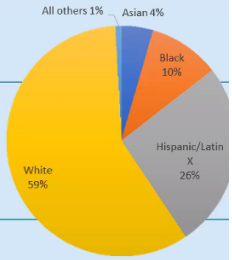
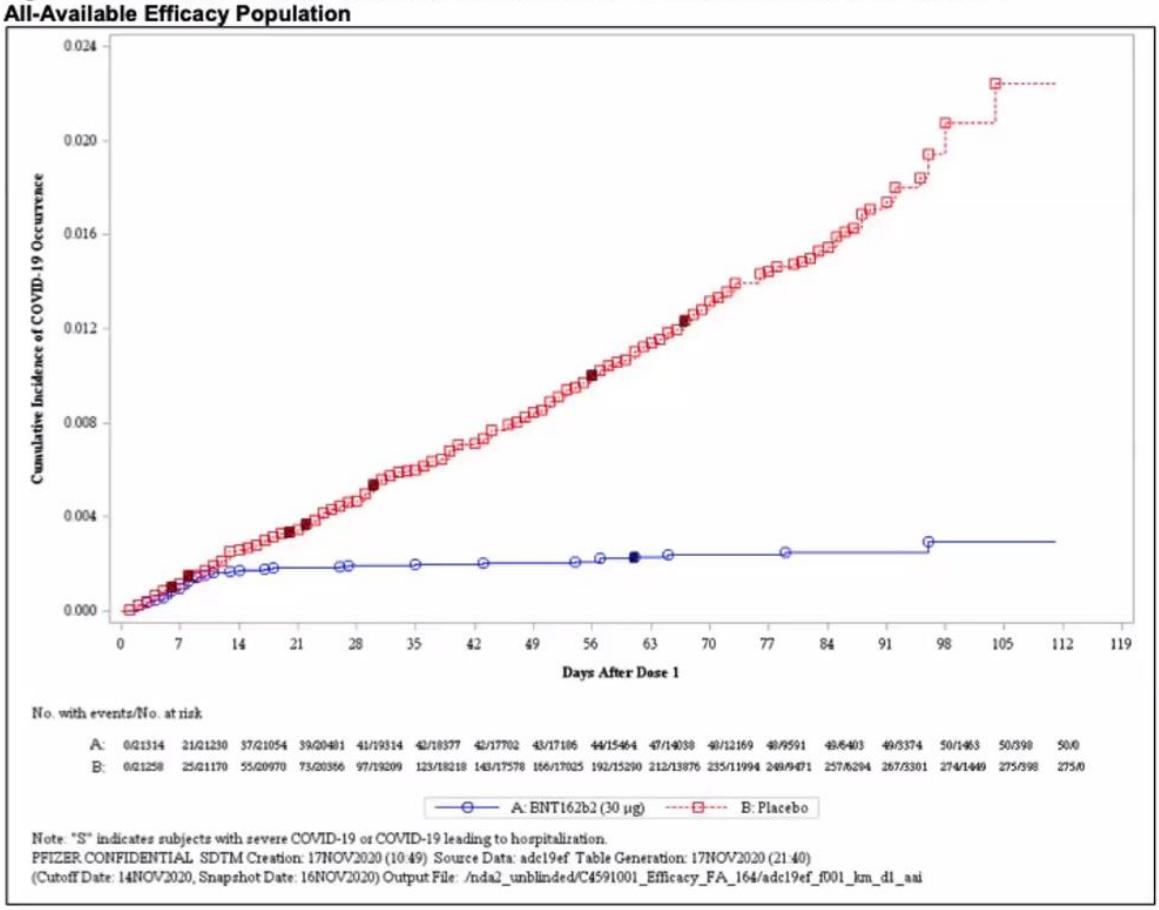
Pfizer Vaccine – Data Brief

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 endorsed12/10/20 • 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.

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	Medicare	Uninsured	Commercial
▪ 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	▪ 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 [redacted] 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	• 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).	▪ 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

Vaccine Distribution Prioritization: Drilldown Framework

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

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

- High risk of exposure is defined as those caring for COVID-19 patients, cleaning areas where COVID-19 patients are admitted, performing procedures at high risk of aerosolization (e.g., intubation, bronchoscopy, suctioning, invasive dental procedures, invasive specimen collection, CPR), handling decedents with COVID-19 and administering vaccine in initial closed or targeted vaccination clinics
- Population includes: nurses, physicians, respiratory techs, dentists, hygienists, nursing assistants, environmental services staff, EMT/ paramedics, home health workers, personal care aides, community health workers, health care trainees (e.g., medical students, pharmacy students, nursing students), morticians/funeral home staff, pharmacists, public health nurses and public health and emergency preparedness workers who meet the above definition of "high risk of exposure"

Long-Term Care staff and residents (e.g., Skilled Nursing Facilities, adult care homes, family care homes and group homes, individuals with intellectual and developmental disabilities who receive home and community-based services and the workers directly providing those services)

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

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

Migrant farm and fisheries workers in congregate living settings with 2+ chronic conditions* or age 65+

Incarcerated individuals with 2+ chronic conditions* or age 65+ and jail and prison staff

Homeless shelter residents with 2+ chronic conditions* or age 65+ and homeless shelter staff

Health care workers not included in Phase 1a with 2+ chronic conditions*

Frontline workers with 2+ chronic conditions* at high risk of exposure (e.g., firefighters, police, workers in meat packing plants, seafood and poultry not in congregate housing, food processing, preparation workers and servers, manufacturing, construction, funeral attendants and undertakers not included in Phase 1a, transportation workers, retail workers (including grocery store workers), membership associations/organizations staff (e.g., religious organizations), education staff (e.g., child care, K-12 and colleges) and workers in government, public health, emergency management and public safety whose functioning is imperative to the COVID-19 response)

Adults age 18+ with 2+ chronic conditions*

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

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

Incarcerated individuals without 2+ chronic conditions*

Homeless shelter residents without 2+ chronic conditions*

Frontline workers at high or moderate risk of exposure without 2+ chronic conditions*

All other health care workers not included in Phase 1a or 1b

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

Other adults age 18-64 with one chronic condition*

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

3 — Students and critical industry workers

Workers in industries critical to the functioning of society and at increased risk of exposure who are not included in Phase 1 or Phase 2

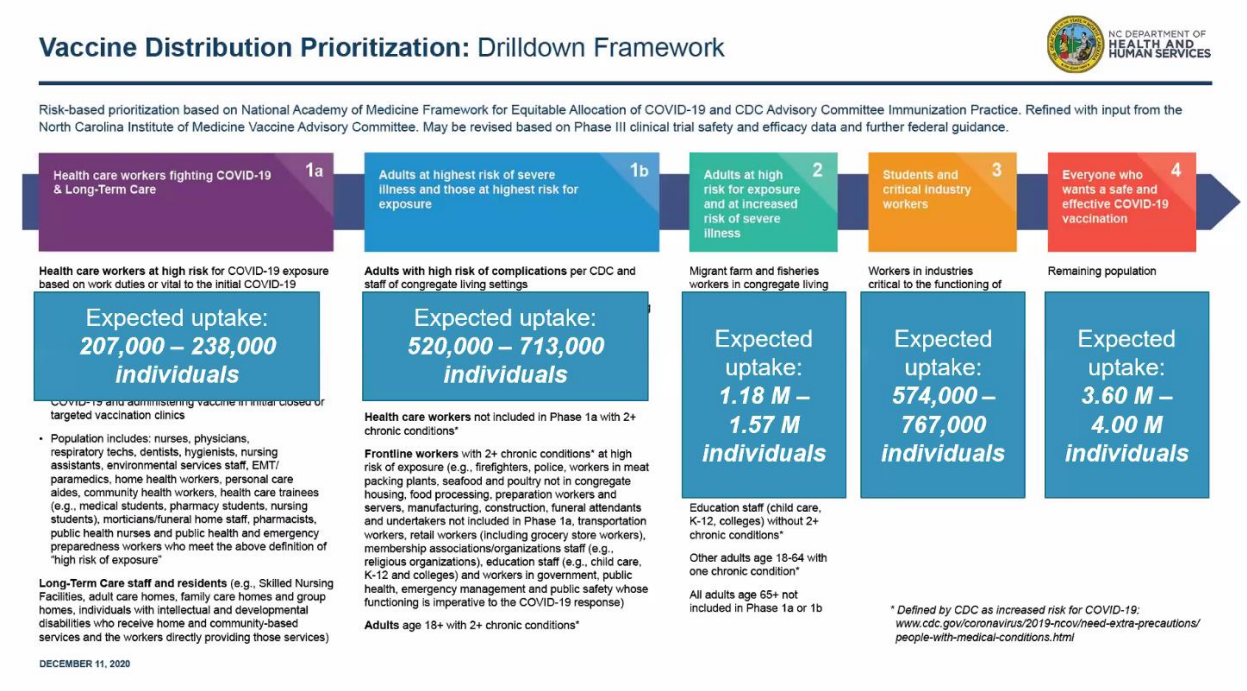
K-12 students (supported by data from clinical trials) and college students

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

Remaining population

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

DECEMBER 11, 2020



CDC Chronic Conditions

The chronic conditions at increased risk of severe COVID-19 illness are defined by CDC:
Cancer
Chronic kidney disease
COPD (chronic obstructive pulmonary disease)
Heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
Immunocompromised state (weakened immune system) from solid organ transplant

Obesity (body mass index [BMI] of 30 kg/m2 or higher but < 40 kg/m2)

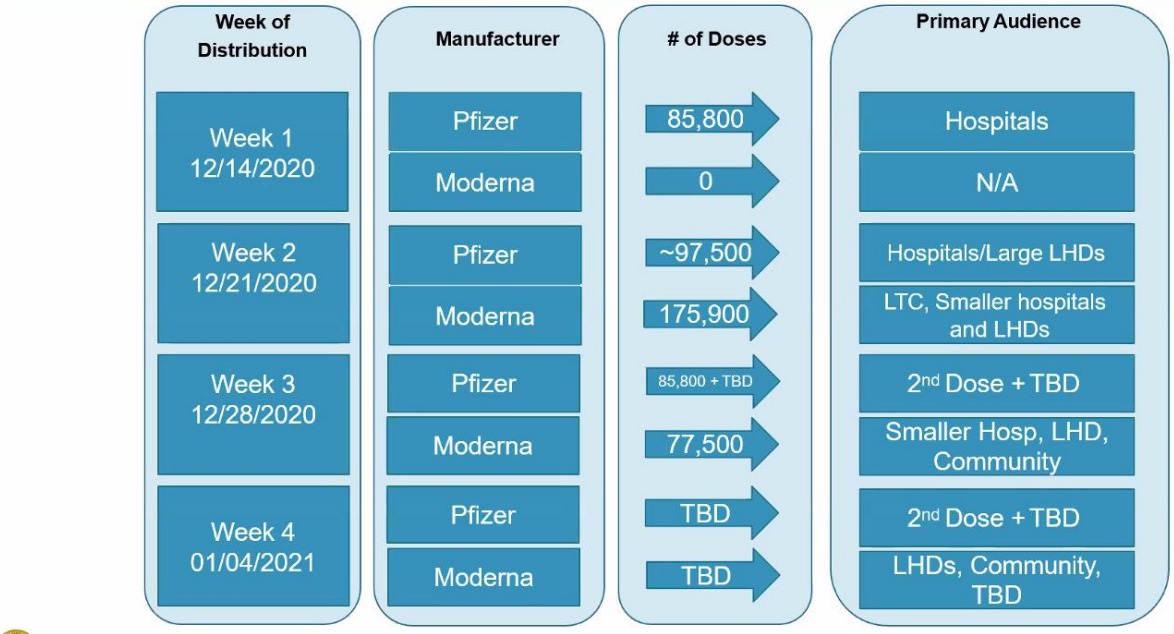
Severe Obesity (BMI ≥ 40 kg/m2)

Pregnancy

Sickle cell disease

Smoking

DRAFT Weekly vaccine allocation by manufacturer



*Assumption: serving all for LTC partnership

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: • 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