NC DHHS COVID-19 Vaccination Briefing

December 9, 2020

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES



COVID-19 Prevention: Key Messages for December

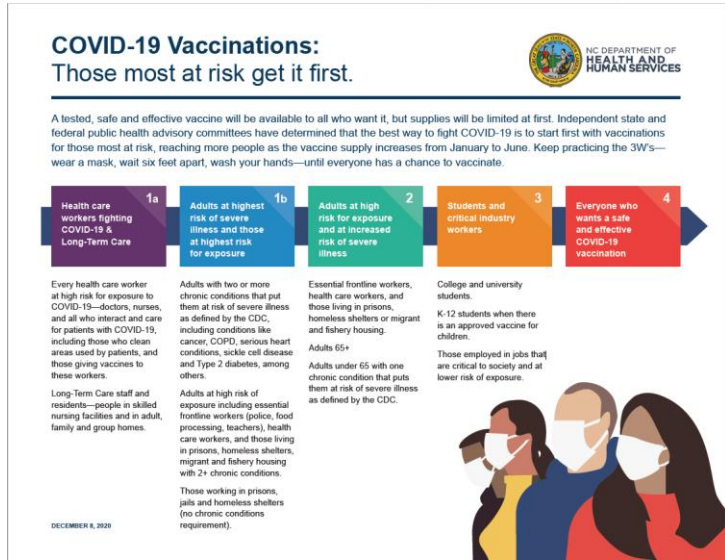
Review & Share the Winter Holidays Guidance

- Avoid holiday travel and gatherings with those you don't live with
- If you must travel or gather: Get tested ahead of time, wear a mask all the time, and keep it small and outdoors
- One-page flyer & detailed guidance (English & Spanish) available at https://covid19.ncdhhs.gov/information/individuals-families-and-communities/guidelines-get-togethers#winter-holidays



Review & Share Vaccines Talking points

- A tested, safe and effective vaccine will be available to all who want it, but supplies will be limited at first.
- The best way to fight COVID-19 is to start first with vaccinations for those most at risk, then reach more people as the vaccine supply increases throughout 2021.
- More information at https://covid19.ncdhhs.gov/vaccines

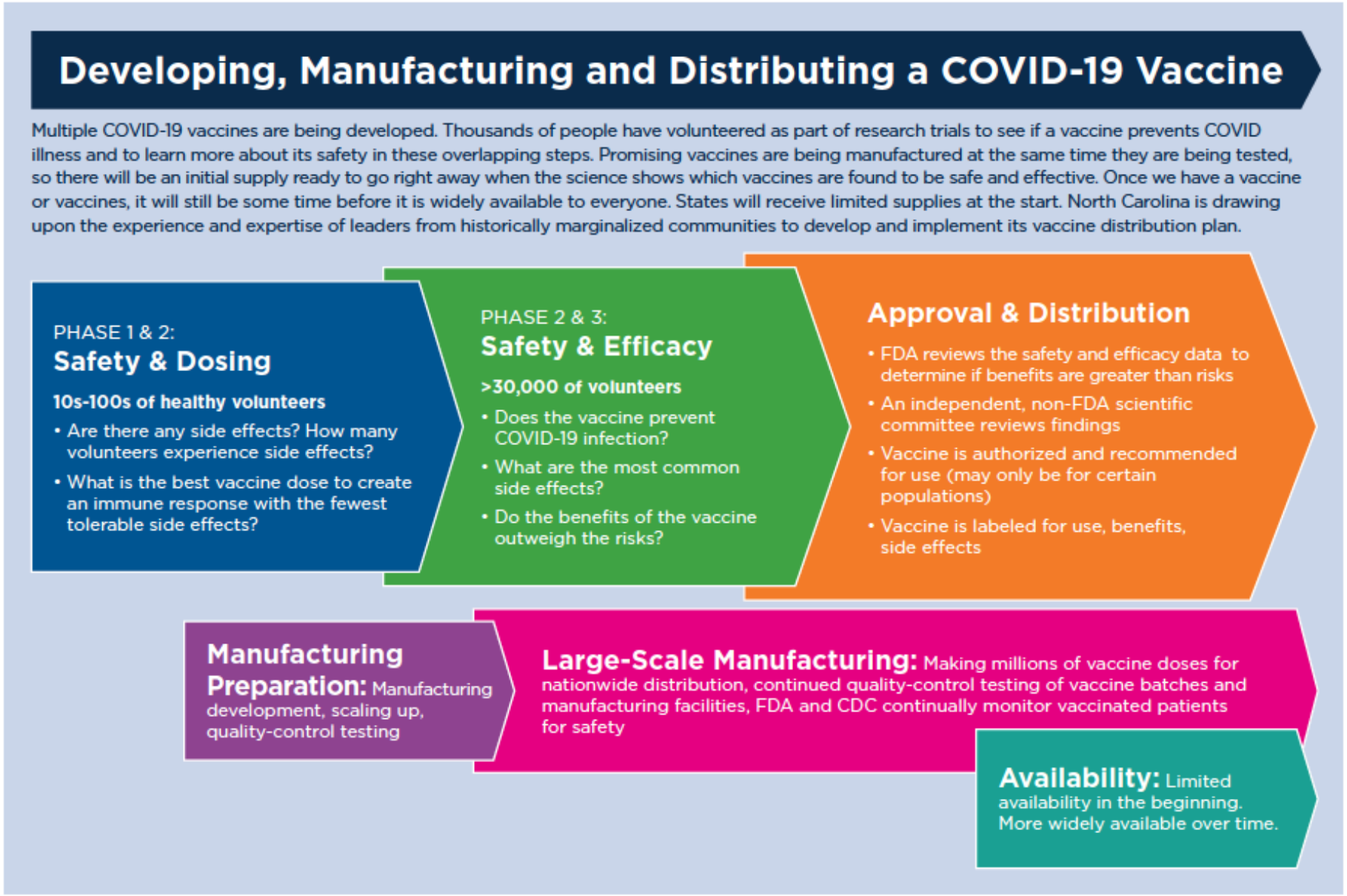


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Agenda

- **Status of Vaccine Development**
- **NC Vaccine Response Principles**
- **Priority Groups**
- **Overview of Plan**
- **Provider Enrollment**
- **Communications**
- **Questions**

The COVID-19 Vaccine Development Process



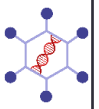
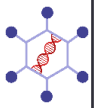
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https://files.nc.gov/covid/documents/Vaccine-Timeline.pdf

Two Leading COVID-19 Vaccine Candidates

	Pfizer Vaccine	Moderna Vaccine
Preliminary Efficacy Data	• Nov 18 Press Release data analysis reported 95% effectiveness in preventing illness. • 162/170 cases were in placebo group • 9/10 severe cases were in placebo group • Phase 3 trial included over 43,000 participants, 42% with diverse backgrounds.	• November 30 Press Release data analysis 94.1% effectiveness in preventing illness. • 185/196 cases were in placebo group • 30/30 severe cases were in placebo group • Phase 3 trial included 30,000 adult participants, 37% with diverse backgrounds.
Timing of EUA	• Applied for EUA 11/20/20 • FDA Review Dec 8-10	• Applied for EUA 11/30 • FDA Review Dec 17th
Temperature and Storage	• Requires ultra-cold storage (-75 degrees Celsius). • Lasts up to 5 days at refrigerated temperatures.	• Requires storage at -20 degrees Celsius (similar to the chickenpox vaccine). • Lasts up to 30 days at refrigerated temperatures.
Dosing	• 2-dose schedule; 21 days apart • Protection after 10 days of 1st dose, 52% after first dose	• 2-dose schedule • Administered 28 days apart.
Type of Vaccine	• Both vaccines use mRNA technology from the coronavirus's own genes to have people's cells make viral proteins to trigger immune system to produce antibodies against the COVID virus. mRNA vaccines can be made faster than older vaccines and require frozen storage to remain stable	
Safety	• No reports of serious safety concerns in either vaccine in either the clinical trials. Temporary reactions (e.g., fever, soreness at site of injection, fatigue) noted 24-48 hours after vaccination	

Updates on Remaining Operation Warp Speed Candidates

	AstraZeneca	Johnson & Johnson Janssen	Sanofi GSK	Novavax
Type	Non-replicating viral vector 	Non-replicating viral vector 	Protein Subunit 	Protein Subunit 
Phase	Phase II/III	Phase III	Phase I/II	Phase II/III
Estimated Availability	Est: Early 2021	Est: Early 2021	Est: First half 2021	Est: Early 2021
Doses Required	Doses: 2 (*testing half-dose: full-dose regimen v. two full doses)* First interim analysis 90% effective with first half-dose	Doses: 1 or 2 (*testing both)*	Doses: 1 or 2 *(testing both)*	Doses: 1
Transport Temp	36°F - 46°F	36°F - 46°F	36°F - 46°F	36°F - 46°F
Storage Temp	36°F - 46°F	36°F - 46°F	36°F - 46°F	36°F - 46°F
Target Supply	3B	1B in 2021	1B by mid 2021	2B+ in 2021
At Risk US Government Purchase	400M	100M	100M	100M

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Sources: BioPharma Dive, NIH, ClinicalTrials.gov, Johnson & Johnson News, Sanofi News

CMS Payment Toolkit Information – Reimbursement Landscape

Provider agreement language updated to reflect that the vaccine must be provided at no cost to recipient;

Vaccine cost covered by federal government; administrative costs covered by Medicare, Medicaid, and commercial insurance; HRSA will reimburse providers for COVID-19 vaccines administered to uninsured individuals.

Medicaid

- As long as a state is claiming enhanced Medicaid match as part of the Public Health Emergency, the state must cover, without cost sharing, "any testing services and treatments for COVID-19, including vaccines;" this extends to vaccines authorized via EUA.

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Medicare

- The CARES Act mandated that Medicare Part B cover a COVID-19 vaccine without any cost sharing in cases where "such vaccine is licensed under section 351 of the Public Health Service Act"; a vaccine authorized by an EUA would not meet this standard.
- To address this gap, CMS announced a new rule on October 28th guaranteeing Medicare coverage for a vaccine approved via EUA; this guarantee applies to beneficiaries enrolled in both traditional Medicare and Medicare Advantage.

Uninsured

- HRSA will reimburse providers for COVID-19 vaccines administered to uninsured individuals, once a COVID-19 vaccine receives either an EUA or full licensure from the FDA.Provider Relief Fund (https://www.hrsa.gov/CovidUninsuredClaim)
- Consistent with HRSA's prior guidance regarding treatment services, an individual with public or private health coverage will be deemed "uninsured" for purposes of the HRSA Program if the individual has a form of health coverage that excludes vaccines (e.g., individuals enrolled in a limited Medicaid family planning program).

Commercial

- Current law and regulations require vaccines recommended by ACIP to be covered as an Essential Health Benefit without cost sharing.

NC COVID-19 Vaccination Plan: Vision of Success

GOAL

Immunize every person living in North Carolina who is eligible and wants to receive a COVID-19 vaccine

GUIDING PRINCIPLES



All North Carolinians have equitable access to vaccines



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



Transparent, accurate, and frequent public communications is essential to building trust



Data is used to promote equity, track progress and guide decision-making



Appropriate stewardship of resources and continuous evaluation and improvement drive successful implementation

Advisors

- **COVID-19 Vaccine Advisory Committee**
  - **Purpose**: Provide updates from industry and stakeholders to ensure alignment
  - Group of >60 stakeholders

- **Historically Marginalized Populations Advisory Group**
  - **Purpose:** Identify and address issues related to HMP in the COVID pandemic response
  - Vaccine team presents regularly to HMP Advisory Group for input and partnership opportunities
  - Group of >80 internal and external stakeholders

- **COVID-19 Vaccine Communications Advisory Group**
  - **Purpose**: Enhance the development of North Carolina's COVID-19 Vaccine Communications Plan and to serve as dissemination partners to extend the reach of the communications efforts, especially to prioritized, critical, and historically marginalized populations

COVID-19 Vaccinations: Those most at risk get it first.

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A tested, safe and effective vaccine will be available to all who want it, but supplies will be limited at first. Independent state and federal public health advisory committees have determined that the best way to fight COVID-19 is to start first with vaccinations for those most at risk, reaching more people as the vaccine supply increases from January to June. Keep practicing the 3W's—wear a mask, wait six feet apart, wash your hands—until everyone has a chance to vaccinate.

1a Health care workers fighting COVID-19 & Long-Term Care

Every health care worker at high risk for exposure to COVID-19—doctors, nurses, and all who interact and care for patients with COVID-19, including those who clean areas used by patients, and those giving vaccines to these workers.

Long-Term Care staff and residents—people in skilled nursing facilities and in adult, family and group homes.

1b Adults at highest risk of severe illness and those at highest risk for exposure

Adults with two or more chronic conditions that put them at risk of severe illness as defined by the CDC, including conditions like cancer, COPD, serious heart conditions, sickle cell disease and Type 2 diabetes, among others.

Adults at high risk of exposure including essential frontline workers (police, food processing, teachers), health care workers, and those living in prisons, homeless shelters, migrant and fishery housing with 2+ chronic conditions.

Those working in prisons, jails and homeless shelters (no chronic conditions requirement).

2 Adults at high risk for exposure and at increased risk of severe illness

Essential frontline workers, health care workers, and those living in prisons, homeless shelters or migrant and fishery housing.

Adults 65+

Adults under 65 with one chronic condition that puts them at risk of severe illness as defined by the CDC.

3 Students and critical industry workers

College and university students.

K-12 students when there is an approved vaccine for children.

Those employed in jobs that are critical to society and at lower risk of exposure.

4 Everyone who wants a safe and effective COVID-19 vaccination



DECEMBER 8, 2020

VACCINE DISTRIBUTION PRIORITIZATION FRAMEWORK

Risk-based prioritization based on National Academy of Medicine Framework for Equitable Allocation of COVID-19 and CDC Advisory Committee Immunization Practice. Refined by input by North Carolina Institute of Medicine Vaccine Advisory Committee. May be revised based on Phase III clinical trial safety and efficacy data and further federal guidance

Phase 1

Phase 1a:

- **Health care workers at high risk** for COVID-19 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**,** health care trainees(e.g., medical students, pharmacy students, nursing students, etc.), morticians/funeral home staff, pharmacists, public health nurses, public health and emergency preparedness workers who meet the above definition of “high risk of exposure.”
- **Long Term Care staff and Residents** (e.g., Skilled Nursing Facilities, adult care homes, family care homes, and group homes; individuals with intellectual and developmental disabilities who receive home and community-based services and the workers directly providing those services)

Phase 1b:

- **Adults with high risk of complications** per CDC and staff of congregate living settings

Operationally prioritize settings based on risk of exposure

- **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 (e.g., 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), education staff (e.g., child care, K-12 or IHE) 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*:

Phase 2

- 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
- Education staff (Child Care, K-12, IHE) without 2+ Chronic Conditions
- Other adults age 18-64 with one chronic condition*
- 65+ year olds with one or no chronic conditions*

Phase 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
- K-12 students (if data from clinical trials), college students

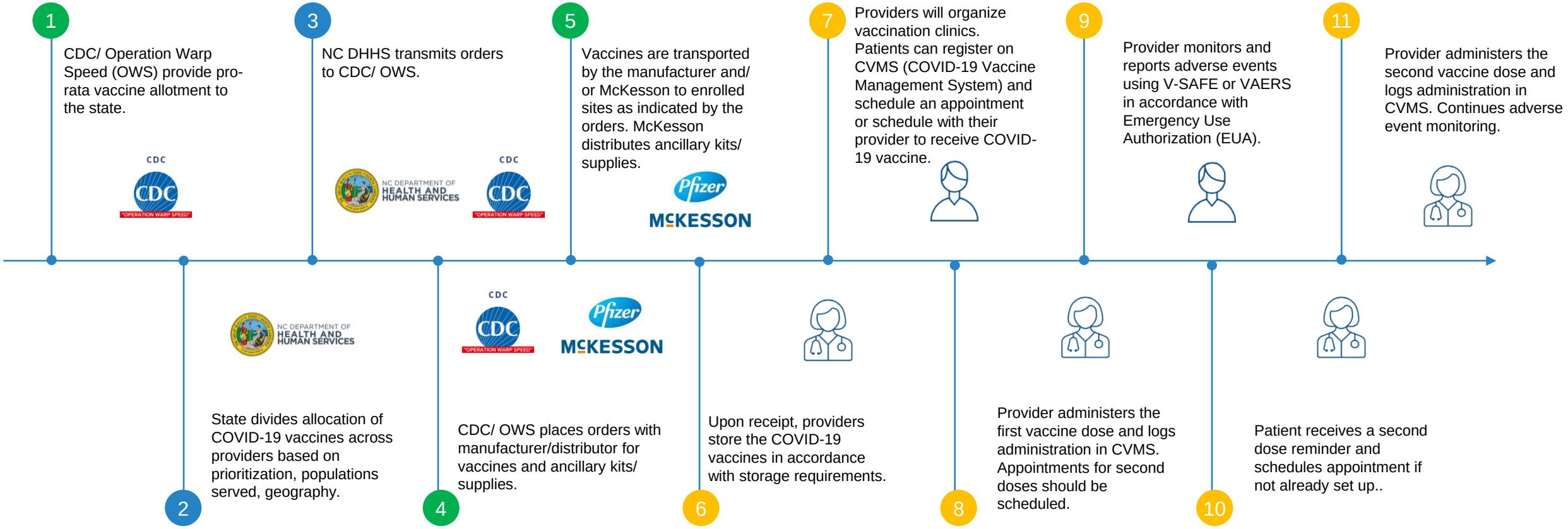
Phase 4

- Remaining population

NC COVID-19 Vaccine Operational Plan: Overview

	Planning *Before vaccine is available*	Implementation *Begins when first vaccine doses are allocated to states*	Adjustment *Large number of vaccine doses available*	Transition *Sufficient supply of vaccine doses for entire population*
Populations	• **Establish priority groups**	• Phase 1 populations • Stabilize health care delivery system and protect individuals at highest risk	• Continue to move through phased populations as vaccine supply allows	• Offer vaccination to all populations through Phases 3 and 4
Vaccination Channels	• **N/A**	• Through local health departments and on-site vaccination clinics (in closed settings)	• Require more points of access, mass vaccination clinics, and broad vaccination sites	• Vaccination in established channels • Fewer mass, mobile, or community-based clinics
Enrollment/ Ordering/ Allotment	• **Identify/enroll providers** • **Expect CDC centralized distribution to providers**	• Continue to enroll providers • Allocations to state, allotted to enrolled providers	• Transition to provider ordering vaccines based on need for population and local demand	• Ordering similar to annual seasonal flu vaccine campaign
Shipment	• **None shipped** • **Expect vaccine and anc. supplies procured and distributed by fed gov't**	• Shipment in increments of 1,000 for some • May require ultra-cold storage & 2-dose series	• Shipment minimum of 100 for most vaccines	• Move to high supply/lower demand
Data	• **Confirm capability for required functionality, data collection, and reporting**	• Data systems for ordering, scheduling, dose tracking, inventory, data collection and reporting requirements	• Data systems for ordering, scheduling, dose tracking, inventory, data collection and reporting requirements	• Data systems for ordering, scheduling, dose tracking, inventory, data collection and reporting requirements

Vaccine Journey



- Federal Responsibility
- State Responsibility
- Provider Level

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Vaccine: Provider enrollment

AS OF 12/1/2020

PROVIDER ENROLLMENT DASHBOARD

115 Hospitals **(100%)**

130 FQHC / RHC / Free & Charitable Clinics **(32%)**

100 LHDs **(100%)**

Enrollment Complete	Currently Enrolling	Next to Enroll	Coming Soon
Phase 1A providers: Hospitals and Local Health Departments (LHDs)	**Phase 1B providers**: FQHC's, Rural Health Centers and Free and Charitable Clinics Federal enrollment of pharmacies (Walgreens and CVS) for long term care settings	Continue **Phase 1B providers** such as corrections facilities, occupational health, providers serving congregate living settings, etc.	Remaining provider enrollment is expected to begin in mid- late December (e.g. primary care, urgent care) Federal enrollment of more pharmacies

NC's provider enrollment strategy is based upon **the prioritization strategy**

Vaccine: Federal long-term care pharmacy program

LTC ENROLLMENT DASHBOARD

~498 Adult Care Homes **(84%%)**

427 Skilled Nursing Facilities **(100%)**

KEY PROGRAM DATES

- **12/7** — **Notification of Fed Government to turn on program**
- **12/21** — **Start pulling vaccines from Moderna allocation banks**
- **12/28** — **Start administering vaccines**

The federal government – in coordination with the CDC – has created the **Pharmacy Partnership for Long-term Care (LTC) Program** in partnership with CVS and Walgreens to vaccinate those in LTC settings

Program Details

As part of this program, pharmacies will:

- Schedule and coordinate clinic dates with each facility
- Order vaccines and associated supplies
- Ensure cold chain management for vaccine
- Provide on-site administration of vaccine including patient information and consents as needed
- Report required vaccination data to local, state/territorial, and federal jurisdictions within 72 hours of administration

Allocation will come from state allocation starting with NC's week 2 allocation

Vaccine: First allocations

Week of Dec 13-19

85,800 doses
(88 increments of 975)

Initial shipment will go to **53 hospitals:**
11 early ship sites – Ultra-cold storage
42 others distributed according to **bed capacity, health care workers, and county population**

Future allocations will factor in **administration data and on-hand inventory**

Hospitals

Week of Dec 20-26

Doses TBD

Pfizer shipments will focus on more **hospitals & health systems**

Hospitals

175,900 doses
(increments of 100)

Moderna shipments will focus initially on **Long Term Care** and then **health departments and community providers**

Long Term Care / Local Health Departments

Vaccine: COVID -19 Vaccine Management System (CVMS)

11/23

CVMS Provider Enrollment Soft Launch invitation to:
- Goshen Community Health
- Carolina Family Health Centers
- Rural Health Group
- Realo Discount Drugs
- Oak Street Health

11/30

CVMS Priority Access Preview attended by 120+ participants

12/8

CVMS MVP Soft Launch for subset of Phase 1a providers

12/10

CVMS MVP Go-Live
And available to Phase 1a and Phase 1b providers

12/17

CVMS MVP R2 Go-Live
Additional features released

TBD

CVMS R3+ Go-Live
Future features and enhancements available within CVMS

What is CVMS?

CVMS is a secure, cloud-based **vaccine management solution** for COVID-19 that **enables vaccine management** and **data sharing** across providers, hospitals, agencies, and local, state, and federal governments on one common platform

When the CVMS is launched on 12/10, providers will be able to:
- **Enroll** in the **COVID-19 Vaccine Program**
- **Employees** can **register** for **vaccination**
- **Manage** vaccine **inventory**
- **Track** vaccine **administration data**

Who will use CVMS?

- State officials will **enroll providers** and verify provider eligibility along with **verifying site readiness**
- Providers will **verify patient eligibility**, **log dosage administration**, and **track** frequency and timing of **additional dosages**
- **Training** for Phase 1 providers started **week of 11/30**
- CVMS will be available to select providers for a **soft launch on 12/8** and the **remaining providers** will have access to the system on **12/10**

Who won't use CVMS?

- **Pharmacies**, such as CVS and Walgreens, **will not use CVMS** to administer and manage vaccines
- Pharmacies will to use their **current systems**
- Building capability to ingest vaccine data files from pharmacies into CVMS

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COVID Vaccine Communications: North Carolina's Commitment

Provide early, transparent, consistent, and frequent communications so that North Carolinians:



Trust the information that they receive from NC DHHS and local health departments about COVID-19 vaccinations



Understand the benefits and risks of COVID-19 vaccinations



Make informed decisions about COVID-19 vaccinations



Know how and where to get a COVID-19 vaccination

Communications Strategy Informed by Research

neimand collaborative

One in three North Carolinians say they will definitely get a COVID 19 vaccine once approved by the FDA and offered for free. Another one in four say they will probably get the vaccine.

Less likely to say they will get vaccine

- Blacks/African Americans
- Females
- High school or some college only
- Lower income groups
- Under age 35

More likely to say they will get vaccine

- Hispanic, Latinx
- Asians
- White Non-Hispanics
- Males
- College or higher educated
- Higher income residents
- Ages 65 and older

Most common reasons for vaccine avoidance:

- Concerned about side-effects
- Feel it hasn't been tested enough
- Don't want to be first to take the vaccine

Core COVID-19 Vaccine Messages

PROCESS

Great care has been taken to make sure COVID-19 vaccines are safe and effective.

- **Scientists had a head start.** Although the vaccines were developed quickly, they were built upon years of work in developing vaccines for similar viruses. Development time was cut without cutting corners.
- **Testing was thorough and successful.** More than 70,000 people participated in clinical trials for two leading vaccines to see if they are safe and effective. To date, the vaccines are nearly 95% effective in preventing COVID-19 with no safety concerns

EXPECTATIONS

A tested, safe and effective vaccine will be available to all who want it, but supplies will be limited at first. The best way to fight COVID-19 is to start first with vaccinations for those most at risk, then reach more people as the vaccine supply increases throughout 2021

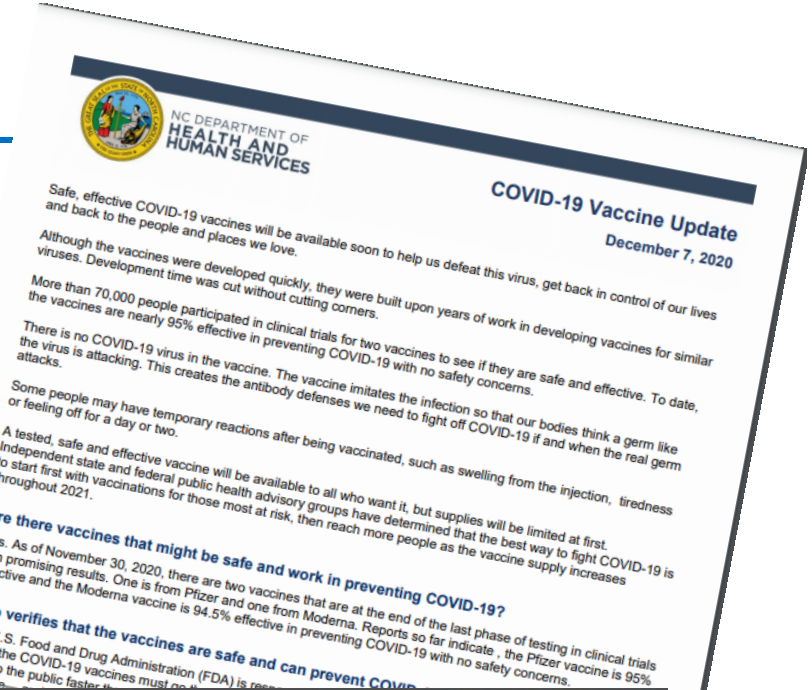
INCLUSIVITY

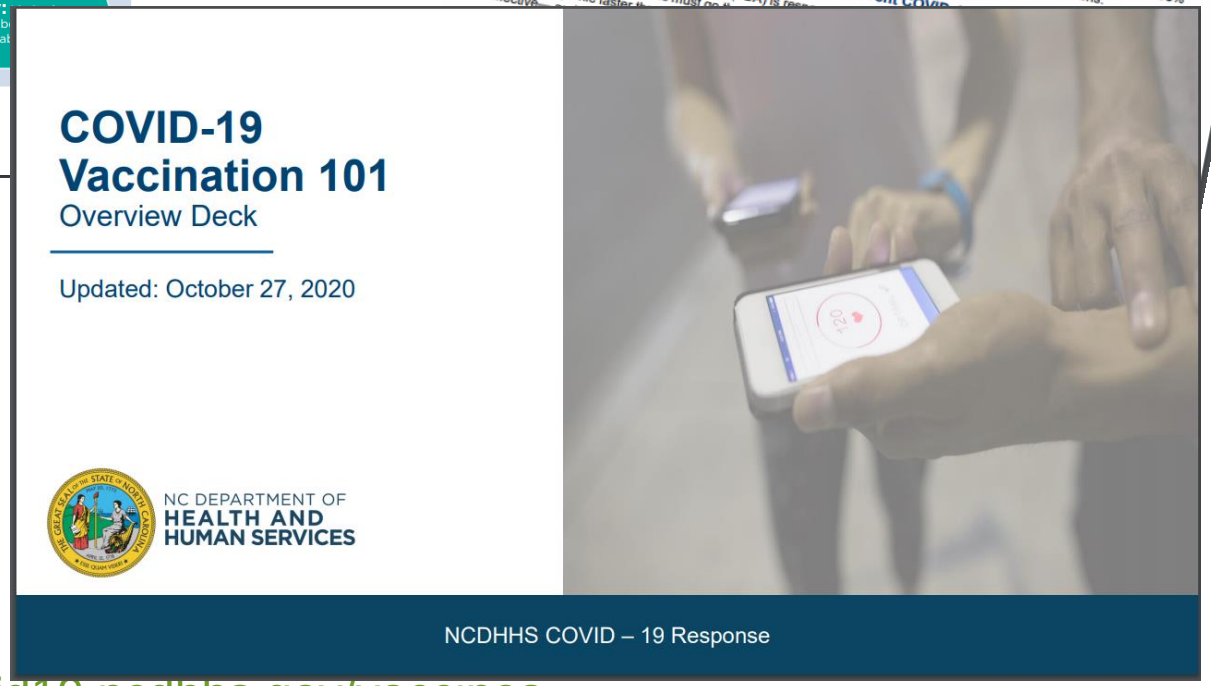
North Carolina is drawing upon the experience and expertise of leaders from historically marginalized communities to develop and implement its vaccine plan

Communication Tools - https://covid19.ncdhhs.gov/vaccines

COVID-19 Communication Tools







https://covid19.ncdhhs.gov/vaccines

Questions?