

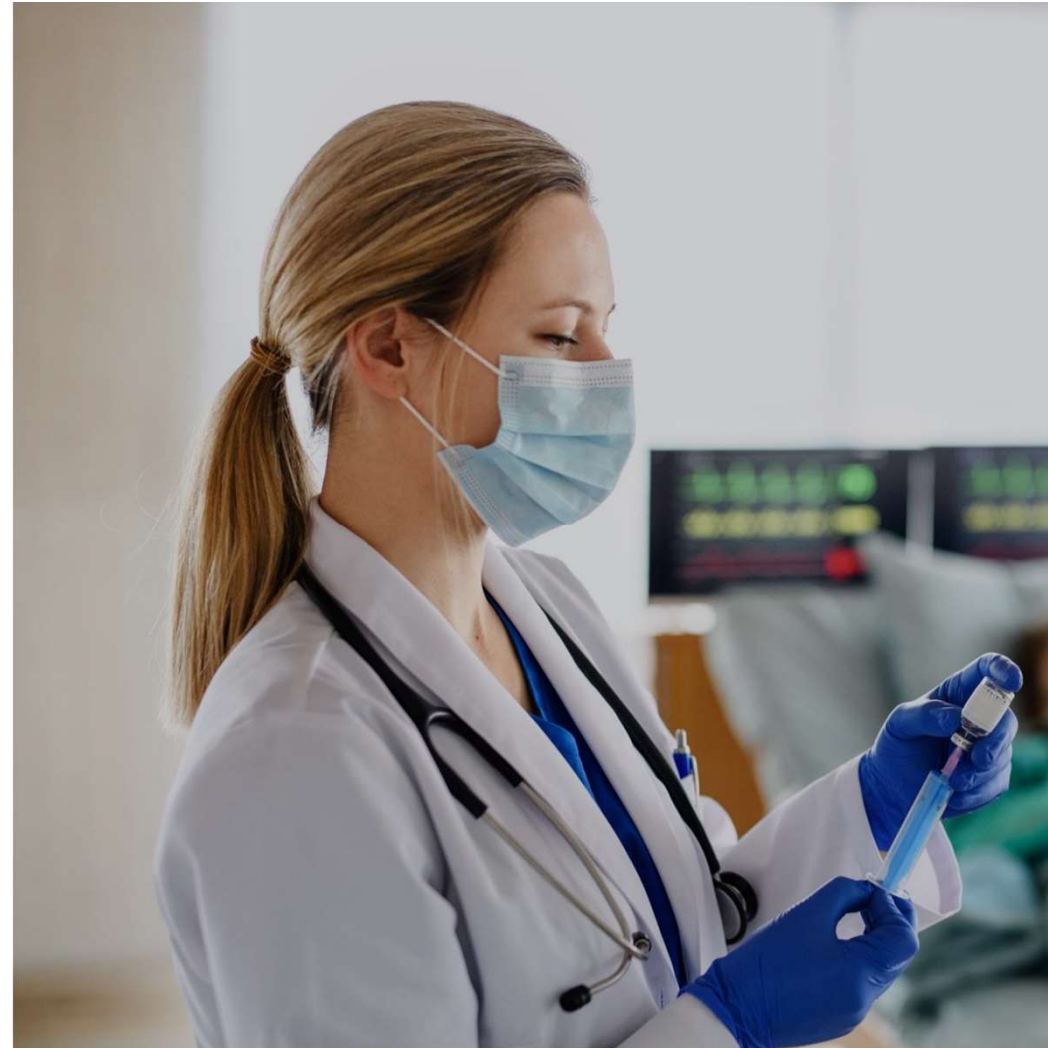
NC DHHS COVID-19 Vaccination Briefing

What North Carolina Practices Need to Know

December 15, 2020



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**



NC DHHS COVID – 19 Response

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>

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>



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



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 3Ws—wear a mask, wait six feet apart, wash your hands—until everyone has a chance to vaccinate.



1a Health care workers fighting COVID-19's long-term care
Every health care worker at high risk for exposure to COVID-19—doctors, nurses, and all who assess 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 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 (grocery, food processing, teachers), health care workers, and those living in prisons, homeless shelters, migrant and factory 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 factory 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



Y'all are doing great...



**KEEP
CALM
AND
CARRY
ON**



Agenda

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

The COVID-19 Vaccine Development Process

Developing, Manufacturing and Distributing a COVID-19 Vaccine

Multiple COVID-19 vaccines are being developed. Thousands of people have volunteered as part of research trials to see if a vaccine prevents COVID illness and to learn more about its safety in these overlapping steps. Promising vaccines are being manufactured at the same time they are being tested, so there will be an initial supply ready to go right away when the science shows which vaccines are found to be safe and effective. Once we have a vaccine or vaccines, it will still be some time before it is widely available to everyone. States will receive limited supplies at the start. North Carolina is drawing upon the experience and expertise of leaders from historically marginalized communities to develop and implement its vaccine distribution plan.

PHASE 1 & 2:

Safety & Dosing

10s-100s of healthy volunteers

- Are there any side effects? How many volunteers experience side effects?
- What is the best vaccine dose to create an immune response with the fewest tolerable side effects?

PHASE 2 & 3:

Safety & Efficacy

>30,000 of volunteers

- Does the vaccine prevent COVID-19 infection?
- What are the most common side effects?
- Do the benefits of the vaccine outweigh the risks?

Approval & Distribution

- FDA reviews the safety and efficacy data to determine if benefits are greater than risks
- An independent, non-FDA scientific committee reviews findings
- Vaccine is authorized and recommended for use (may only be for certain populations)
- Vaccine is labeled for use, benefits, side effects

Manufacturing

Preparation: Manufacturing development, scaling up, quality-control testing

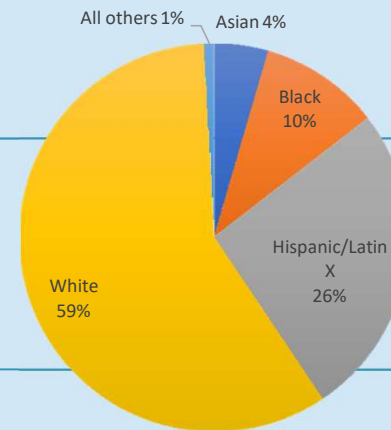
Large-Scale Manufacturing: Making millions of vaccine doses for nationwide distribution, continued quality-control testing of vaccine batches and manufacturing facilities, FDA and CDC continually monitor vaccinated patients for safety

Availability: Limited availability in the beginning. More widely available over time.

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

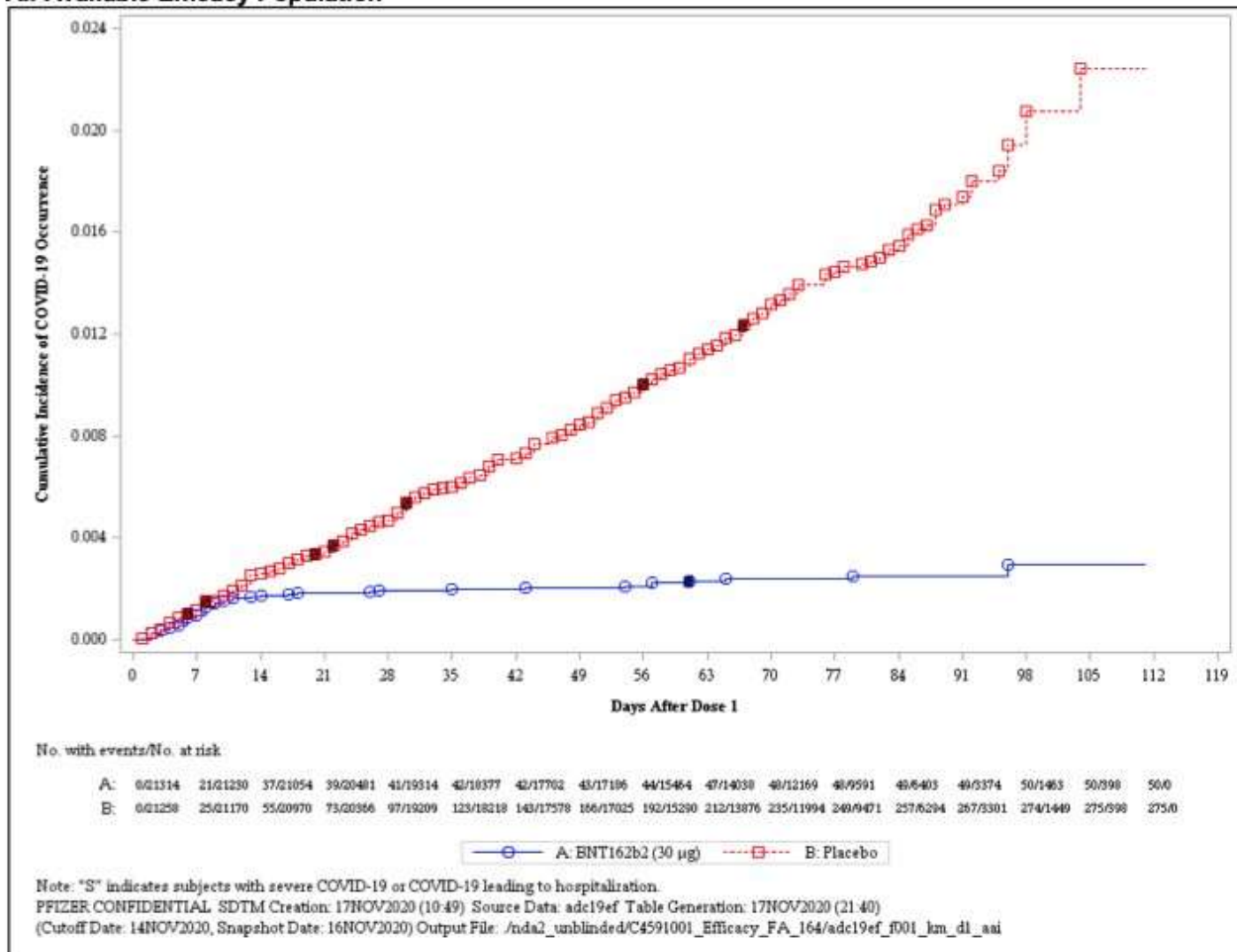
- Dosing**
- 2-dose schedule; 21 days apart (17-21 days), some protection starts 14 days after 1st dose,
 - Insufficient data to determine protection of 1 dose because almost all got a second dose

- 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

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 screenshot shows the VAERS website interface. At the top, there's a navigation menu with options: 'About VAERS', 'Report an Adverse Event', 'VAERS Data', 'Resources', and 'Submit Follow-Up Information'. Below the navigation, there's a main heading 'VAERS Vaccine Adverse Event Reporting System' with the website URL 'www.vaers.hhs.gov'. The primary content area is titled 'Have you had a reaction following a vaccination?' and provides instructions in both English and Spanish. It includes a 'What is VAERS?' section with a photograph of a family. Below this, there are four main action buttons: 'REPORT AN ADVERSE EVENT', 'SEARCH VAERS DATA', 'REVIEW RESOURCES', and 'SUBMIT FOLLOW-UP INFORMATION'. At the bottom, there are three sections: 'HELPFUL LINKS', 'LEARNING TOOLS', and 'VACCINE SAFETY INFORMATION', each containing various links and resources.

- ❖ 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

An advertisement for v-safe. At the top, three icons (bandage, smartphone, thumbs up) are followed by the text: "Get vaccinated. Get your smartphone. Get started with v-safe." Below this, a hand holds a smartphone displaying the v-safe logo and the text "v-safe after vaccination health checker". To the right of the phone, a purple speech bubble contains the text: "Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose." Below the speech bubble, another purple box contains the text: "When you get your COVID-19 vaccination, ask your healthcare provider about getting started with v-safe". At the bottom left is the CDC logo. At the bottom right, it says "Learn more about v-safe www.cdc.gov/vsafe".

**Get vaccinated.
Get your smartphone.
Get started with v-safe.**

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

When you get your COVID-19 vaccination, ask your healthcare provider about getting started with **v-safe**

Learn more about **v-safe**
www.cdc.gov/vsafe

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

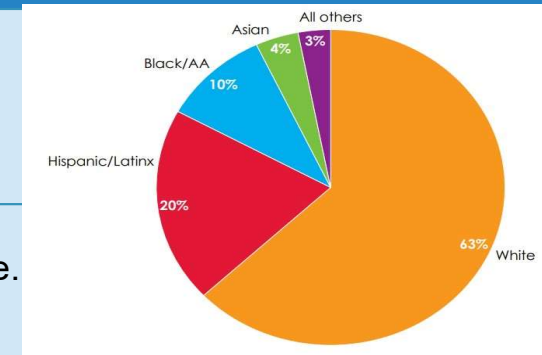
Moderna Vaccine

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

				
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 (<i>testing half-dose: full-dose regimen v. two full doses</i>) First interim analysis 90% effective with first half-dose	Doses: 1 or 2 (<i>testing both</i>)	Doses: 1 or 2 (<i>testing both</i>)	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

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 \(https://www.hrsa.gov/CovidUninsuredClaim\)](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

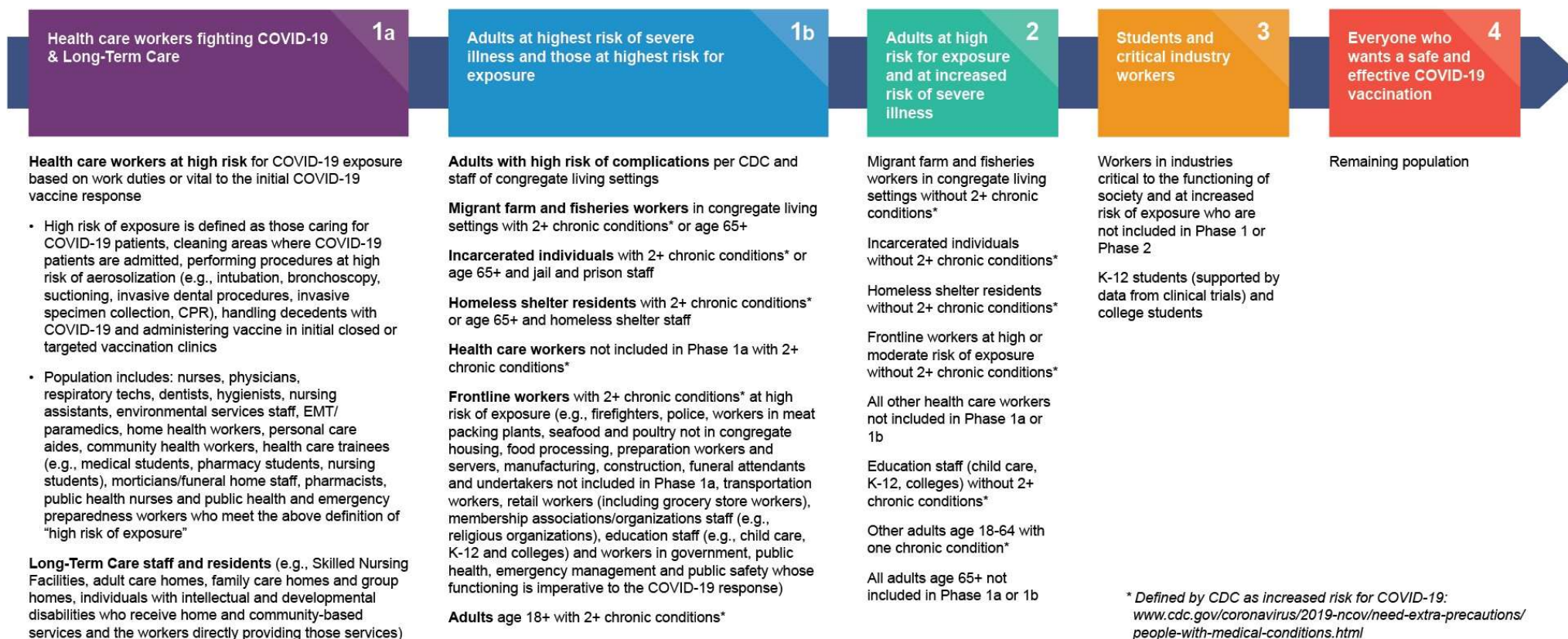
Advisors

- **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



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.

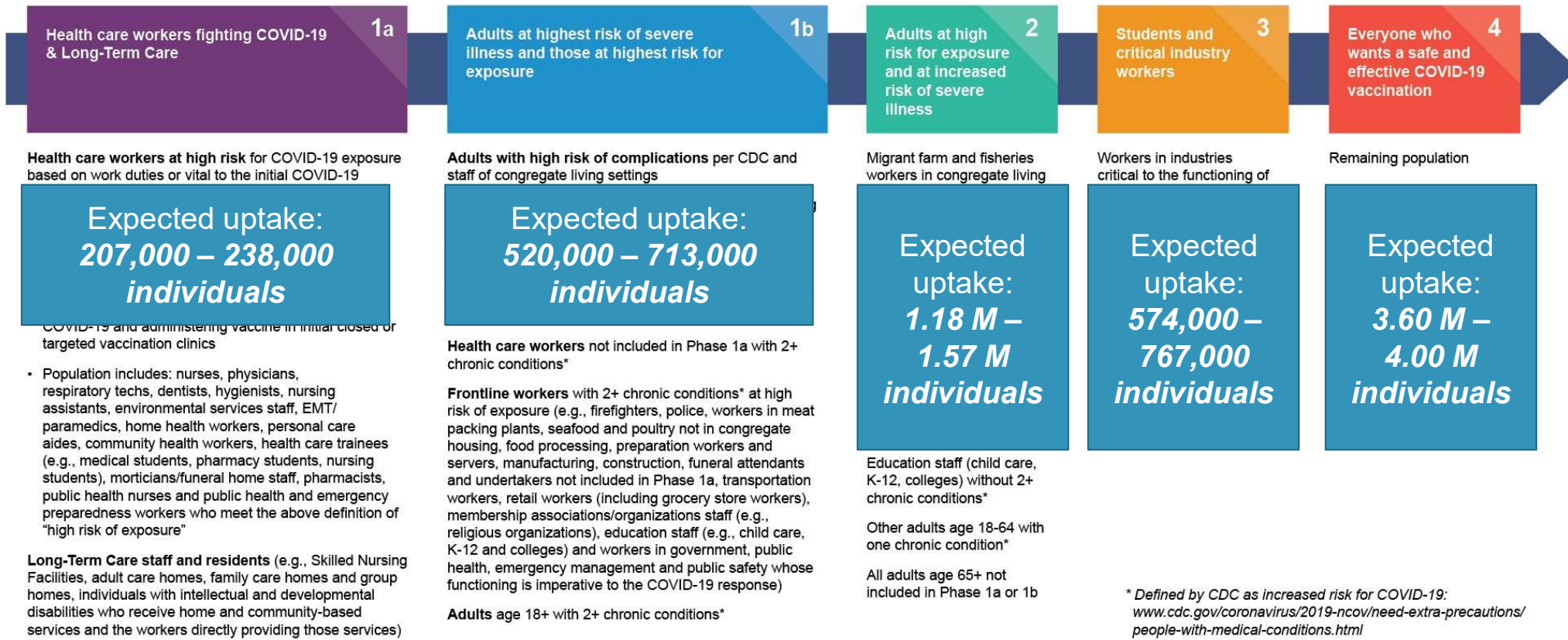


* Defined by CDC as increased risk for COVID-19: www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

Vaccine Distribution Prioritization: Drilldown Framework



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

Who is Being Vaccinated in December? **Phase 1a**

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

Who is Being Vaccinated in December? **Phase 1a**

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

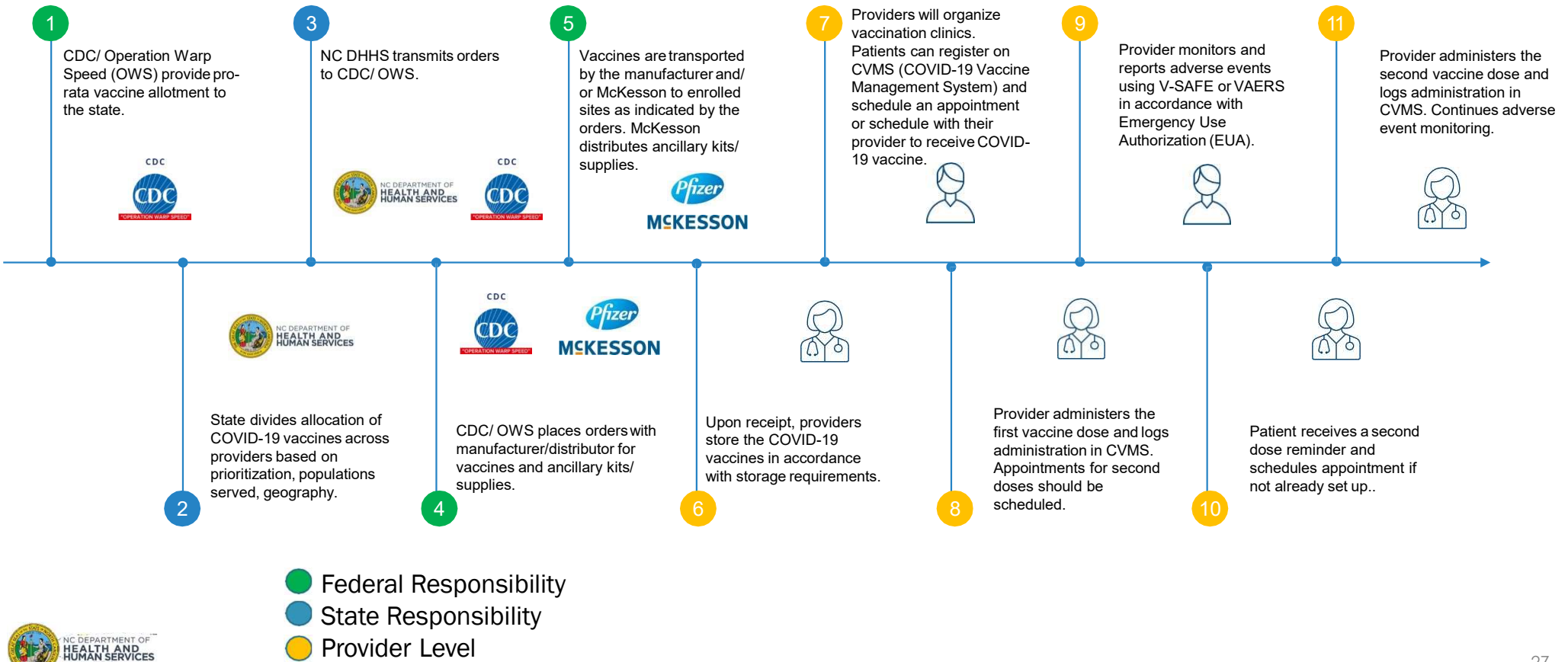
Long-Term Care (LTC) staff and residents

- 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 <i>Before vaccine is available</i>	 Implementation <i>Begins when first vaccine doses are allocated to states</i>	Adjustment <i>Large number of vaccine doses available</i>	Transition <i>Sufficient supply of vaccine doses for entire population</i>
Populations	<ul style="list-style-type: none"> Establish priority groups 	<ul style="list-style-type: none"> Phase 1 populations Stabilize health care delivery system and protect individuals at highest risk 	<ul style="list-style-type: none"> Continue to move through phased populations as vaccine supply allows 	<ul style="list-style-type: none"> Offer vaccination to all populations through Phases 3 and 4
Vaccination Channels	<ul style="list-style-type: none"> N/A 	<ul style="list-style-type: none"> Initially through health systems, long term care, local health departments and on-site vaccination clinics 	<ul style="list-style-type: none"> Require more points of access, mass vaccination clinics, community based, and broad vaccination sites 	<ul style="list-style-type: none"> Vaccination in established channels Fewer mass, mobile, or community-based clinics
Enrollment/ Ordering/ Allotment	<ul style="list-style-type: none"> Identify/enroll providers Expect CDC centralized distribution to providers 	<ul style="list-style-type: none"> Continue to enroll providers Allocations to state, allotted to enrolled providers 	<ul style="list-style-type: none"> Transition to provider ordering vaccines based on need for population and local demand 	<ul style="list-style-type: none"> Ordering similar to annual seasonal flu vaccine campaign
Shipment	<ul style="list-style-type: none"> None shipped Expect vaccine and anc. supplies procured and distributed by fed gov't 	<ul style="list-style-type: none"> Shipment in increments of 975 for some, 100 for others Some require ultra-cold storage & 2-dose series 	<ul style="list-style-type: none"> Shipment minimum of 100 for most vaccines 	<ul style="list-style-type: none"> Move to high supply/lower demand
Data	<ul style="list-style-type: none"> Confirm capability for required functionality, data collection, and reporting 	<ul style="list-style-type: none"> Data systems for ordering, scheduling, dose tracking, inventory, data collection and reporting requirements 	<ul style="list-style-type: none"> Data systems for ordering, scheduling, dose tracking, inventory, data collection and reporting requirements 	<ul style="list-style-type: none"> Data systems for ordering, scheduling, dose tracking, inventory, data collection and reporting requirements

Vaccine Journey



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



Initial provider enrollment:
Hospitals and Local Health Departments (LHDs)

Currently Enrolling



FQHC's, Rural Health Centers and Free and Charitable Clinics

Federal enrollment of pharmacies (Walgreens and CVS) for long term care settings

Next to Enroll



Corrections health, occupational health, providers serving congregate living settings, etc.

Coming Soon



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



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)



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 **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

Week of Distribution	Manufacturer	# of Doses	Primary Audience
Week 1 12/14/2020	Pfizer	85,800	Hospitals
	Moderna	0	N/A
Week 2 12/21/2020	Pfizer	~97,500	Hospitals/Large LHDs
	Moderna	175,900	LTC, Smaller hospitals and LHDs
Week 3 12/28/2020	Pfizer	85,800 + TBD	2 nd Dose + TBD
	Moderna	77,500	Smaller Hosp, LHD, Community
Week 4 01/04/2021	Pfizer	TBD	2 nd Dose + TBD
	Moderna	TBD	LHDs, Community, TBD

*Assumption: serving all for LTC partnership

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Vaccine: COVID -19 Vaccine Management System (CVMS)

★ 11/23	★ 11/30	★ 12/8	★ 12/10	★ 12/17	★ TBD
CVMS Provider Enrollment Soft Launch invitation to: <ul style="list-style-type: none"> • Goshen Community Health • Carolina Family Health Centers • Rural Health Group • Realo Discount Drugs • Oak Street Health 	CVMS Priority Access Preview attended by 120+ participants	CVMS MVP Soft Launch for subset of Phase 1a providers	CVMS MVP Go-Live And available to Phase 1a and some Phase 1b providers	CVMS MVP R2 Go-Live Additional features released	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) - <https://immunize.nc.gov/providers/covid-19training.htm>

The screenshot shows the North Carolina Immunization Branch website. The header includes the logo and the text "North Carolina Immunization Branch". Below the header, there is a section for "COVID-19 Training" with a video thumbnail titled "Coronavirus Disease 2019 (COVID-19)". Underneath, there are links to "COVID-19 Vaccine Management System - CVMS", "CVMS Introduction (PDF 237 KB) (12/08/2020)", "CVMS Readiness Training (mp4) (12/09/2020)", and "CVMS Readiness Checklist (Word document) (12/10/2020)". A red circle highlights the "CVMS Readiness Checklist" link. To the right of the website content, there is a "Provider Enrollment" section with a red circle around the title. The text describes the enrollment process and lists resources: "CVMS Provider Enrollment Demo (MP4) (12/08/2020)", "HCP User Onboarding Template (12/10/2020)", and "Recipient Bulk Upload Template (12/10/2020)".

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.

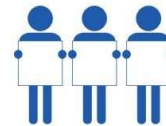
The Provider Enrollment steps are located in the **CVMS Readiness Checklist** for all new Provider as well as a specific section of the Immunization Branch site to the Provider Enrollment process

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.



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.



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.



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



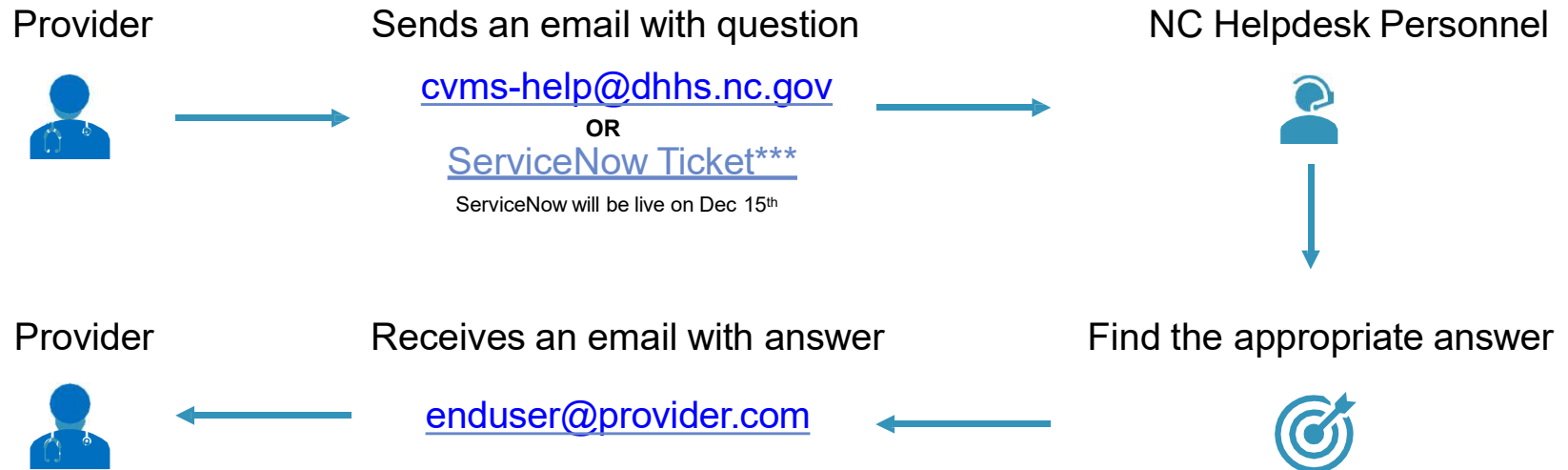
ServiceNow will be live on Dec 15th

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



Helpdesk hours of operations



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 Carolina 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

COVID-19 Vaccine Communications

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.

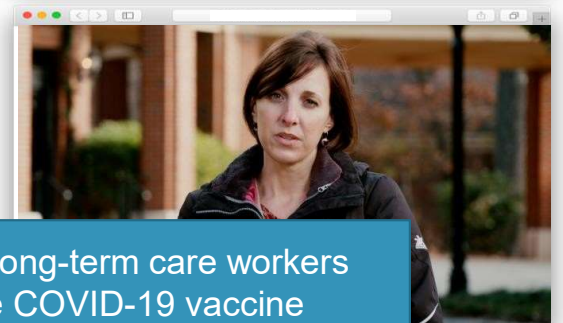
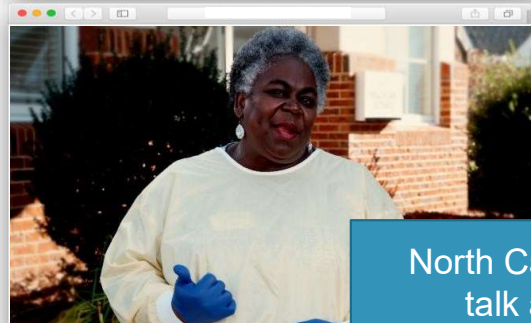
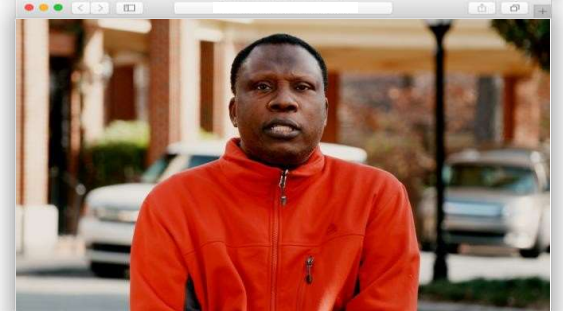
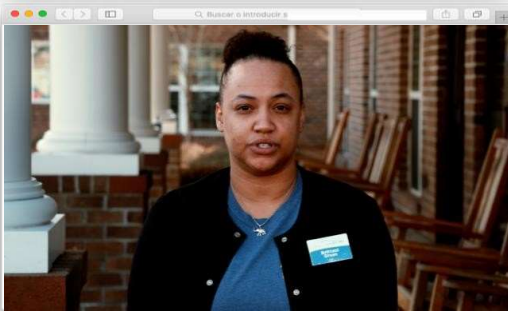
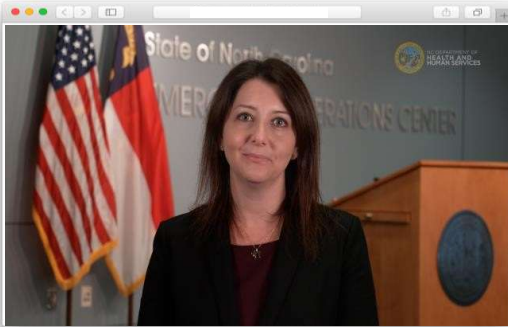


Make the Call to Action

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 about the COVID-19 vaccine



Online Resources | Updated Regularly

<https://covid19.ncdhhs.gov/vaccines>

COVID-19 Vaccines: Your best shot against COVID-19.

Tested, safe and effective COVID-19 vaccines will help us defeat the virus, get back in control of our lives and back to the people and places we love.

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

Tested, safe and effective. More than 70,000 people volunteered in clinical trials for two vaccines (Pfizer and Moderna) to see if they are safe and work to prevent COVID illness. To date, the vaccines are 95% effective in preventing COVID-19 with no serious safety concerns noted in the clinical trials. The U.S. Food and Drug Administration (FDA) makes sure the vaccines are safe and can prevent people from getting COVID-19. Like all drugs, vaccine safety is always being monitored.

You can find out where you can take your shot at <https://covid19.ncdhhs.gov/vaccines>.

Take your shot at no cost. The COVID-19 vaccine will be available to everyone for free, whether or not you have health insurance.

You'll need two shots to build up your immunity. After a person gets a first dose, they will need to come back 3 to 4 weeks later for a second dose. You will get a printed card and email reminder of when to get your second dose.

Continue to practice the 3Ws until everyone has their shot at fighting COVID. Wear a mask. Wait six feet apart. Wash your hands. That's the best way to protect each other until everyone gets their shot.

For more information: covid19.ncdhhs.gov/vaccines

Frequently Asked Questions

Safe, effective COVID-19 vaccines will help us defeat this virus, get back in control of our lives and back to the people and places we love.

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 vaccinators for those most at risk, reaching more people as the vaccine supply increases from January to June. Keep practicing the 3Ws—wear a mask, wait six feet apart, wash your hands—until everyone has a chance to vaccinate.

Vaccine Development and Authorization

- + What is an Emergency Use Authorization (EUA)?
- + What happens after an EUA is issued?
- + How do the Pfizer and Moderna vaccines work?
- + How can someone enroll in a clinical trial for a vaccine?

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

Actualización de la vacuna COVID-19
18 de noviembre de 2020

Las vacunas COVID-19 nos ayudarán a vencer este virus y regresar a las personas y lugares que amamos. Las vacunas imitan una infección, para que nuestro cuerpo piense que un germen, como un virus, está atacando y hace producir anticuerpos que debemos combatir si el germen real ataca.

Se están desarrollando algunas vacunas para COVID-19. Estas vacunas se están probando en miles de voluntarios en todo el país y el mundo. Estas fases de ensayos están diseñadas para responder preguntas como:

- ¿Es segura la vacuna?
- ¿Son graves los efectos secundarios?
- ¿Cuáles son los efectos secundarios más comunes?
- ¿Cómo se comparan con otras vacunas?

Al mismo tiempo que se están probando, por lo que habrá un tiempo cuando la ciencia demuestre que las vacunas son seguras y efectivas, todavía pasará algún tiempo antes de que estén disponibles para todos. Los suministros de vacunas serán limitados al principio.

Las vacunas que se encuentran al final de la última fase de prueba en este momento son las de Pfizer y otra de Moderna.

COVID-19 Vaccination 101 Overview Deck

Updated: December 14, 2020



COVID-19 vaccines 101 deck



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

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 vaccinators for those most at risk, reaching more people as the vaccine supply increases from January to June. Keep practicing the 3Ws—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 assisted living 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 disease, and diabetes. Adults 65+.
- 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.
- 3 Students and critical industry workers**
College and university students. K-12 students when there is an approved vaccine for children.
- 4 Everyone who wants a safe and effective COVID-19 vaccination**

DECEMBER 8, 2020

Infographic on prioritization



Questions?

