NC DHHS COVID-19 Vaccination Briefing

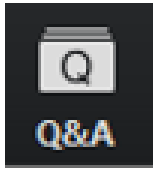
Updates and answers from 12-15-20

December 22, 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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It's only day 2 of week 2

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

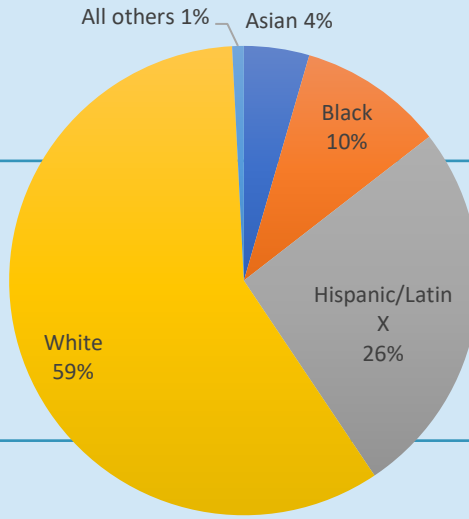
Appropriate stewardship of resources and continuous evaluation and improvement drive successful implementation

Agenda

- Update on Vaccines data and authorization
- Prioritization
- Logistics of accessing vaccine
- Provider Enrollment and CVMS
- Data Dashboard
- Questions

Pfizer Vaccine – Data Brief

Enrollment	• Phase 3 trial **concluded** - 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 endorsed12/10/20 • FDA EUA 12/11/20, ACIP recommendation 12/12/20 – 16 years and up
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-**full** 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 **is degraded quickly by normal cellular processes.** mRNA technology has been developing for past 2-3 years for other viruses
Safety	• No reports of serious safety during clinical trials. 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.



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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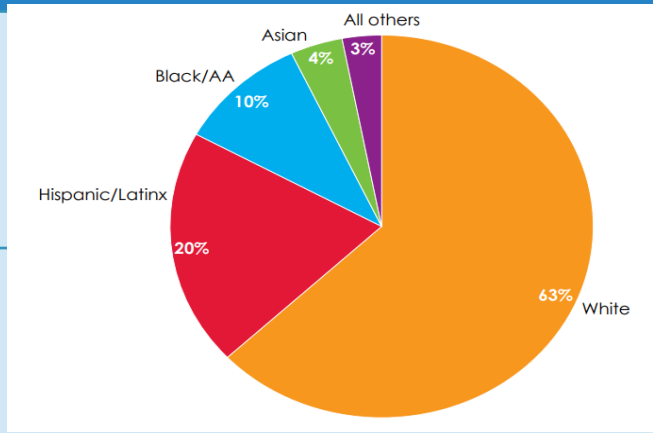
Moderna Vaccine

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

Preliminary Efficacy Data	• 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
	  • 95.5% effective 18-<65, 86.4% effective ≥ 65
	• Lasts at least 90 days after 2nd dose

Timing of EUA	• Applied for EUA 11/30 • FDA External Advisory Board Recommended Dec 17th • Expect decision on FDA EUA 12/18/20, ACIP recommendation 12/19 – 18 years and up
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 (24-28 days).
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. There were no anaphylactic or severe hypersensitivity reactions with close temporal relation to the vaccine.



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

Symptom	18-<64 year olds		> 55 years	
	Dose 1	Dose 2	Dose 1	Dose 2
Local reaction				
Pain at site	87%	90%	74%	83%
Redness at site	3%	9%	2%	7%
Swelling at site	7%	13%	4%	11%
Systemic				
Fatigue	39%	68%	34%	51%
Headache	35%	63%	25%	46%
Muscle pain	24%	6%	20%	47%
Chills	9%	48%	5%	31%
Diarrhea	11%	10%	8%	8%
Joint pain	17%	45%	17%	35%
Fever	1%	17%	0.3%	10%
Nausea/Vomiting	10%	21%	5%	12%

NEUROLOGIC CONDITIONS: BELL'S PALSY & GBS

- Cases of Bell's Palsy reported in both Pfizer (4 in vaccine group/0 in placebo) and Moderna (3 in vaccine group, 1 in placebo) clinical trials
- Not above frequency expected in general population
- FDA has not concluded that cases were causally related to vaccination
- Post-authorization safety surveillance will be important, Any occurrence of Bell's Palsy should be reported to VAERS
- Persons with h/o Bell's Palsy may receive an mRNA vaccine
- No cases of Guillain-Barre syndrome in either Pfizer or Moderna clinical trials

INGREDIENTS

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	Polyethylene glycol (PEG) 2000 dimyristoyl glycerol (DMG)
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102 (Proprietary to Moderna)
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

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Neither of the Pfizer-BioNTech or Moderna COVID-19 vaccines contains preservatives.

PRECAUTIONS - ALLERGIES

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 or the Moderna COVID-19 Vaccine

Per CDC ACIP Precaution

- A history of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) is a precaution but not a contraindication to vaccination for both the Pfizer-BioNTech and Moderna COVID-19 vaccines (as these vaccines contain ingredients in common).

- These persons may still receive mRNA COVID-19 vaccination, but they should be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination.

- A history of mild allergic reaction to a vaccine or injectable therapy, such as localized urticaria alone without signs or symptoms of anaphylaxis, is not a contraindication or precaution to vaccination with either mRNA COVID-19 vaccine.

- Allergic reactions (including severe allergic reactions) not related to vaccines or injectable therapies (e.g., food, pet, venom, or environmental allergies; allergies to oral medications [including the oral equivalents of injectable medications]) are not a contraindication or precaution to vaccination with either mRNA COVID-19 vaccine.

- The vial stoppers of these mRNA vaccines are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for persons with a latex allergy.

- 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

Special Population Considerations

- **Persons with underlying medical conditions or immunocompromised persons**
  - Vaccine may be administered to persons with underlying medical conditions or who are immunocompromised 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

- **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

Special Population Considerations for Moderna & Pfizer

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	**CONDITIONS** • Immunocompromising conditions • Pregnancy • Lactation **ACTIONS** • Additional information provided* • 15 minute observation period	**CONDITIONS** • Moderate/severe acute illness **ACTIONS** • Risk assessment • Potential deferral of vaccination • 15 minute observation period if vaccinated	**CONDITIONS** • None **ACTIONS** • N/A
ALLERGIES	**ALLERGIES** • History of food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies • History of allergy to oral medications (including the oral equivalent of an injectable medication) • Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis) • Family history of anaphylaxis • Any other history of anaphylaxis that is not related to a vaccine or injectable therapy **ACTIONS** • 30 minute observation period: Persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause • 15 minute observation period: Persons with allergic reaction, but not anaphylaxis	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including mRNA COVID-19 vaccines†) • History of severe allergic reaction (e.g., anaphylaxis) to an injectable therapy **ACTIONS:** • Risk assessment • Potential deferral of vaccination • 30 minute observation period if vaccinated	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to any component of an mRNA COVID-19 vaccine† **ACTIONS** • Do not vaccinate

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

FOR BOTH PFIZER AND MODERNA

- **Not interchangeable**

- Both doses administered intramuscularly:
  - Second doses administered within a grace period of ≤4 days from the recommended date for the second dose are considered valid; however, doses administered earlier do not need to be repeated.
  - The second dose should be administered as close to the recommended interval as possible; however, there is no maximum interval between the first and second dose for either vaccine.

- **Co-Administration**: No data on the safety and efficacy of mRNA COVID-19 vaccines administered simultaneously with other vaccines. The vaccine series should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines. If mRNA COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

FOR BOTH PFIZER AND MODERNA

- **Duration of Immunity**: The need for and timing of booster doses for mRNA COVID-19 vaccines has not been established. No additional doses beyond the two-dose primary series are recommended at this time.

- 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 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
  - No COVID test recommended prior to vaccination

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 COVID-19 Vaccine

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

Helpful Links

Helpful Links
❖ Pfizer Website ❖ Pfizer data briefing document for FDA – Result of Phase 3 of clinical trials ❖ Full Pfizer-BioNTech COVID-19 Vaccine EUA Letter of Authorization ❖ Pfizer Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers) ❖ Pfizer Fact Sheet for Recipients and Caregivers ❖ The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine ❖ Moderna data briefing document for FDA – Results of Phase 3 clinical trials ❖ Moderna COVID-19 Vaccine EUA Letter of Authorization ❖ The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine ❖ Moderna Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers) ❖ Moderna Fact Sheet for Recipients and Caregivers ❖ Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the US ❖ CDCs COVID-19 Vaccination Communication Toolkit for Medical Center, Clinics, and Clinicians

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.

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, healthcare 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

Healthcare 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*

Goals of Phase 1 – Next 2 months will be critical

Phase 1a: The goal of the first phase of vaccination is to stabilize the health care workforce critical to caring for patients with COVID-19 and to protect North Carolinians who are at the highest risk of being hospitalized or dying from COVID-19.

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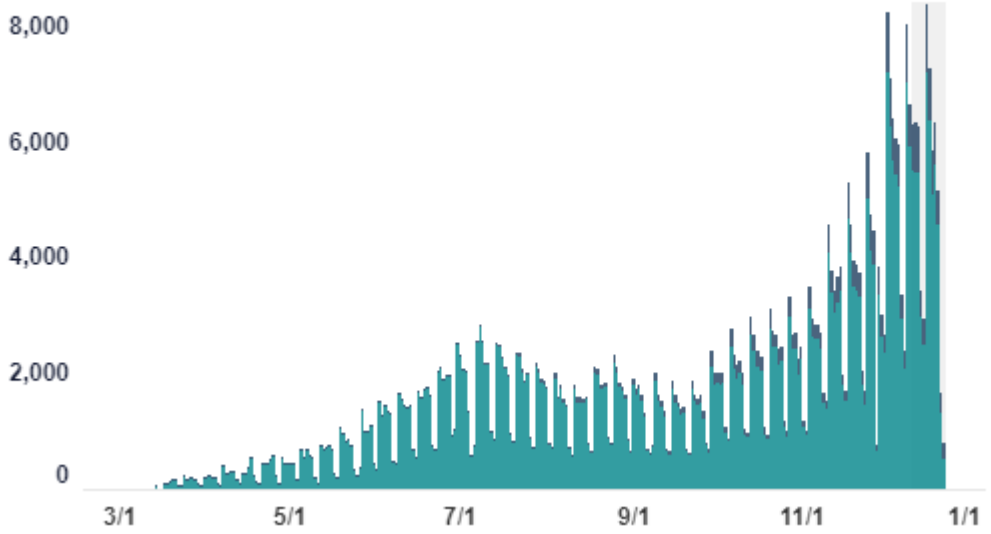
PREVENT HOSPITALIZATIONS AND DEATH

Is North Carolina seeing a downward trajectory over 14 days, or sustained leveling in new cases?



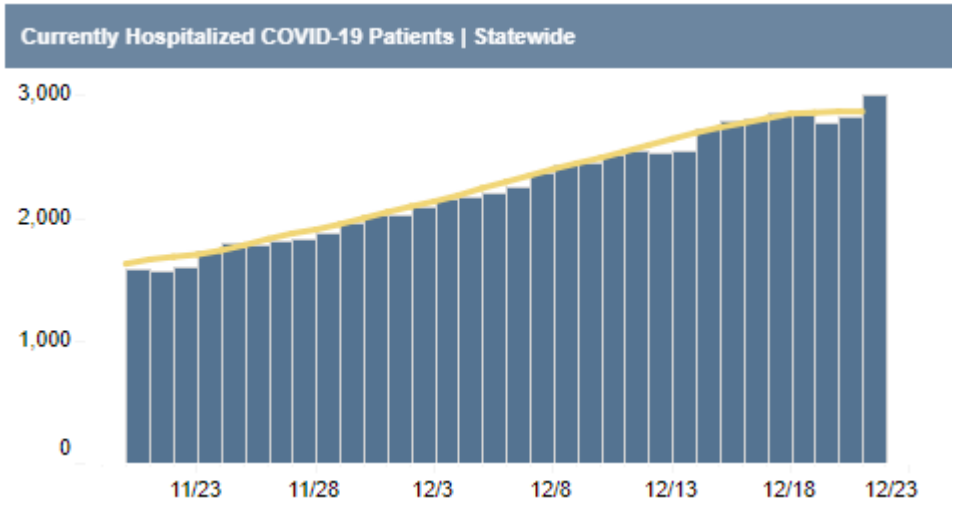
TOTAL CASES
North Carolina

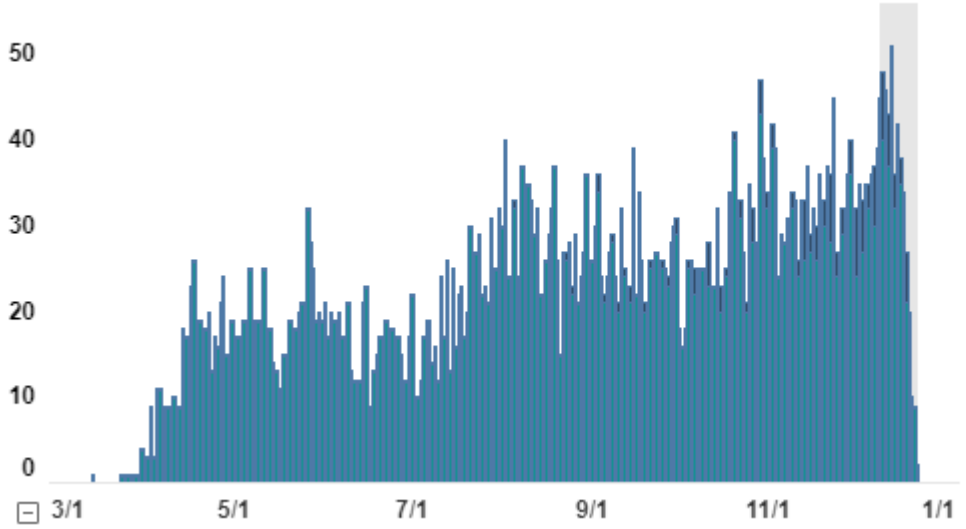
488,902

MOLECULAR (PCR) POSITIVE CASES
451,384

ANTIGEN POSITIVE CASES
37,518

Specimen collection date missing for 295 cases.





TOTAL DEATHS
North Carolina

6,291

MOLECULAR (PCR) POSITIVE
5,980

ANTIGEN POSITIVE
311

Date of death missing for 6 deaths.

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Stabilize COVID-19 Health Care Work Force – Phase 1a

Health care workers critical to caring for patients with COVID-19 at high risk for COVID-19 exposure based on work duties or vital to the initial COVID-19 vaccine response are included in Phase 1a.

Health care workers at high risk for exposure to COVID-19 are defined as those:

- caring for patients with COVID-19
- working directly in areas where patients with COVID-19 are cared for, including staff responsible for cleaning, providing food service, and maintenance in those areas
- performing procedures at high risk of aerosolization on patients with COVID-19 (e.g., intubation, bronchoscopy, suctioning, invasive dental procedures, invasive specimen collection, CPR)
- handling decedents with COVID-19

Outpatient providers who have an increased risk of exposure beyond that of a typical general outpatient setting should be included in in the first phase (1A). This could include outpatient providers who are focused on COVID-19 patient evaluation, respiratory care such as respiratory diagnostic testing centers, members of a dedicated respiratory care team, or frequently involved in COVID-19 testing sites. Outpatient dentists or dental hygienists are included in Phase 1a if they meet the above criteria for outpatient providers.

Health care workers administering vaccine in initial mass vaccination clinics are part of this first phase.

How do health care workers in phase 1a get their vaccine – Work in Progress

Due to very limited supplies, vaccines were available first through a small number of hospitals. These hospitals were chosen based on bed capacity, health care workers, and county population. Additional hospitals and Local Health Departments have begun to receive vaccine in Week 2.

LHDs, health care employers, hospitals and health systems all play a role in vaccinating health care workers in Phase 1a.

Local Health Departments are compiling lists of health care providers who are not affiliated with a hospital or health system and who meet the criteria for Phase 1a. Local Health Departments will pre-register eligible health care workers in the state's COVID-19 Vaccination Management System (CVMS) or can register eligible individuals at the time of vaccination.

Health care employers (e.g., medical practices, hospice providers, EMS) should determine which of their employees meet the criteria of being at high risk for exposure to COVID-19 as defined above, meaning that they interact with or care for patients with COVID-19 or work in designated COVID-19 areas (e.g., cleaning). If they are not already working with their Local Health Department, health care employers should:

- Contact their local health department to submit their list of eligible health care workers in order to pre-register employees for vaccination.
- Understand that the ability for Local Health Departments to schedule appointments will depend on the supply of vaccine available.
- Know that Local Health Departments will prioritize responding to and scheduling vaccinations first for those with workers eligible for Phase 1a and based upon vaccine availability.

Hospitals and health systems are compiling lists of and pre-registering their employees and affiliated staff who meet the criteria for Phase 1a. They also may:

- Vaccinate non-employed or non-affiliated community-based health care workers who meet Phase 1a eligibility criteria.
- Work with the Local Health Department to coordinate access to vaccine for non-affiliated health care workers for those they pre-register.

How do you register in CVMS for a vaccine in phase 1a?

Local health departments and local hospitals have two options for registering qualifying health care providers in the COVID-19 Vaccine Management System (CVMS):

- **Pre-enter information**: Upload health care worker information (e.g., name, email)into CVMS. Uploaded health care workers with an email address will then receive an email to complete their registration. At this time, the local hospital or local health department will notify registered, eligible health care workers about their options to schedule the vaccine appointment.

- **Point of care registration**: People will be able to call and schedule and appointment or and arrive to a vaccination site during the appropriate prioritization phase and the site will be able to register them for getting a vaccine at that time, if not already registered.

- In future CVMS versions, people will be able to **self-register** in CVMS

Long Term care - Phase 1a

Long-Term Care (LTC) staff and residents

- Long Term care staff and residents qualify in Phase 1a
- This includes skilled nursing facilities, adult care homes, family care homes, group homes, and intermediate care facilities for individuals with IDD (ICF-DD), assisted living.
- LTC facilities will be notified when vaccines will be available to be administered to staff and residents.

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
- It is **too late** to register for the federal Long Term Pharmacy program now.
- Those that did not enroll in the federal program can work with local health departments to get vaccinated. We are also enrolling other long-term pharmacies to provide vaccinations to LTC facilities and exploring possibilities of mobile providers

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

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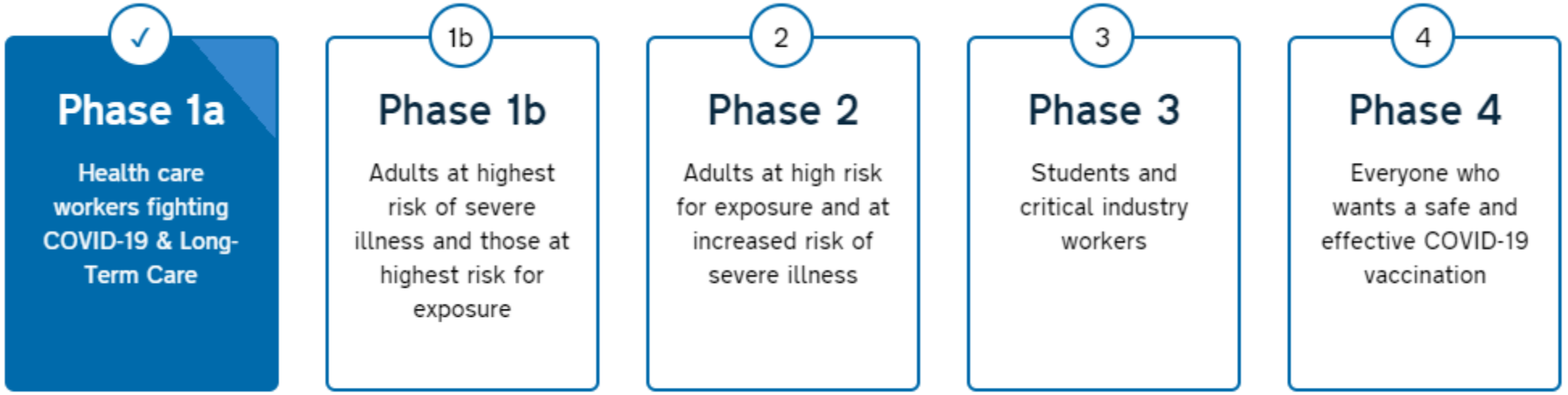
Phase 1b - Working to reconcile

NC's proposed Plan for Phase 1b	ACIP Recommendations
Adults with high risk of complications per CDC and staff of congregate living settings **<u>Operationally prioritize settings based on risk of exposure</u>** • **Migrant farm and fisheries workers** in congregate housing with 2+ Chronic Conditions* or ≥ age 65 • **Incarcerated individuals** with 2+ Chronic Conditions* or ≥ age 65 and jail and prison staff • **Homeless shelter residents** with 2+ Chronic Conditions* ≥ 65 and homeless shelter staff • **Health care workers** not included in Phase 1A with 2+ Chronic Conditions • **Frontline workers*** with 2+ Chronic Conditions at high risk of exposure • **Other Adults** with 2+ Chronic Conditions*:	**Phase1b**: • Persons aged ≥ 75 years • Frontline essential workers **Phase 1c**: • Persons aged 65-74 years • Persons aged 16-64 years with high-risk medical conditions • Other essential workers

Working to Reconcile

How will people know when we move through the phases?

- Website - https://covid19.ncdhhs.gov/vaccines



- Communication to providers
- Exploring a public listserve that can notify people as we move through the phases

Phase 1b - Where will people be able to receive a vaccine when it is their time?

- In the beginning, only hospitals and local health departments have vaccine. At the beginning of Phase 1b, people may need to receive it through those organizations

- We have and will continue to enroll other providers. As we are able to enroll them and have enough vaccine to allocate to them, people will be able to get it from their providers,

- If it is time for you or your patient, and you are not enrolled or you do not have vaccine, then you can contact the local health department or another vaccination site.

- People will be able to call and schedule and appointment or pre-register and arrive to a vaccination site during the appropriate prioritization phase and the site will be able to register them for getting a vaccine at that time, if not already registered. In the future, people will be able to register themselves for vaccination through the system through the COVID-19 Vaccine Management System. But that functionality is not currently available.

Moving through the phases

- As we continue to enroll more providers and as we have more vaccine, we will be able to allocate to more community providers, occupational health clinics, pharmacies, so there will be more options for people in the later phases

- When we have more widespread vaccine, we anticipate people utilizing a vaccine vaccine finder search app?

- How quickly North Carolina moves through the prioritized phases for vaccination depends on the available vaccine supply. The federal government is notifying us each week of how much vaccine we are receiving. Currently, we only find out the week before what our allocation is for the next week for each vaccine, making it difficult to estimate when we can move to a next phase. We hope to be able to move to the next phase (1B) early in 2021.

Vaccine: Provider enrollment

AS OF 12/20/2020

PROVIDER ENROLLMENT DASHBOARD

Hospitals **(100%)**

228 Provider Organizations

Sites

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: 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 61,425

Pfizer

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

Hospitals

Local Health Departments

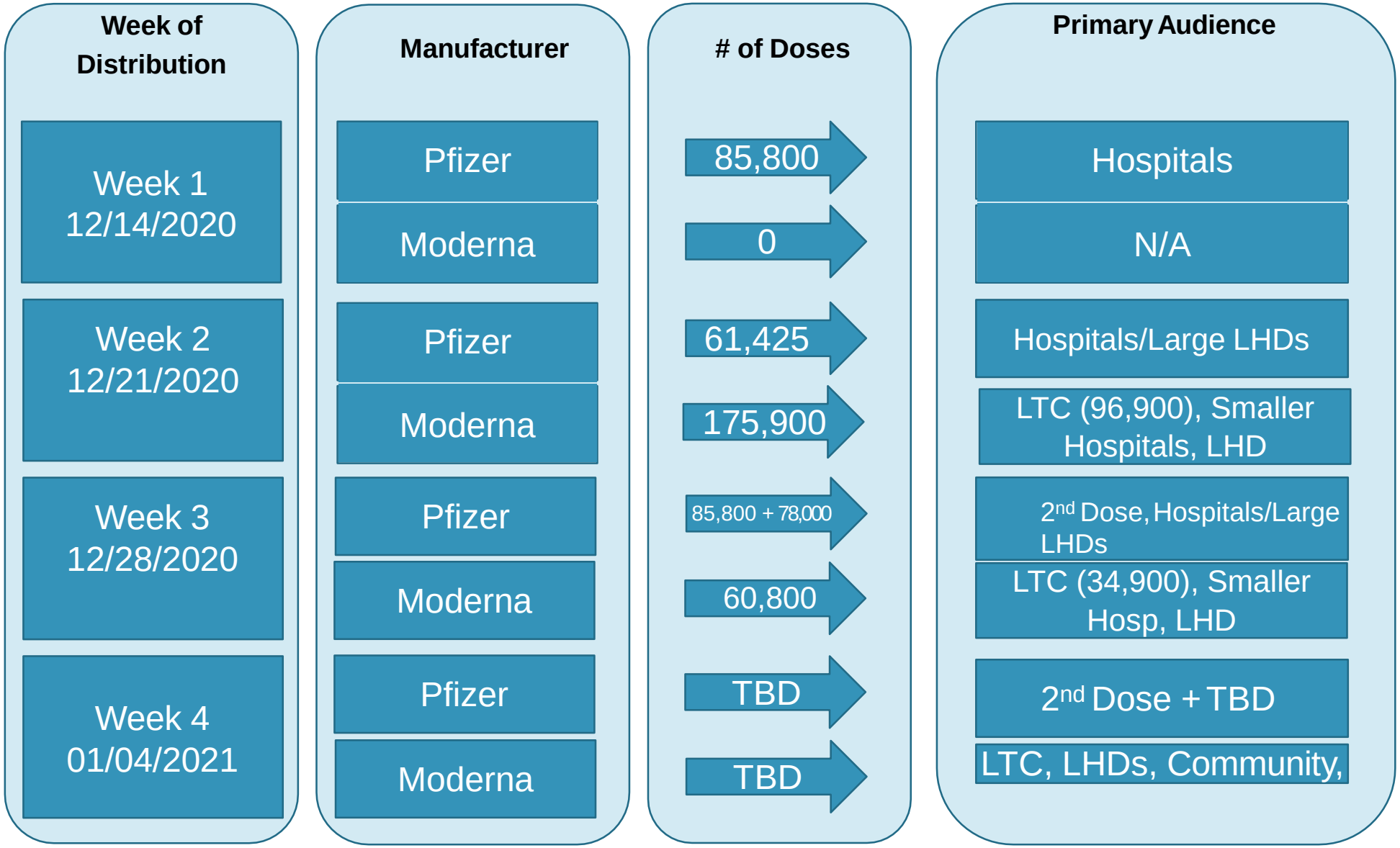
175,900 doses
(increments of 100)

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

Weekly vaccine allocation by manufacturer



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

12/21

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 who will be administering vaccine** and verify provider eligibility along with **verifying site readiness. This includes pharmacies enrolling directly with the state**
- Providers will **verify patient eligibility**, **log dosage administration**, and **track** frequency and timing of **additional dosages**
- **Training and enrollment** for early providers has started
- **Early January -** Open to others

Who won't use CVMS?

Pharmacies enrolled in the federal programs **(Long Term Care Program and Retail Pharmacy Program)** will use their **current systems** to report to federal program
- However, these pharmacies will have to share data with NC within 72 hours
- Building capability to ingest vaccine data files from pharmacies into CVMS
- Pharmacies enrolled directly with the state must use CVMS

PROVIDER ENROLLMENT/ADMINISTRATIVE/ CVMS/

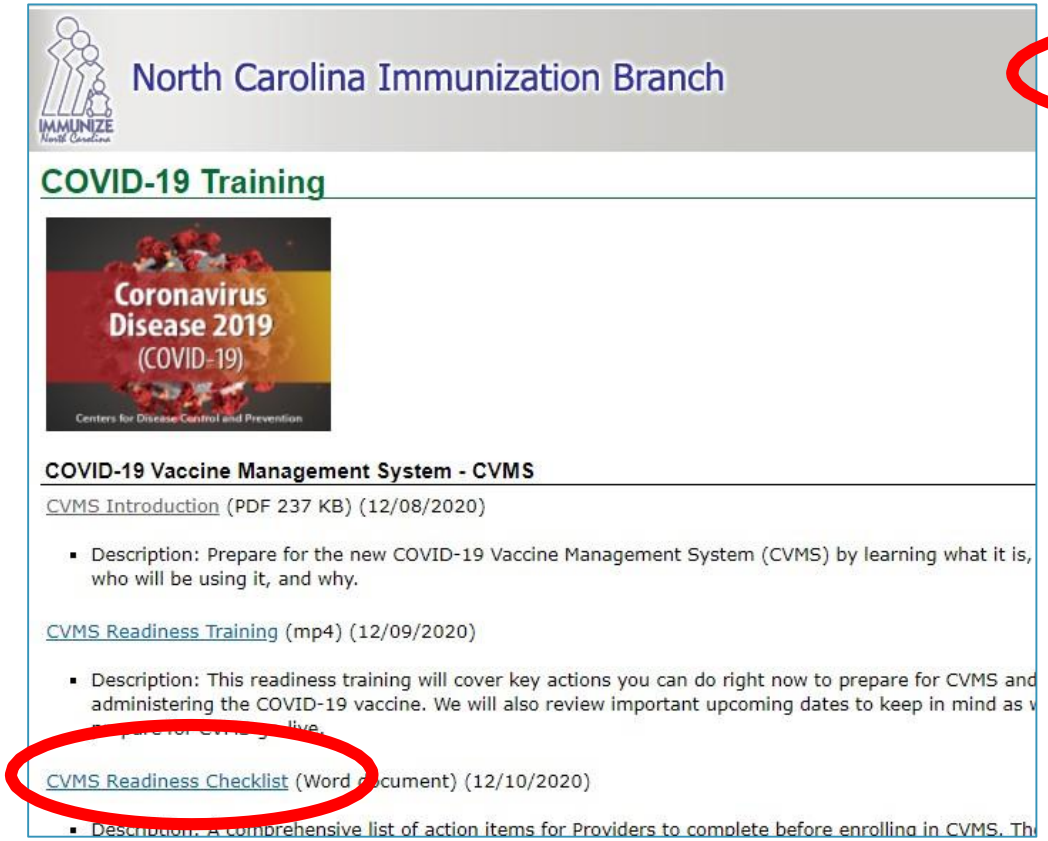
1. Do providers need to enroll in order to be able to receive vaccine for staff and patients and be able to administer vaccine? **Yes**

2. Do all the providers at an outpatient clinic need to enroll if working at the same clinic? **Provider enrollment is by the site. However, all providers that will prescribe vaccine must be listed on the provider enrollment agreement.**

3. When it is time for broader provider enrollment for our clinics, how will we know and where will go to start the enrollment process? **We will send out board provider communication when it is time. They can also check the immunization website - https://immunize.nc.gov/providers/covid-19training.htm**

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.

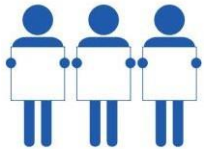
The Provider Enrollment steps are located in the **CVMS Readiness Checklist** for all new Provider as well as a specific section of the Immunization Branch site to the Provider Enrollment process

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: 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

Which automatically creates a

ServiceNow Ticket

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 (https://immunize.nc.gov/providers/covid-19training.htm). 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.*

Data Dashboard - https://covid19.ncdhhs.gov/dashboard/vaccinations

Vaccinations Data: December 14, 2020 – December 22, 2020
Updated every Tuesday

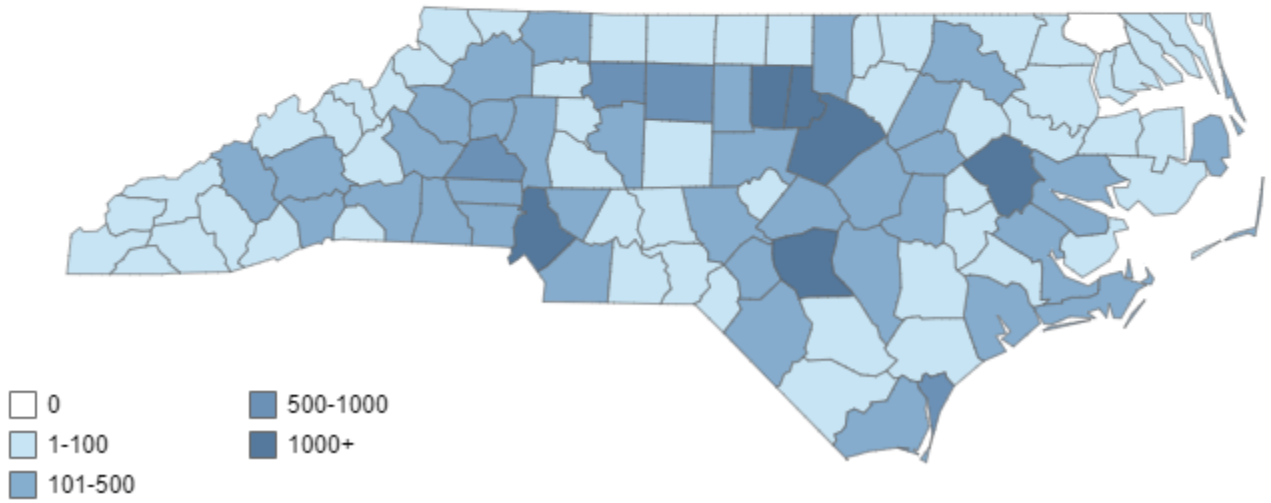
People Vaccinated by County of Residence

RECEIVED FIRST DOSE

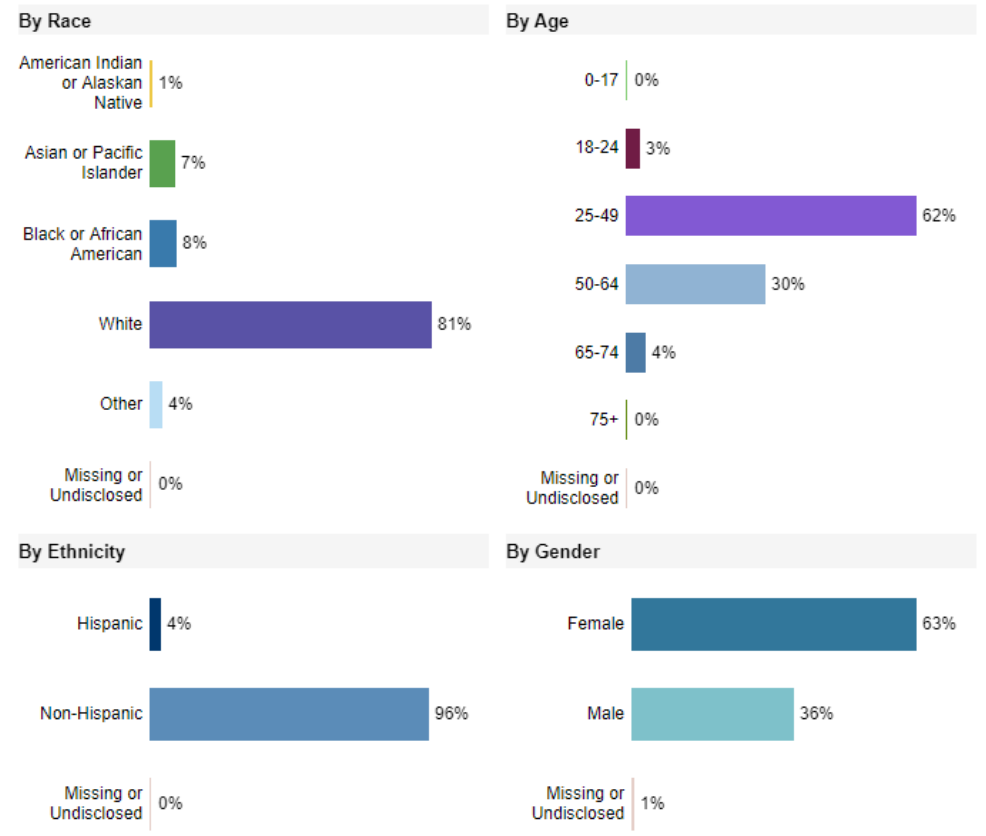
24,500

COMPLETED VACCINE SERIES

0



People Vaccinated by Demographics



The dashboard reflects data through 8:00 a.m., Tuesday, December 22, 2020. It shows less than a week of data for the state. Most hospitals in North Carolina did not receive their first shipment from Pfizer until Thursday, December 17, 2020 and continued ramping up vaccine administration through the weekend. There can be a 72-hour lag in data reported to state. Additional data reported after 8:00 a.m. December 22, 2020 will be reflected in the next dashboard update on December 29, 2020.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

Questions?

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

What is meant by “effectiveness”

- Primary end point in trials was COVID-19 illness 7-14 days after the second dose
  - Pfizer required negative PCR test at baseline
  - Moderna allowed participants with evidence of SARS-CoV-2 infection before and during vaccination regimen

- Data are limited to know effectiveness against asymptomatic infection or transmissions of SARS-CoV-2
  - Moderna PCR tested participants before 2nd dose with suggestion of protection against asymptomatic infection