEM
African American / Black Community	HMP	emails	NAACP; Andrea Harris Task Force; General Baptist State Convention of NC; African Methodist Episcopal NC Group; National Panhellenic Council (NC....AA), Prince Hall Masonic groups, etc.

Stakeholder Group	State Lead	Methods of Communication and Frequency	Partners Available to Assist
LatinX / Hispanic Community	HMP	email	
American Indian Community	HMP	email	Tribal Chief, Tribal Chairman or the Tribal Administrators for each tribe; NC Commission of Indian Affairs; Urban Indian Associations; local health departments
Immigrant Community	HMP	Email	Farmer worker health, Rural Health
Refugee Community	HMP	email	
Disability Community	Office of Disability and Health	email	NC Centers for Independent Living, Disability Rights NC, The Arc of NC, Family Support Network of NC, First in Families of NC, Autism Society of NC, NC Council on Developmental Disabilities, National Alliance on Mental Illness NC, Brain Injury Association of NC, Easterseals/UCP NC, NC Down Syndrome Alliance, Family Resource Center of the South Atlantic, Epilepsy Alliance NC
LGBTQ+ Community	HMP	email	Equality NC, Blue Ridge Pride Center, Youth OUTright, Time Out Youth, Transcend Charlotte, LGBTQ Center of Durham, Guilford Green Foundation & LGBTQ Center, Onslow County LGBTQ+ Community Center, LGBT Center of Raleigh, Frank Harr Foundation, North Star LGBT Community Center, PFLAG Triangle

Stakeholder Group	State Lead	Methods of Communication and Frequency	Partners Available to Assist
Rural Community	Office of Rural Health	email	Food banks, Cooperative Extension agencies, faith-based organizations/churches, senior centers, and fire/EMS
Asian Community	HMP	email	Carolina Asia Center – Connected with multiple Asia-focused organizations in North Carolina

Appendix 6: Tribal Planning Tool

The success of a COVID-19 vaccine program for tribal nations depends on the strong partnerships between state and federal government and tribal nations. On September 24, 2020, Deputy HHS Secretary Hargan announced the initiation of tribal consultation to seek input from tribal leaders on COVID-19 vaccination planning for Indian Country. The announcement stated, "Tribal leaders will be able to express their preference for how a COVID-19 vaccine is distributed to their communities, whether through state and local jurisdictions, or through the Indian Health Service (IHS), and how they can support this effort."

To ensure that citizens living on tribal lands will receive vaccine, it is vital that jurisdictions coordinate with tribal governments.

CDC provided the table below to states for completion and addition to state COVID-19 plans for federally recognized tribal nations. For North Carolina, the Eastern Band of the Cherokee Indians is represented in this tool. Other tribes are included in planning and found in other annexes, particularly Annex 2.

State	Affiliation	Tribe (Select from dropdown)	Facility Name	Population	Distribution Method (Select from dropdown)	Address	City	Zip Code	Phone	Facility Type	Pharmacy	Website
NC	Tribal	Eastern Cherokee	CIHA Dental Surgery	0	Will not receive vaccine	60 Hospital Road	Sylva	28779	828-497-9163	Health Location	No	NULL
NC	Tribal	Eastern Cherokee	CIHA Hospital	13000	IHS	1 Hospital Road	Cherokee	28719	828-497-9163	Hospital	No	NULL
NC	Tribal	Eastern Cherokee	CIHA Murphy Clinic	0	Will not receive vaccine	328 Airport Road	Marble	28905	N/A	Health Station	No	NULL
NC	Tribal	Eastern Cherokee	CIHA Snowbird Health Station	0	Will not receive vaccine	50 Indian School House Road	Robbinsville	28771	828-497-9163	Health Station	No	NULL

Appendix 7: Safety Data Sheet- Dry Ice

https://chemmanagement.ehs.com/9/pdf/?libraryID=XAE175&pageID=3&newWindow=true&autoOpened=false&documentQueueID=0 Updated 01/1/2020. Accessed 10/14/2020

MSDS #1001

Safety Data Sheet
Dry Ice

Identity: Carbon Dioxide – Solid (Dry Ice). Dry ice is the solid form of carbon dioxide.

General Information

Date MSDS Prepared: January 1, 2020

Emergency Contact (24 hour) PERS 800-633-8253

Product is considered Hazardous by the OSHA Hazardous Communication Standard 29 CFR 1910.100

Proprietary: No
NIOSH (RTECS) Number: FF6400000
Exposure Limits:
Carbon Dioxide:
5000 ppm (9000 mg/m3) OSHA TWA
5000 ppm (9000 mg/m3) ACGIH TWA: 30,000 ppm (54,000 mg/me) ACGIH STREL
5000 ppm (9000 mg/m3) NIOSH recommended 10 hour TWA:
30,000 ppm (54,000 mg/m3) NIOSH recommended STEL
5000 ppm (9000 mg/m3) DFG MAK TWA:
10,000 ppm (18,000 mg/m3) DFG MAK 60 minute peak, momentary value
Measurement method: Gas collection bag: Gas chromatography with thermal conductivity
Detector: (NIOSH III #S249I)

Physical/Chemical Characteristics

Appearance and Odor: Solid pellets or block - white opaque solid, odorless to slightly pungent
Boiling Point: -109.4 F
Melting Point: -109.3 F
Vapor Pressure (MM hg/70F): 831 PSIA
Solubility In Water: APPRECIABLE
Composition: Carbon Dioxide > 99% CAS Number 124-38-9

Fire Fighting Measures

FLASH POINT (test method):	Not applicable
AUTOIGNITION TEMPERATURE	Not applicable

FLAMMABLE LIMITS IN AIR, % by volume	**LOWER**: Not applicable	**UPPER**: Not applicable

UNUSUAL FIRE AND EXPLOSION HAZARDS: None Known
HAZARDOUS COMBUSTION PRODUCTS: Not applicable. Thermal decomposition releases carbon monoxide and oxygen.

Reactivity Data

Dry ice sublimes; if confined in a gas tight container, it will build up a pressure of 850 psig at 70° F. Do not put dry ice in an airtight container or confined space
Stability: It is stable
Conditions To Avoid (Stability): Moisture
Materials to Avoid: Carbonic acid/salt/corrosive chemicals
Hazardous Polymerization Occurrence: No

Health Hazard Data

Route of Entry-Inhalation: Yes
Route of Entry-Skin: No
Route of entry-Ingestion: No
Health Hazard Acute and Chronic: Concentration in excess of 1.5% carbon dioxide may cause death. At higher concentrations, displaces oxygen in air below levels necessary to support life.
Carcinogenicity-NTP: No
Carcinogenicity-IARC: No
Carcinogenicity-OSHA: No
Explanation Carcinogenicity: None
Signs/Symptoms of Overexposure: At concentrations >1.5%: Hyperventilation/headaches/ dyspnea/perspiration. At 6-10%: Headaches/dyspnea/perspiration, tremors, visual disturbances. >10%: Unconsciousness without warning. Cryogenic burns.
Emergency/first Aid Procedures: Inhalation: Remove to fresh air. Assisted respirant and supplemental oxygen should be given if not breathing. Frozen tissues should be flooded/soaked with tepid water. Don't use hot water. Obtain medical attention in all cases.

Precautions for Safe Handling and Use

Steps if Material Released/Spill: Ventilate indoor areas well to avoid hazardous CO_2 concentrations. Ventilate area well and avoid contact with cold vapors/dry ice. CO_2 is heavy gas and will remain in low spots without assisted ventilation.
Special Precautions for Handling of Solid Carbon Dioxide: Do not handle solid Carbon Dioxide with bare hands. Use heavy gloves, dry ice tongs or plastic scoop or shovel. Handle blocks of dry ice carefully, as injuries can occur if one is accidentally dropped on the feet. Containers of solid Carbon Dioxide should be stored upright and be firmly secured to prevent falling or being knocked over. Containers should be vented, to prevent the build-up of Carbon Dioxide gas. Carbon Dioxide sublimates at -78.5°C (-109.3°F); containers should be thermally insulated and kept at the lowest possible temperature to maintain the solid and avoid generation of Carbon Dioxide gas. Storage containers and equipment used with Carbon Dioxide should not be located in sub-surface or enclosed areas, unless engineered to maintain a concentration of Carbon Dioxide below the TLV (TLV=5000 ppm) in the event of a release. Solid consignment of

dry ice in a gas-tight vessel can lead to catastrophic failure of the vessel by over-pressurization. Storage of dry ice should never occur in a gas-tight container.

Control Measures

Respiratory Protection: SCBA in oxygen deficient atmospheres where CO_2 >1.5%. Do not use air purifying respirators.
Ventilation: Local Exhaust: At point sources of CO_2 vapors. Mechanical (general): Low lying area are not naturally ventilated.
Protective Gloves: Impermeable/loose fitting (leather)
Eye Protection: Safety glasses

Transportation Data

Shipping information: Packages should be transported in a secure position in a well ventilated vehicle. Product transported in an enclosed, non ventilated compartment of a vehicle can present serious safety hazards.
HAZARD CLASS: 9
PACKING GROUP/Zone: III
IDENTIFICATION NUMBER: UN1845
PRODUCT RQ: None
SHIPPING LABEL(s): Class 9 (Miscellaneous Hazardous Materials)
PLACARD (when required): Class 9
SPECIAL SHIPPING INFORMATION:
Dry ice is regulated by the Department of Transportation when transported by aircraft. For shipment by ground transportation, dry ice is not required to be subject to DOT Regulations, but may be placarded as as Class 9 Miscellaneous hazardous material and placarded and labeled accordingly.

Disposal Information

WASTE DISPOSAL METHOD: Place outside in a protected area with good ventilation and allow to sublime. Prevent waste from contaminating the surrounding environment. Keep personnel away. Discard any product, residue, disposable container, or liner in an environmentally acceptable manner, in full compliance with federal, state and local regulations. If necessary, call your local supplier for assistance.

Label Information

Label Required: Yes
Technical Review Date: January 1, 2018
Label Date: January 1, 2018
Common Name: Solid Carbon Dioxide/Dry Ice
Chronic Hazard: Yes
Acute Health Hazard-Severe (3)
Contact Hazard-Slight
Fire Hazard- Minimal (0)
Reactivity Hazard-None (0)

Special Hazard Precautions: Concentration in excess of 1.5% carbon dioxide may cause death. At higher concentrations, displaces oxygen in air below levels necessary to support life.
Target organs: Respiratory system, skin
Protect Eye: Y
Protect Skin: Y
Protect Respiratory: Y

Appendix 8: Dry Ice Safety Instructions

Requisite safety precautions when handling dry ice:

- AVOID INHALATION! Always handle in a well-ventilated area.
- AVOID CONTACT! Skin contact with dry ice can lead to frostbite.

When handling dry ice, always use appropriate personal protective equipment (PPE):

- Wear closed-toed shoes.
- Wear a lab coat or covering garment.
- Wear appropriate eye protection, including goggles and/or a face shield. Use tongs to handle dry ice when possible.
- Use cryogenic gloves to manually handle dry ice. Nitrile exam gloves will not provide enough protection. If a nitrile glove material comes into contact with dry ice while you are wearing it, it will freeze to your hand and be very hard to remove. **Never handle dry ice with bare hands.**

Dispose of excess dry ice as follows:

- Place in a well-ventilated location, outdoors or a fume hood, at room temperature; the remainder of the ice will sublimate away.
- Never dispose of dry ice in a trash can, chemical waste container or other garbage/waste can.
- Never dispose of dry ice in a sink, toilet, or other fixture; the temperature difference can damage the plumbing.

Appendix 9: COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. September 16, 2020

Scenario 1: FDA has authorized vaccine A for Emergency Use Authorization (EUA) in 2020

Availability Assumptions

Vaccine availability under EUA by				
Candidate	**End of Oct 2020**	**End of Nov 2020**	**End of Dec 2020**	**Notes**
Vaccine A	~2 million (M) doses	10M–20M doses	20M–30M doses	Ultra-cold (-70 °C) storage requirements, for large sites only

Distribution, Storage, Handling, and Administration Assumptions

Vaccine A

SHIPMENT

3 separately acquired components (mixed on site)

1. Vaccine
   - Direct to site from manufacturer (on dry ice)
   - Multidose vials (5 doses/vial)
2. Diluent
   - Direct to site from the US Government (USG) at room temperature)
3. Ancillary supply kits (for administration and mixing)
   - Direct to site from USG (at room temperature)

ON-SITE VACCINE STORAGE

Frozen (-70 °C ± 10 °C)

- Must be used/recharged within 10 days
- Storage in shipping container OK (replenish dry ice within 24 hours of receiving shipment and again 5 days later)

Thawed but NOT reconstituted (2–8 °C)

- Must use within 5 days (discard unused doses after 5 days)

Reconstituted (room temperature)

- Must use within 6 hours (discard any unused, reconstituted vaccine after 6 hours)

ORDERS

Large quantities, to large administration sites only

- Minimum order: ~1,000 doses
- Maximum order: ~5,000 doses

ADMINISTRATION

2-dose series (21 days between doses)

- On-site mixing required; reconstitute with diluent just prior to administration
- Administer by intramuscular (IM) injection

INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINE ADMINISTRATION SITES

Healthcare personnel — public health, closed point of dispensing (POD), temporary/off-site vaccination clinics + potential for mobile clinics

Other essential workers — public health, closed POD, temporary/off-site vaccination clinics + potential for mobile clinics

People at higher risk of severe COVID-19 illness — potential for mobile clinics to long-term care facilities (LTCFs)

Additional Considerations for Early Vaccination Planning

- "Healthcare personnel" includes paid or unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to people with COVID-19 or infectious materials.
- Jurisdictions should plan for real-time shipment of doses.
- Administration sites (during Phase 1) will not be required to store vaccine products beyond the period of time Vaccine A can be stored in the ultra-cold shipment box.
- Given the challenging storage, handling, and administration requirements, early vaccination should focus on administration sites that can reach critical populations with as much throughput as possible.
- Stability testing is ongoing for Vaccine A; the storage and handling requirements presented here may shift. The requirements in these scenarios are likely the strictest set of requirements for which planning is needed.
- Jurisdictions should consider partnering with the private sector and with local hospital systems to provide vaccine in closest proximity to the critical populations as possible, given limitations with the product. For example: Vaccine A may be administered through mobile clinics if multiple mobile clinics are planned over a short period of time to ensure sufficiently high throughput.

Scenario 2: FDA has authorized vaccine B for EUA in 2020

Availability Assumptions

Vaccine availability under EUA by				
Candidate	**End of Oct 2020**	**End of Nov 2020**	**End of Dec 2020**	**Notes**
Vaccine B	~1M doses	~10M doses	~15M doses	Central distributor capacity required (-20 °C)

Distribution, Storage, Handling, and Administration Assumptions

Vaccine B	
SHIPMENT ***2 separately shipped components*** 1. Vaccine • To central distributor (at -20 °C) • Multidose vials (10 doses/vial) 2. Ancillary supply kits • Direct to site from USG (at room temperature)	**ON-SITE VACCINE STORAGE** ***Frozen (-20 °C)*** • Storage in shipping container OK ***Refrigerated (2–8 °C)*** • Must use within 14 days ***Room temperature*** • Must use within 6 hours (discard any unused vaccine after 6 hours)
ORDERS ***Central distribution capacity required*** • Required by Dec 2020 • Maintained at -20 °C	**ADMINISTRATION** ***2-dose series (28 days between doses)*** • No on-site mixing required • Administer by IM injection
INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINE ADMINISTRATION SITES ***Healthcare personnel*** — healthcare clinics + healthcare occupational health clinics + public health, closed POD, temporary/off-site vaccination clinics + mobile clinics ***Other essential workers (specifics TBA)*** —occupational health + hospital clinics + public health, closed POD, temporary/off-site vaccination clinics ***People at higher risk of severe COVID-19 illness (e.g., LTCF residents)*** — commercial pharmacy partners + mobile clinics	

Additional Considerations for Early Vaccination Planning

- "Healthcare personnel" includes paid or unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to people with COVID-19 or infectious materials.
- Jurisdictions should plan for real-time shipment of doses.
- Administration sites (during Phase 1) will not be required to store vaccine products beyond the period of time Vaccine B can be stored at 2–8 °C.
- Given the challenging storage, handling, and administration requirements, early vaccination should focus on administration sites that can reach critical populations with as much throughput as possible.
- Stability testing is ongoing for Vaccine B; the storage and handling requirements presented here may shift. The requirements in these scenarios are likely the strictest set of requirements for which planning is needed.
- Jurisdictions should consider partnering with the private sector and with local hospital systems to provide vaccine in closest proximity to the prioritized populations as possible, given limitations with the product.

Appendix 10: Managing Workplace Fatigue During COVID-19

CDC Centers for Disease Control and Prevention

What Workers and Employers Can Do to Manage Workplace Fatigue during COVID-19
Managing Workplace Fatigue

Updated May 19, 2020

The coronavirus disease (COVID-19) pandemic has touched all aspects of society including how we work. Emergency responders, health care workers, and others providing essential services to the community have been especially stretched thin, working longer hours than usual, working more shifts or even overnight, and leaving less time to sleep and recharge.

Under regular circumstances, adults need 7-9 hours of sleep per night, along with opportunities for rest while awake, optimal health, and well-being. Long work hours and shift work, combined with stressful or physically demanding work, can lead to poor sleep and extreme fatigue. Fatigue increases the risk for injury and deteriorating health (infections, illnesses, and mental health disorders).

While there is no one solution to fit everyone's needs, here are some general strategies that workers and employers can use to manage workplace fatigue and work safely.

What can workers do when they feel too fatigued to work safely?

Recognize these are stressful and unusual circumstances and you may need more sleep or time to recover.

Tips to improve sleep:

- You'll sleep better if your room is comfortable, dark, cool, and quiet.
- If it takes you longer than 15 minutes to fall asleep, set aside some time before bedtime to do things to help you relax. Try meditating, relaxation breathing, and progressive muscle relaxation.
- Before you begin working a long stretch of shifts, try "banking your sleep"– sleeping several extra hours longer than you normally do.
- After you've worked a long stretch of shifts, remember it may take several days of extended sleep (for example, 10 hours in bed) before you begin to feel recovered. Give yourself time to recover.
- Avoid sunlight or bright lights 90 minutes before you go to sleep, when possible. Exposure to light just before bedtime can cause you to feel more awake.
  - If you work a night shift and drive home during sunlight hours, try wearing sunglasses to reduce your exposure to sunlight during your drive home.
  - Consider using blackout shades at home when sleeping.
- Take naps when you have the opportunity.
  - A 90-minute nap before working a night shift can help prevent you from feeling tired at work.
- Eat healthy foods and stay physically active because it can improve your sleep.
- Before you go to sleep, avoid foods and drinks that can make falling asleep more difficult:
  - Avoid alcohol, heavy meals, and nicotine for at least 2-3 hours before bedtime.
  - Don't drink caffeine within 5 hours of bedtime.

Know what to do if you feel too tired to work safely.
Know what to do if you feel too tired to work safely.

- Use a buddy system while you're at work. Check in with each other to ensure everyone is coping with work hours and demands.
- Watch yourself and your coworkers for signs of fatigue — like yawning, difficulty keeping your eyes open, and difficulty concentrating. When you see something, say something to your coworkers so you can prevent workplace injuries and errors.
- Find out if your employer has a formal program to help you manage fatigue on the job. Read information about the program and ask questions so you fully understand your employer's policies and procedures for helping employees manage fatigue.
- Report any fatigue-related events or close-calls to a manager to help prevent injuries and errors.
- Do not work if your fatigue threatens the safety of yourself or others. Report to a manager when you feel too tired to work safely.

What steps should employers take to reduce workplace fatigue for workers?

- Recognize that these are stressful and unusual circumstances and risk for fatigue may be increased.
- Create a culture of safety with clear coordination and communication between management and workers. This can include establishing a Fatigue Risk Management Plan or strategies for fatigue mitigation on the job. Share and ensure that employees understand the processes.
- Spot the signs and symptoms of fatigue (e.g., yawning, difficulty keeping eyes open, inability to concentrate) in yourself and your employees and take steps to mitigate fatigue-related injury or error.
  - The Epworth Sleepiness Scale is a short survey that can be posted in a common area for workers to quickly rate their fatigue.
  - Create a procedure that does not punish workers for reporting when they, or their coworkers, are too fatigued to work safely. Build it into team comradery as an example of how management and staff can support each other.
  - Develop processes to relieve a worker from their duties if they are too fatigued to work safely.
    - If available, and agreeable with workers, consider assigning workers who are just starting their shifts onto safety-critical tasks.
    - If possible, rotate workers or groups of workers through tasks that are repetitive and/or strenuous. Tools or workstations that are unavoidably shared need to be properly cleaned and disinfected between usage.
    - If possible, schedule physically and mentally demanding workloads and monotonous work in shorter shifts and/or during day shifts.
- Provide information for workers on the consequences of sleep deprivation and resources to assist workers manage fatigue.
- Allow staff enough time to organize their off-duty obligations and get sufficient rest and recovery.
  - Schedule at least 11 hours off in-between shifts (each 24-hour period), and one full day of rest per seven days for adequate sleep and recovery.
  - Avoid penalizing those who may have restricted availability to work extra shifts/longer hours (e.g., caring for dependents).
- If rotating shift work is needed, use forward rotations (day to evening to night) and provide staff with sufficient notice when scheduling, particularly if there is a shift change.
- Avoid scheduling staff for more than 12 hours, if possible.
- Formalize and encourage regularly scheduled breaks in clean and safe areas where social distancing can be maintained. Recognize the need for additional time for increased hand hygiene and putting on and taking off required personal protective equipment (PPE).
- Provide alternative transportation to and from work and mandatory paid rest time prior to driving commutes after work, when possible.
  - Consider arranging for nearby offsite housing for those working extended shifts and at high risk for COVID-19, such as health care workers. Nearby housing will reduce travel times, allowing for more rest and recovery.

Where can I get more information?

Fatigue

- CDC Sleep and Sleep Disorders website: https://www.cdc.gov/sleep/index.html
- NIOSH Science Blog — Managing Fatigue During Times of Crisis: Guidance for Nurses, Managers and Other Health Care Workers: blogs.cdc.gov/niosh-science-blog/2020/04/02/fatigue-crisis-hcw/
- National Response Team Guidance for Managing Fatigue During Disaster Operations: www.cdc.gov/niosh/topics/oilspillresponse/pdfs/NRT-Fatigue-for-Emergency-Workers.pdf
- National Sleep Foundation Guidelines During the COVID-19 Pandemic website: www.sleepfoundation.org/sleep-guidelines-covid-19-isolation
- American Academy of Sleep Medicine: Sleep Education website: sleepeducation.org

COVID-19
COVID-19

- NIOSH Workplace Safety and Health Topic website: www.cdc.gov/niosh/emres/2019_ncov.html
- CDC COVID-19 website: www.cdc.gov/coronavirus/2019-ncov/
- CDCINFO: 1-800-CDC-INFO (1-800-232-4636) | TTY: 1-888-232-6348 | website: www.cdc.gov/info

Last Updated May 19, 2020