NC DHHS COVID-19 Vaccination Briefing

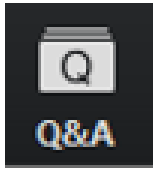
What North Carolina Practices Need to Know

December 15, 2020

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

Logistics for today's COVID-19 Forum

Question during the live webinar



Technical assistance

technicalassistanceCOVID19@gmail.com

https://www.communitycarenc.org/newsroom/coronavirus-covid-19-information

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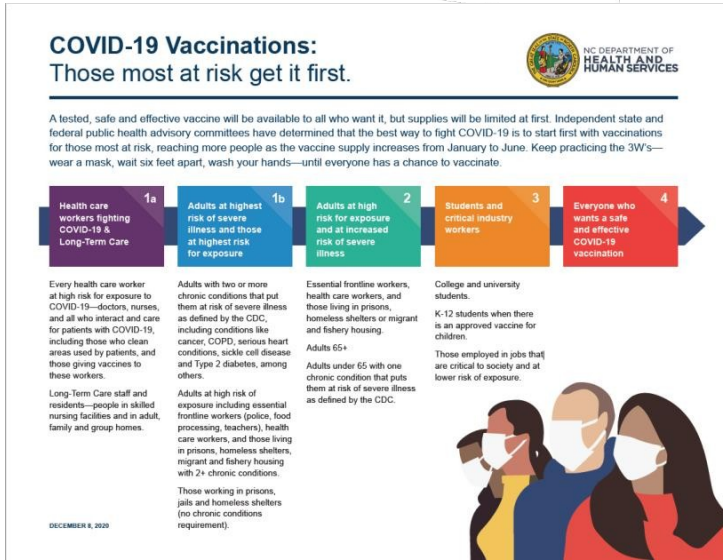
COVID-19 Prevention: Key Messages for December

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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Y’all are doing great…

Agenda

- Vaccine Authorization and Guidance
- NC Vaccine Response Principles
- Priority Groups
- Overview of Plan
- Provider Enrollment
- Communications
- Questions

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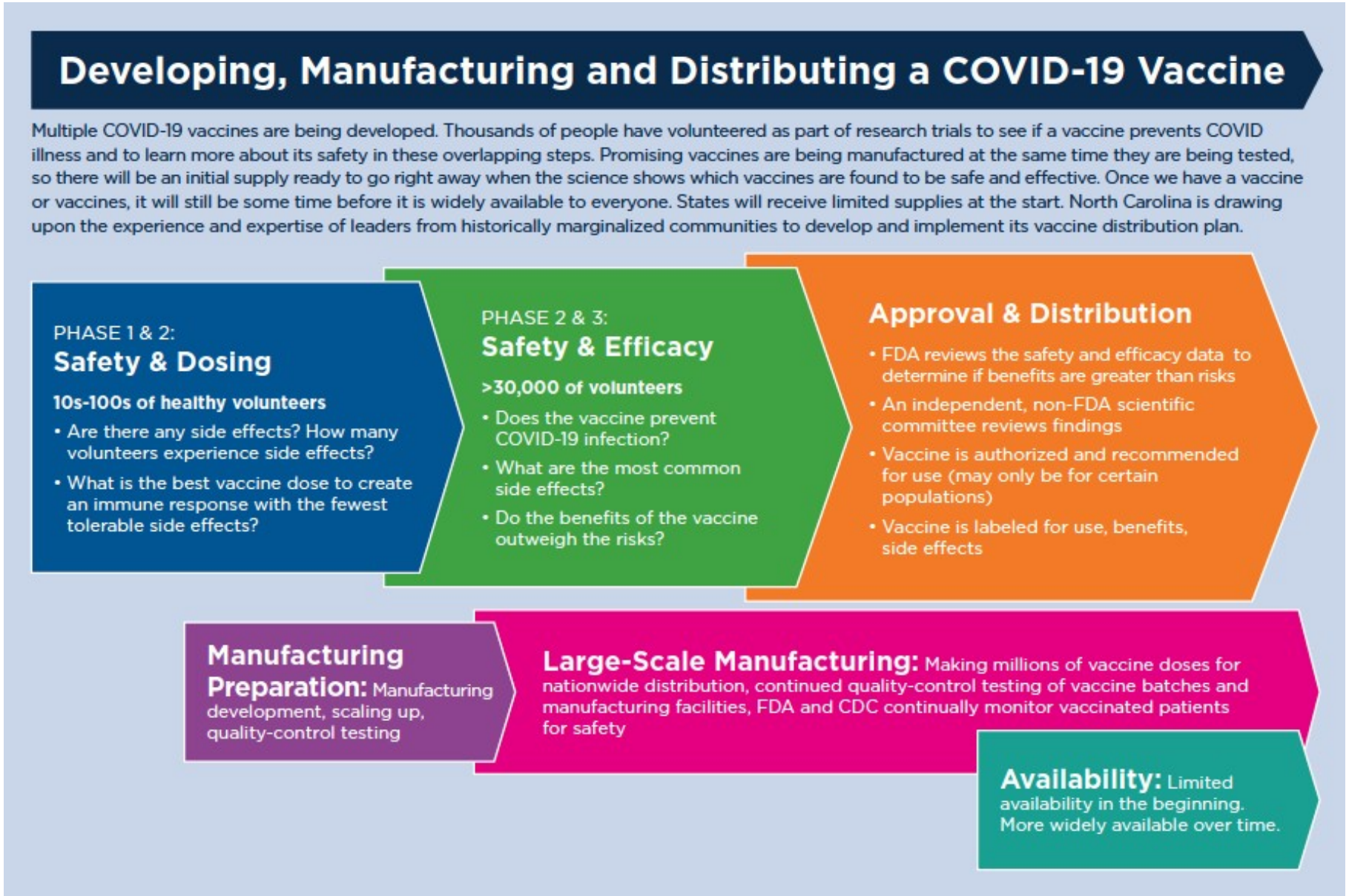
The COVID-19 Vaccine Development Process



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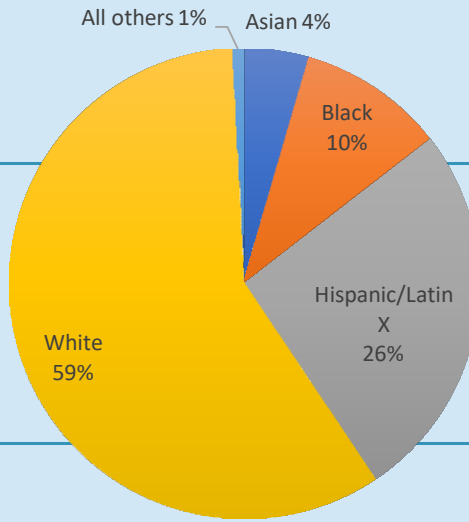
https://files.nc.gov/covid/documents/Vaccine-Timeline.pdf

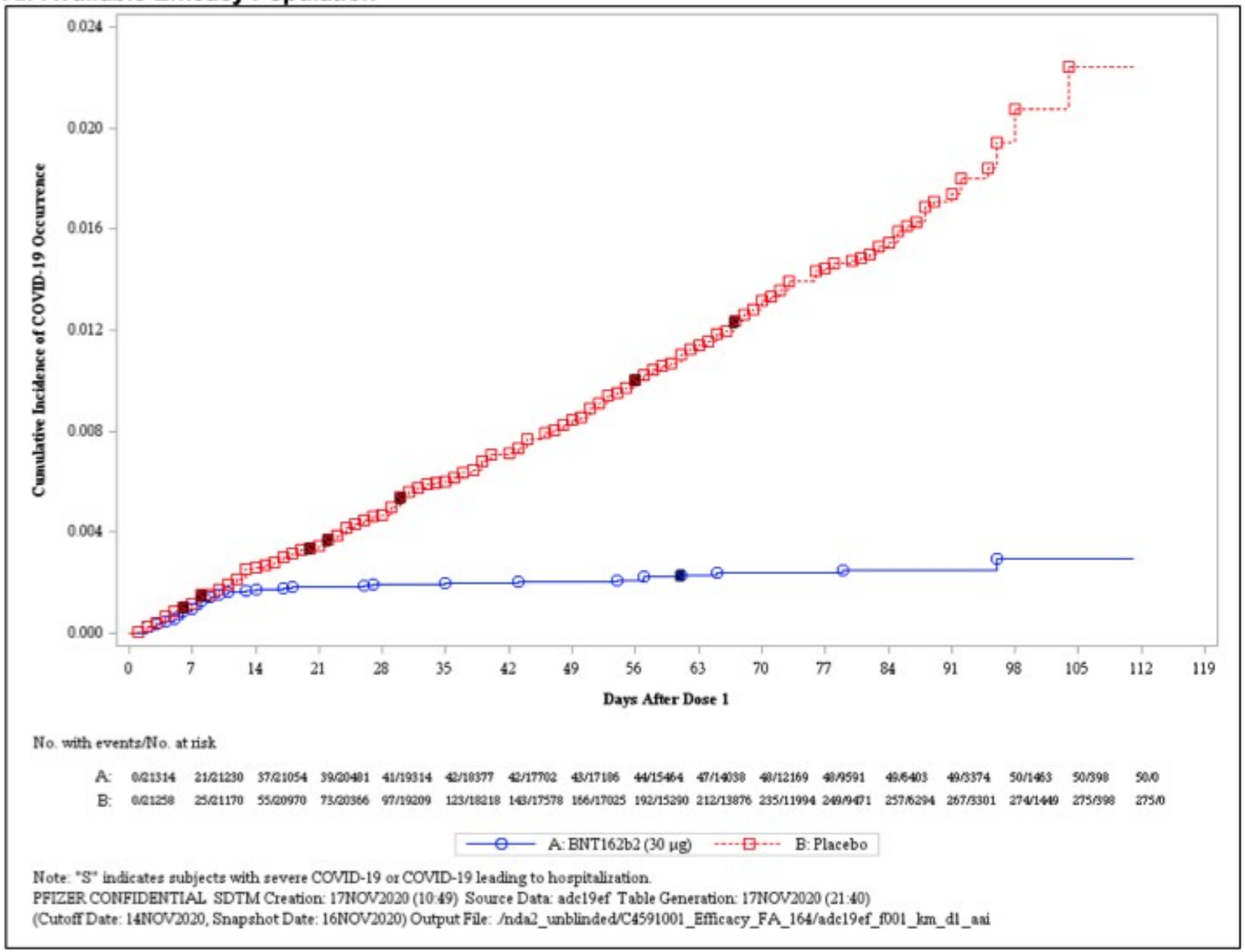
Pfizer Vaccine – Data Brief

Enrollment	• Phase 3 trial included over 43,000 participants, 42% with diverse backgrounds • 16 - 85 years, 46% with co-morbidities (e.g., cancer, heart disease, lung disease, diabetes, obesity, hypertension)
Efficacy Data	• 95% effectiveness in preventing illness, 7 days after second dose. • 162/170 cases were in placebo group, 9/10 severe cases were in placebo group • Uniform effectiveness across age, co-morbidity, demographic groups • No waning of protection for at least 2 months after second doses • Did not look at data on if a vaccinated person can carry/transmit the virus
Authorization	• Applied for EUA 11/20/20, FDA Advisory Committee endorsed 12/10/20 • FDA EUA 12/11/20, ACIP recommendation 12/12/20
Storage	• Requires ultra-cold storage (-75 degrees Celsius). • Permanent or shipping container refill with dry ice every 5 days up 30 days. 5 days at refrigerated temps
Dosing	• 2-dose schedule; 21 days apart (17-21 days), some protection starts 14 days after 1st dose, • Insufficient data to determine protection of 1 dose because almost all got a second dose
Type of Vaccine	• mRNA technology from the coronavirus's own genes. Tiny piece of genetic material that instructs people's cells make 1 viral protein (spike protein) that triggers immune system to produce antibodies against the COVID virus. mRNA technology has been developing for past 2-3 years for other viruses
Safety	• No reports of serious safety during clinical trials. 4 cases of Bell's palsy in vaccine group, same as general rate in population, but will monitor. Temporary reactions (e.g., soreness at site, fatigue, headache, fever) noted 24-48 hours after vaccination, lasts 1-2 days, more after second dose, less with people over 55.



Equal percentage of people with and without evidence of prior infection in placebo group became infected (1.3%). "While limited, these data do suggest that previously infected individuals can be at risk of COVID-19 re-infection and could benefit from vaccination."

Figure 2. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1, Dose 1 All-Available Efficacy Population



FREQUENCY OF TEMPORARY REACTIONS IN CLINICAL TRIALS BY DOSE AND AGE GROUP, MORE WITH SECOND DOSE, LESS WITH OLDER PEOPLE

Symptom	18-55 year olds		> 55 years	
	Dose 1	Dose 2	Dose 1	Dose 2
Local reaction				
Pain at site	83%	78%	71%	66%
Redness at site	5%	6%	5%	7%
Swelling at site	6%	6%	7%	8%
Systemic				
Fatigue	47%	59%	34%	51%
Headache	42%	52%	25%	39%
Muscle pain	21%	37%	14%	29%
Chills	14%	35%	6%	23%
Diarrhea	11%	10%	8%	8%
Joint pain	11%	22%	9%	19%
Fever	3.7%	16%	1.4%	11%
Vomiting	1%	2%	0.5%	0.7%

3/15,000 people receiving vaccine outside of clinical trial had a severe allergic reaction

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More from FDA Emergency Use Authorization

Data points from EUA

- Authorized for use for people 16 years of age and older
- Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.
- Lactation Risk Summary Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.
- There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

Helpful Links

- Pfizer Website
- Pfizer data briefing document for FDA
- Full Pfizer-BioNTech COVID-19 Vaccine EUA Letter of Authorization
- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers)
- Fact Sheet for Recipients and Caregivers
- The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine
- Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine
- CDCs COVID-19 Vaccination Communication Toolkit for Medical Center, Clinics, and Clinicians

MORE FROM THE FDA EUA – INGREDIENTS, ALLERGIES

- **Ingredients** - Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine contains:
  - 30 mcg of a nucleosidemodified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.
  - lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), **0.05 mg 2[(polyethylene glycol)**-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3- phosphocholine, and 0.2 mg cholesterol)
  - 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose.
  - The diluent (0.9% Sodium Chloride Injection) contributes an additional 2.16 mg sodium chloride per dose.
  - **The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative.**

- **Contraindications** - Do not administer to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine

- **Warnings** - Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

MORE FROM FDA EUA – CONSENT

- Due to the FDA Emergency Use Authorization, written informed consent as part of participation in an investigational vaccine development process is no longer required.

- Per the EUA, the vaccination provider, must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.cvdvaccine.com to obtain the Fact Sheet) prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine, including:
  - FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine.
  - The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine.
  - The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
  - Information about available alternative vaccines and the risks and benefits of those alternatives.

- Consent must be obtained prior to vaccination, but that consent can be verbal or written.

COVID-19 Vaccine Safety Monitoring Overview

- Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems with vaccine. VAERS continuously monitors the safety of vaccines given to children and adults in the US. VAERS is co-administered by CDC and FDA.

- The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
  - vaccine administration errors whether or not associated with an adverse event
  - serious adverse events* (irrespective of attribution to vaccination)
  - cases of Multisystem Inflammatory Syndrome (MIS) in adults and children
  - cases of COVID-19 that result in hospitalization or death.

- Vaccination provider should provide V-safe information for patients to self-enroll and report adverse events
  - CDC has developed a new, voluntary smartphone-based tool, v-safe, that uses text messaging and web surveys to provide personalized health check-ins after patients receive a COVID-19 vaccination. V-safe allows patients to report any side effects after COVID-19 vaccination to CDC in almost real time. It also gives them a convenient reminder to get their second COVID-19 vaccine dose if they need one.

COVID-19 Vaccine Safety Monitoring Website Links and Phone Number

Vaccine Adverse Event Reporting System (VAERS)

www.vaers.hhs.gov

(800) 822-7967

V-safe is a smartphone-based tool **only for COVID-19 vaccine** that uses text messaging and web surveys to provide personalized health check-ins to vaccine recipients following COVID-19 vaccination and serves as an important active surveillance system for adverse events.

V-safe also provides second dose vaccine reminders

All providers who administer COVID-19 vaccine are asked to provide printed hard copies of the v-safe information sheet to each vaccinated individual and counsel them on the importance of enrolling in v-safe.

CENTERS FOR DISEASE CONTROL AND PREVENTION – ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

- **Vaccine Administration**
  - Pfizer-BioNTech COVID-19 vaccine should be administered alone with minimum interval of 14 days before or after administration with any other vaccines
  - Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection
  - Vaccination should be deferred until recovery from acute illness (if person had symptoms) and criteria have been met to discontinue isolation
  - No minimal interval between infection and vaccination - however, current evidence suggests reinfection uncommon in the 90 days after initial infection and thus persons with documented acute infection in the preceding 90 days may defer vaccination until the end of this period, if desired
- **Persons who previously received passive antibody therapy for COVID-19**
  - Currently no data on safety or efficacy of COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment
  - Vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses
- **Persons with underlying medical conditions or immunocompromised persons**
  - Vaccine may be administered to persons with underlying medical conditions who have no contraindications to vaccination
  - Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19 and may still receive COVID-19 vaccine unless otherwise contraindicated

ACIP CLINICAL RECOMMENDATIONS

- **Pregnancy and Lactation**
  - COVID-19 and pregnancy – Increased risk of severe illness (ICU admission, mechanical ventilation and death) – Might be an increased risk of adverse pregnancy outcomes, such as preterm birth
  - mRNA vaccine is not a live virus and the mRNA is degraded quickly by normal cellular processes
  - If a woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine and is pregnant or lactating, she may choose to be vaccinated.

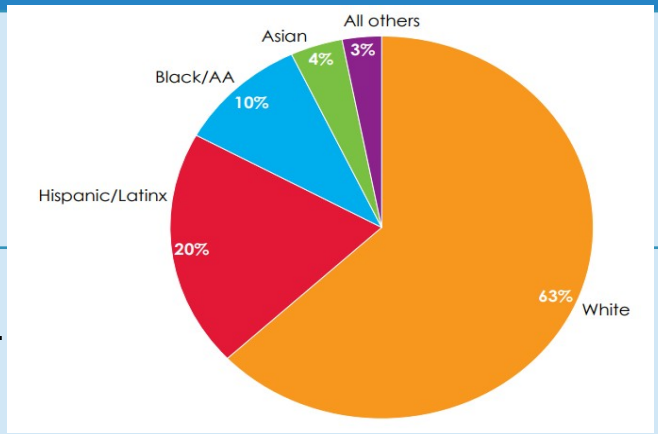
- **Contraindications and Precautions**
  - Because of reports of anaphylactic reactions vaccinated outside of clinical trials,
  - **Per EUA Contraindications** - Do not administer to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine

  - ACIP proposed additional guidance:
    - Persons who have had a severe allergic reaction to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) should not receive the Pfizer-BioNTech vaccine at this time
    - Vaccine providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
      - Persons with a history of anaphylaxis: 30 minutes
      - All other persons: 15 mins

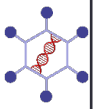
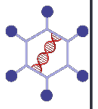
Moderna Vaccine	
Enrollment	• Phase 3 trial included 30,000 adult participants • 37% with diverse backgrounds. • 27% with co-morbidities • (e.g., diabetes, heart disease, lung disease, obesity)

Preliminary Efficacy Data	• November 30 Press Release data analysis
	  • 94.1% effectiveness in preventing illness, 14 days after second dose.
	  • 185/196 cases were in placebo group
	  • 30/30 severe cases were in placebo group
	• Lasts at least 90 days after 2nd dose

Timing of EUA	• Applied for EUA 11/30 • FDA Review Dec 17th
Temperature and Storage	• Requires storage at -20 degrees Celsius (similar to the chickenpox vaccine) for up to 6 months. • Lasts up to 30 days at refrigerated temperatures.
Dosing	• 2-dose schedule • Administered 28 days apart
Type of Vaccine	• mRNA technology
Safety	• No reports of serious safety concerns. Temporary reactions (e.g., fever, soreness at site of injection, fatigue) noted 24-48 hours after vaccination, more after second dose



Updates on Remaining Operation Warp Speed Candidates

	AstraZeneca	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.

First dose $16.94

Second dose $28.39

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.

First dose $16.94

Second dose $28.39

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

Vaccine Distribution Prioritization: Drilldown Framework

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Risk-based prioritization based on National Academy of Medicine Framework for Equitable Allocation of COVID-19 and CDC Advisory Committee Immunization Practice. Refined with input from the 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.

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

Health care workers at high risk for COVID-19 exposure based on work duties or vital to the initial COVID-19 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-19 and 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), morticians/funeral home staff, pharmacists, public health nurses and 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)

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

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

Migrant farm and fisheries workers in congregate living settings 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* or age 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/organizations staff (e.g., religious organizations), education staff (e.g., child care, K-12 and colleges) and workers in government, public health, emergency management and public safety whose functioning is imperative to the COVID-19 response)

Adults age 18+ with 2+ chronic conditions*

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

Migrant farm and fisheries workers in congregate living settings 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, colleges) without 2+ chronic conditions*

Other adults age 18-64 with one chronic condition*

All adults age 65+ not included in Phase 1a or 1b

3 — Students and critical industry workers

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 (supported by data from clinical trials) and college students

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

Remaining population

** Defined by CDC as increased risk for COVID-19: www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html*

Vaccine Distribution Prioritization: Drilldown Framework

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

Health care workers at high risk for COVID-19 exposure based on work duties or vital to the initial COVID-19

Expected uptake: ***207,000 – 238,000 individuals***

COVID-19 and 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), morticians/funeral home staff, pharmacists, public health nurses and 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)

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

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

Expected uptake: ***520,000 – 713,000 individuals***

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/organizations staff (e.g., religious organizations), education staff (e.g., child care, K-12 and colleges) and workers in government, public health, emergency management and public safety whose functioning is imperative to the COVID-19 response)

Adults age 18+ with 2+ chronic conditions*

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

Migrant farm and fisheries workers in congregate living

Expected uptake: ***1.18 M – 1.57 M individuals***

Education staff (child care, K-12, colleges) without 2+ chronic conditions*

Other adults age 18-64 with one chronic condition*

All adults age 65+ not included in Phase 1a or 1b

3 — Students and critical industry workers

Workers in industries critical to the functioning of

Expected uptake: ***574,000 – 767,000 individuals***

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

Remaining population

Expected uptake: ***3.60 M – 4.00 M individuals***

** Defined by CDC as increased risk for COVID-19: www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html*

Where are people in Phase 1a getting vaccinated?

Health care workers at highest risk for COVID-19 exposure

- Administering vaccine in initial closed or targeted vaccination clinics
- In hospitals or local health departments who have received early shipments of vaccine

Long-Term Care (LTC) staff and residents

- On-site in long-term care facilities in the Pharmacy Partnership for Long-Term Care Program with CVS and Walgreens
- Some will also be vaccinated in local health departments if not with a facility participating in the Pharmacy Partnership program, through other long-term pharmacies, other mobile providers

How will people know if they are in Phase 1a?

Health care workers at high risk for COVID-19 exposure

- Health care employers should determine who meets the criteria for phase 1a
- Health care employers should work with local hospitals or local health departments to determine availability of vaccine and vaccine clinics
- Health care employers should notify employees if they qualify for Phase 1a with instructions for where to be vaccinated

Long-Term Care (LTC) staff and residents

- All long-term care staff and residents qualify in Phase 1a
- LTC facilities will be notified when vaccines will be available to be administered to staff and residents.

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**	• Initially through health systems, long term care, local health departments and on-site vaccination clinics	• Require more points of access, mass vaccination clinics, community based, 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 975 for some, 100 for others • Some 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

1. CDC/ Operation Warp Speed (OWS) provide pro-rata vaccine allotment to the state.
2. State divides allocation of COVID-19 vaccines across providers based on prioritization, populations served, geography.
3. NC DHHS transmits orders to CDC/ OWS.
4. CDC/ OWS places orders with manufacturer/distributor for vaccines and ancillary kits/ supplies.
5. Vaccines are transported by the manufacturer and/ or McKesson to enrolled sites as indicated by the orders. McKesson distributes ancillary kits/ supplies.
6. Upon receipt, providers store the COVID-19 vaccines in accordance with storage requirements.
7. Providers will organize vaccination clinics. Patients can register on CVMS (COVID-19 Vaccine Management System) and schedule an appointment or schedule with their provider to receive COVID-19 vaccine.
8. Provider administers the first vaccine dose and logs administration in CVMS. Appointments for second doses should be scheduled.
9. Provider monitors and reports adverse events using V-SAFE or VAERS in accordance with Emergency Use Authorization (EUA).
10. Patient receives a second dose reminder and schedules appointment if not already set up..
11. Provider administers the second vaccine dose and logs administration in CVMS. Continues adverse event monitoring.

- Federal Responsibility
- State Responsibility
- Provider Level

Vaccine: Provider enrollment

AS OF 12/1/2020

PROVIDER ENROLLMENT DASHBOARD

117 Hospitals **(100%)**

101 FQHC / RHC / Free & Charitable Clinics

100 LHDs **(100%)**

Enrollment Complete	Currently Enrolling	Next to Enroll	Coming Soon
Initial provider enrollment: Hospitals and Local Health Departments (LHDs)	FQHC's, Rural Health Centers and Free and Charitable Clinics Federal enrollment of pharmacies (Walgreens and CVS) for long term care settings	Corrections health, occupational health, providers serving congregate living settings, etc.	Remaining provider enrollment is expected to begin in early January 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 **(79%%)**

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 2 weeks' allocations

First doses, second doses held back by federal gov to ship at later date

Week of Dec 13-19

85,800 doses
(88 increments of 975)

Pfizer

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

Pfizer shipments will focus on **hospitals with week 1 allocations & Large health departments**

Hospitals

Local Health Departments

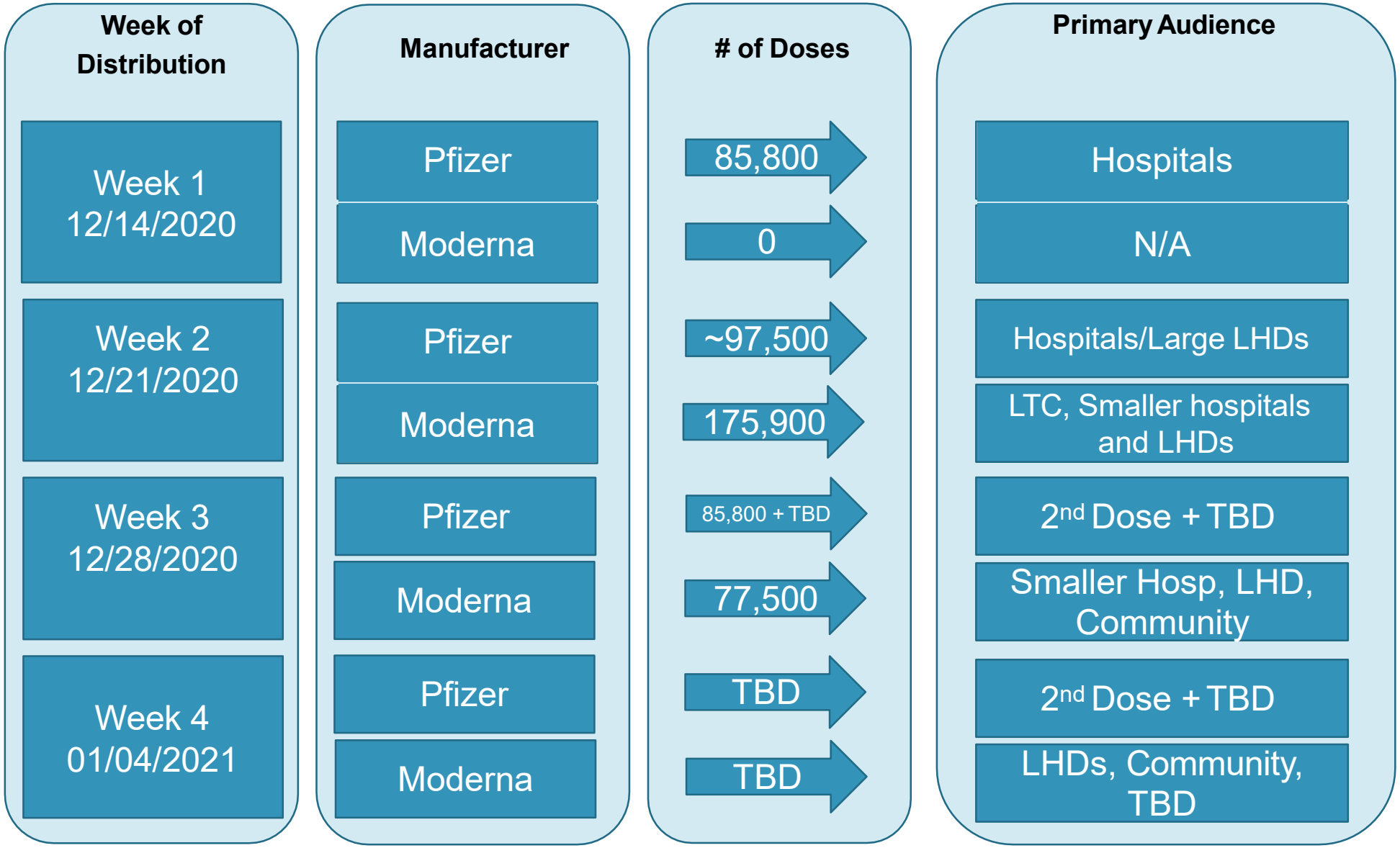
175,900 doses
(increments of 100)

moderna

Moderna shipments will focus initially on **Long Term Care (96,900), smaller hospitals and health departments (79,000)**

Hospitals/Long Term Care/ Local Health Departments

DRAFT Weekly vaccine allocation by manufacturer



*Assumption: serving all for LTC partnership

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 some 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

CVMS launched initial functionality on 12/10. Providers will be able to:
- **Enroll** in the **COVID-19 Vaccine Program**
- **Register** their employees for vaccination
- **Manage** vaccine **inventory**
- **Track** vaccine **administration data**

Who will use CVMS?

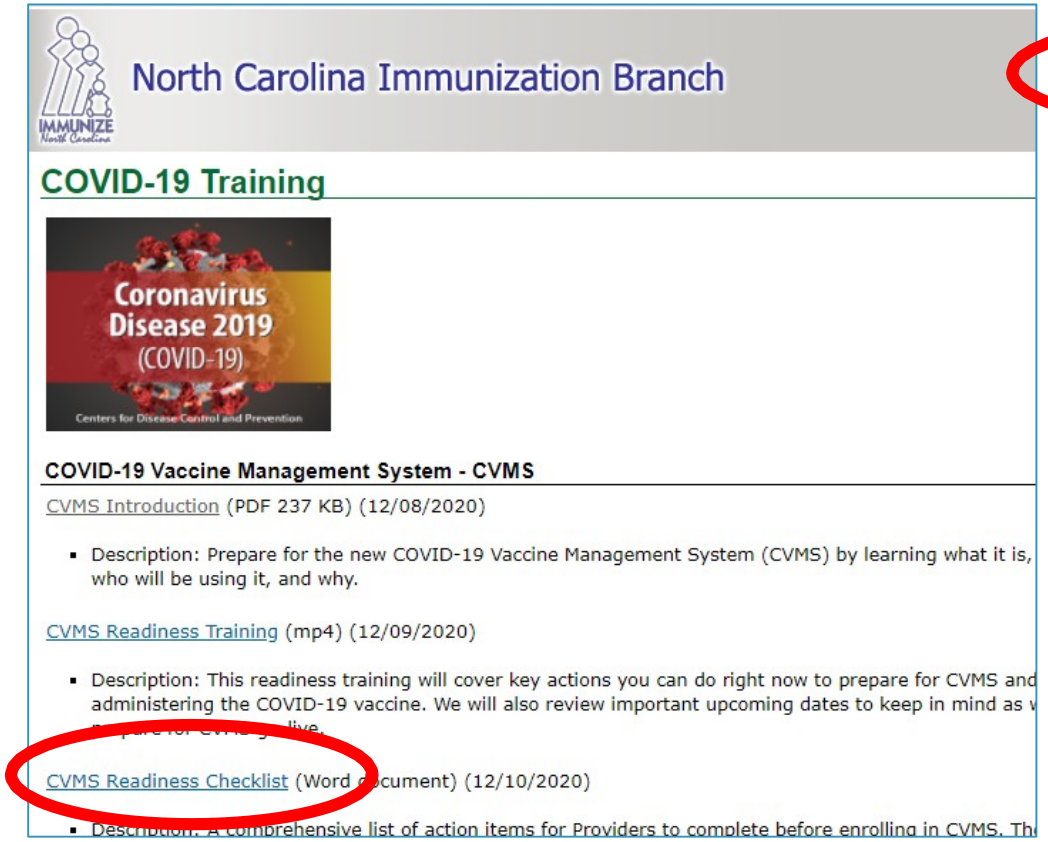
- State officials will **enroll providers** and verify provider eligibility along with **verifying site readiness**
- Providers will **verify patient eligibility**, **log dosage administration**, and **track** frequency and timing of **additional dosages**
- **Training** for Phase 1a providers started **week of 11/30**
- **Go live 12/10 –** began to enroll and train more targeted early providers
- **Early January -** Open to others

Who won't use CVMS?

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

How to Navigate Provider Enrollment

To begin the Provider Enrollment process for CVMS a provider can get all they need on the Immunization Website - https://immunize.nc.gov/providers/covid-19training.htm



North Carolina Immunization Branch

COVID-19 Training

COVID-19 Vaccine Management System - CVMS

CVMS Introduction (PDF 237 KB) (12/08/2020)

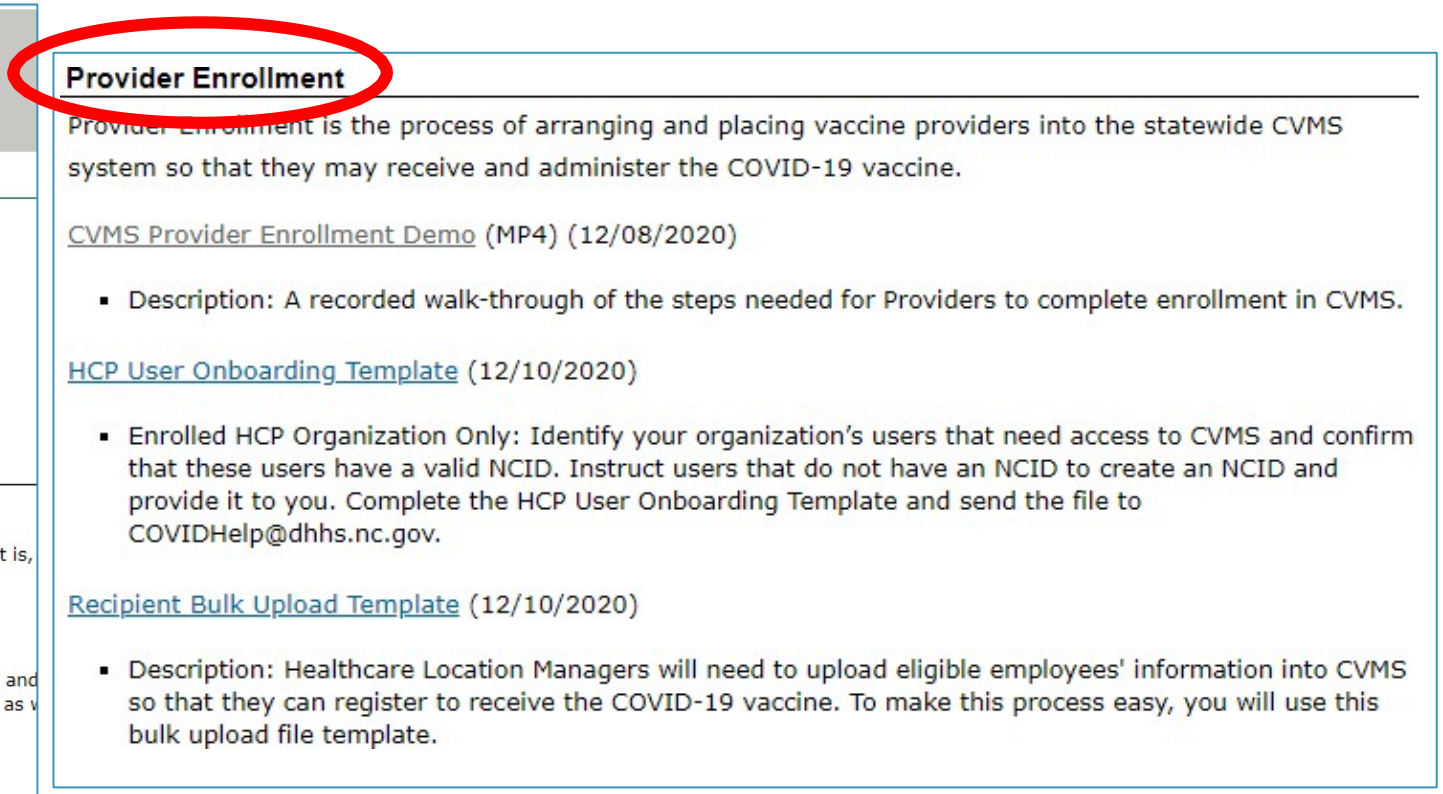
- Description: Prepare for the new COVID-19 Vaccine Management System (CVMS) by learning what it is, who will be using it, and why.

CVMS Readiness Training (mp4) (12/09/2020)

- Description: This readiness training will cover key actions you can do right now to prepare for CVMS and administering the COVID-19 vaccine. We will also review important upcoming dates to keep in mind as

CVMS Readiness Checklist (Word Document) (12/10/2020)

- Description: A comprehensive list of action items for Providers to complete before enrolling in CVMS. Th



Provider Enrollment

Provider Enrollment is the process of arranging and placing vaccine providers into the statewide CVMS system so that they may receive and administer the COVID-19 vaccine.

CVMS Provider Enrollment Demo (MP4) (12/08/2020)

- Description: A recorded walk-through of the steps needed for Providers to complete enrollment in CVMS.

HCP User Onboarding Template (12/10/2020)

- Enrolled HCP Organization Only: Identify your organization's users that need access to CVMS and confirm that these users have a valid NCID. Instruct users that do not have an NCID to create an NCID and provide it to you. Complete the HCP User Onboarding Template and send the file to COVIDHelp@dhhs.nc.gov.

Recipient Bulk Upload Template (12/10/2020)

- Description: Healthcare Location Managers will need to upload eligible employees' information into CVMS so that they can register to receive the COVID-19 vaccine. To make this process easy, you will use this bulk upload file template.

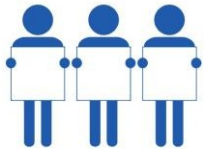
The Provider Enrollment steps are located in the **CVMS Readiness Checklist** for all new Provider as well as a specific section of the Immunization Branch site to the Provider Enrollment process

CVMS Training and Support Resources

NC DHHS will provide a range of tools and methods for CVMS and vaccine training including: communications, user guides, live trainings, and helpdesk support.

Communications: Includes CVMS Provider Portal announcements, enhancement updates, training event invitations, and information about new user guides and video demonstrations. Communications will be tailored to individual roles and responsibilities.

User Guide: Step-by-step guide that combines text instructions and screenshots to walk users through each task in the CVMS Provider Portal. It breaks down tasks into key steps and includes annotated screen shots and helpful tips.



Live Training: Live training will include step-by-step demonstrations of key tasks in CVMS, with opportunities to ask questions and do “replays” to take a closer look with the trainers. A key feature of live training is its high engagement and interaction from trainees.

Helpdesk: email help for all CVMS users during published hours for all CVMS related questions.

ServiceNow will be live on Dec 15th

ServiceNow: CVMS Vaccine Support portal will contain a number of Knowledge Articles and FAQ’s that will provide information such as self-help, troubleshooting and task resolution.

Initial training of Phase 1 enrolled Providers is currently in progress.

COVID-19 Vaccine Helpdesk is **live today** to help you!!!

Helpdesk process

Provider

Sends an email with question

cvms-help@dhhs.nc.gov

OR

ServiceNow Ticket***

ServiceNow will be live on Dec 15th

NC Helpdesk Personnel

Find the appropriate answer

Receives an email with answer

enduser@provider.com

Provider

Helpdesk hours of operations

Monday – Friday	Saturday - Sunday
8:00 AM to 5:00 PM	**10:00 AM to 6:00 PM**

Questions about CVMS

- **How does someone get training on CVMS?/What is the easiest way to get signed up for the CVMS?** *The quickest and easiest way to get training on the CVMS system and all that you need to do to enroll and then use the tool to track vaccine and its administration is through the Immunization Branch Website . All appropriate materials, check lists for enrolling, and then the steps to complete once enrolled are contained within. There is also links to training documents and recordings for your end user learning.*
- **Will the CVMS have a guided questionnaire/logic to help clinicians decide what phase people of distribution that their patients fall into?** *CVMS will automatically determine Priority Tier and Eligibility for recipients in a future release, so health care providers will only have to confirm. The Readiness Checklist contains a summary of the prioritization approach that North Caroline is currently following.*
- **Will CVMS integrate into EHRs, including CureMD and Patagonia, which covers the majority of health departments in the state?** *CVMS does not currently integrate with any electronic health record systems. This is an area that the State is investigating for future enhancements for CVMS to help reduce the amount of double entry of data and to streamline the Healthcare Providers' experience*
- **How will CVMS works with NCIR and how will the medical home know that a patient got a vaccine from a pharmacist CVMS will interface with NCIR to store vaccine info?** *The state is using CVMS to track all COVID-19 vaccines administrated across the State. CVMS will interface with NCIR to capture complete immunization information. The State is exploring how to integrate the COVID-19 vaccine administration data from pharmacies participating in the federal Pharmacy Partnership for Long-Term Care Program into CVMS.*

COVID-19 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

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

North Carolina's Commitment

Create a proactive, inclusive, evidence-based communications plan that:

- Is guided by research in understanding barriers, values, and motivations for vaccine uptake across different populations
- Leads with transparency with early and frequent communication about process and plans
- Determines proactive and culturally sensitive and linguistically responsive communication approaches for critical populations as well as the general public
- Communicates clearly and in an impactful way with all stakeholders from start to finish in appropriate languages with tailored and tested messages for target populations
- Engages trusted community leaders and sources to promote trust

NC's Communication Strategy Informed by Research

Addressing Vaccine Confidence – Actionable Data

Many North Carolinians are hesitant about COVID-19 vaccines, particularly Black/African American populations due to longstanding and continuing racial injustices in our health care system.

North Carolina didn't need another poll to tell us people had concerns. Instead, we partnered with the Neimand Collaborative and Artemis Strategy Group to uncover the underlying drivers of awareness, choice and action in health care decisions – **actionable data**.

Our research:

- Measures experience, attitudes, knowledge/familiarity and potential barriers with health information and vaccines broadly, and COVID-19 specifically, to identify:
  - Perceived benefits and risks of COVID-19 vaccinations;
  - Emotional motivations for and against COVID-19 vaccination; and,
  - Trusted sources and spokespeople about COVID-19 vaccinations.

NC's Communication Strategy Informed by Research

Methodology

Surveys conducted from November 10 - November 22, 2020

- Online survey of **1922** North Carolina residents aligned to census data

North Carolina Sub-Population	Number of People Who Completed Surveys
Rural County Residents	748
Urban County Residents	667
Suburban/Regional City County Residents	490
COVID Critical County Residents	315
Blacks/African Americans	441
Hispanics/Latinx	180
American Indians	40
Health Care Workers	119

Qualitative interviews conducted from November 28 - December 8, 2020

- 30 in-depth interviews were conducted via Zoom or phone with Black/African American, Hispanic/LatinX and American Indian North Carolina adult respondents. Mix of rural, urban, suburban
- About one third of them were Health Care Workers

NC's Communication Strategy Informed by Research

Summary Findings and Campaign Implications

Potential early adoption is weak. Less than half of North Carolina residents are both adherent health decision makers (they tend to follow their doctor's recommendations) and see greater reward than risk in a vaccine—yet a significant number express hesitancy.

The COVID vaccine is not a normal vaccination product. It's new and perceptions of and experiences with other vaccines don't necessarily apply.

Most people are taking a wait and see approach, regardless of demographics. Across demographics, women are the most hesitant—they want to make the right decision for their families.

Hesitancy is driven by legitimate concerns about testing, safety, side effects, effectiveness, "warp speed," and political polarization. These concerns must be addressed ***before*** any discussion of potential benefits, which are clear to the majority of North Carolinians.

The messengers are 90% of message effectiveness. There is less nuance in messaging than there is messengers. The top three most compelling messages were the same across race and ethnicity. Public health officials are respected, but people also need to see the positive experiences of peers and community leaders.

Vaccine supply and vaccination experience play a large role in communications among a public eager for a cure but waiting to see the positive experiences of "people like them" and a diverse range of others.

COVID-19 Vaccine Message Strategy

- **Don't frighten people into wanting to take the shot.** They already fear & take COVID seriously. Acknowledge vaccine fears and hesitancy as valid
- **Give people honest information** about vaccine development, testing, safety, reactions.
- **Build trust in and during the prioritized vaccine rollout**: Confidence to frontline workers, patience to eager early adopters, and witness to those who are waiting and seeing.
- **Direct people to "their spot" for reliable information:** Official sources or community/peers
- **Solve for the logistics of getting people to vaccination sites** that may not be connected to their everyday health experiences and health care.
- **Assure everyone of equitable and inclusive access**.
- **Have a clear call to action** that works across all campaign phases and compliments the 3W's

COVID-19 Vaccine Message Themes

Convey Safety in Development Process

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

Scientists had a head start. The vaccines were developed quickly, they were built upon years of work in developing vaccines for similar viruses.

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 95% effective in preventing COVID-19.

Demonstrate Commitment to Transparency & Inclusivity

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

Set Expectations

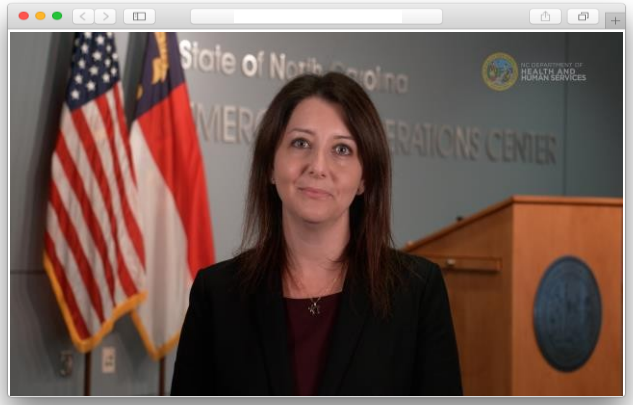
Those who need it most will get it first. A tested, safe and effective vaccine will be available to all who want it, but supplies will be limited at first. The best way to fight COVID-19 is to start first with vaccinations for those most at risk, then reach more people as the vaccine supply increases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

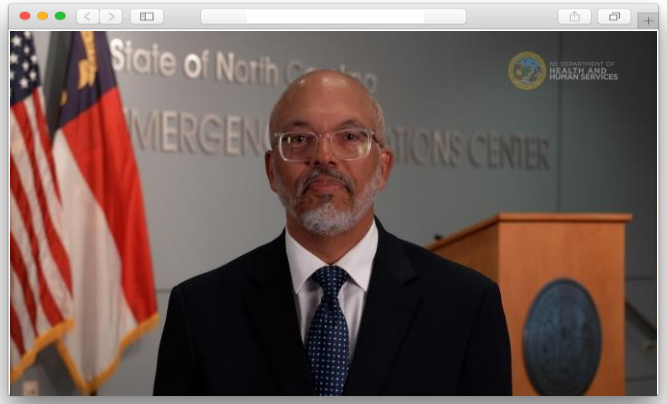
Make the Call to Action

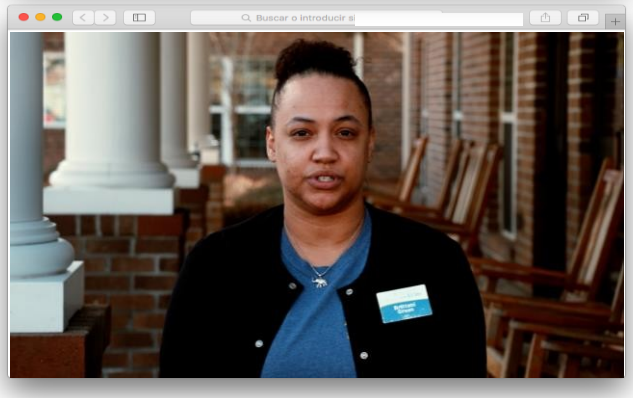
You have a spot. Take your shot. Continue to practice the 3W's until everyone has their shot at fighting COVID-19

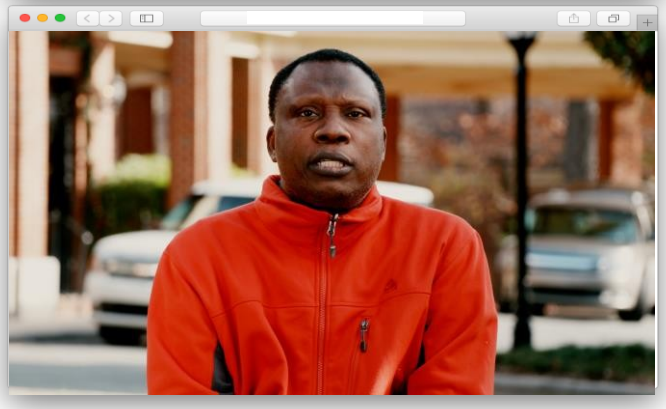
PSAs | Leveraging Trusted Voices

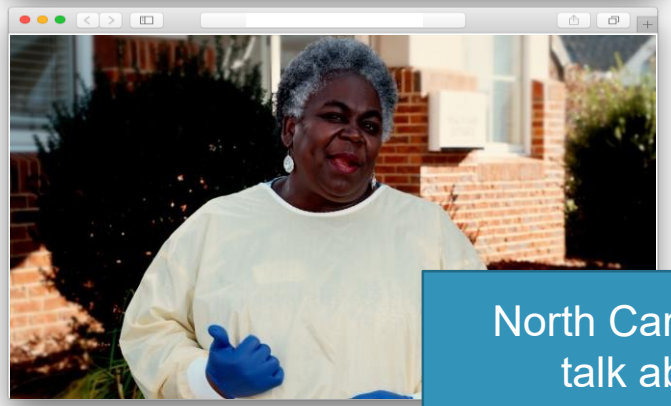
https://covid19.ncdhhs.gov/vaccines

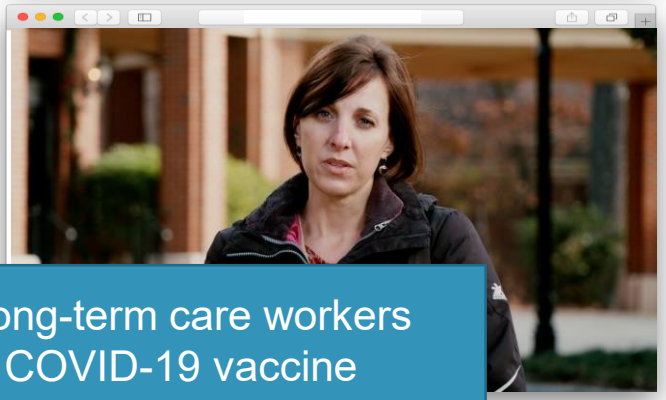












North Carolina long-term care workers talk abut the COVID-19 vaccine

Online Resources | Updated Regularly

https://covid19.ncdhhs.gov/vaccines

New one-page flyer on COVID-19 vaccines to give your patients

FAQ online and in a pdf in English and Spanish (updating weekly)

COVID-19 vaccines 101 deck

Infographic on prioritization

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

Questions?

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES