NC DHHS COVID-19
Vaccination Briefing

What North Carolina Practices Need to Know

December 15, 2020
Logistics for today’s COVID-19 Forum

Question during the live webinar

Technical assistance
technicalassistanceCOVID19@gmail.com

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.

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
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.

https://files.nc.gov/covid/documents/Vaccine-Timeline.pdf
### Pfizer Vaccine – Data Brief

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

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

![Pie chart showing distribution of participants by race/ethnicity](chart.png)
Figure 2. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1, Dose 1 All-Available Efficacy Population

No. of events/No. at risk

A: 821334 2121330 2721354 362061 4619314 4218957 4217702 4117196 4415944 4714930 4913196 4912951 4512403 4912371 501243 561298 500
B: 621258 2521170 2520970 2520556 2520289 12918218 14177575 18617025 18216200 21121376 23511994 24914471 2571294 2671330 2741448 2751290 2751290

Note: "S" indicates subjects with severe COVID-19 or COVID-19 leading to hospitalization.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adcf9ef Table Generation: 17NOV2020 (21:40)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: /indb2_unblended/C4591081_Efficacy_FA_164/adcf14e_f001_km_41_sai
### FREQUENCY OF TEMPORARY REACTIONS IN CLINICAL TRIALS BY DOSE AND AGE GROUP, MORE WITH SECOND DOSE, LESS WITH OLDER PEOPLE

<table>
<thead>
<tr>
<th>Symptom</th>
<th>18-55 year olds</th>
<th>&gt; 55 years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dose 1</td>
<td>Dose 2</td>
</tr>
<tr>
<td>Local reaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain at site</td>
<td>83%</td>
<td>78%</td>
</tr>
<tr>
<td>Redness at site</td>
<td>5%</td>
<td>6%</td>
</tr>
<tr>
<td>Swelling at site</td>
<td>6%</td>
<td>6%</td>
</tr>
<tr>
<td>Systemic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>47%</td>
<td>59%</td>
</tr>
<tr>
<td>Headache</td>
<td>42%</td>
<td>52%</td>
</tr>
<tr>
<td>Muscle pain</td>
<td>21%</td>
<td>37%</td>
</tr>
<tr>
<td>Chills</td>
<td>14%</td>
<td>35%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>11%</td>
<td>10%</td>
</tr>
<tr>
<td>Joint pain</td>
<td>11%</td>
<td>22%</td>
</tr>
<tr>
<td>Fever</td>
<td>3.7%</td>
<td>16%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>1%</td>
<td>2%</td>
</tr>
</tbody>
</table>

3/15,000 people receiving vaccine outside of clinical trial had a severe allergic reaction.
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
• **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)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3- phosphocholine, and 0.2 mg cholesterol)
  - 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose.
  - The diluent (0.9% Sodium Chloride Injection) contributes an additional 2.16 mg sodium chloride per dose.
  - The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative.

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

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

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

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

• Consent must be obtained prior to vaccination, but that consent can be verbal or written.
COVID-19 Vaccine Safety Monitoring Overview

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

The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):

- vaccine administration errors whether or not associated with an adverse event
- serious adverse events* (irrespective of attribution to vaccination)
- cases of Multisystem Inflammatory Syndrome (MIS) in adults and children
- cases of COVID-19 that result in hospitalization or death.

Vaccination provider should provide **V-safe information** for patients to self-enroll and report adverse events

CDC has developed a new, voluntary smartphone-based tool, v-safe, that uses text messaging and web surveys to provide personalized health check-ins after patients receive a COVID-19 vaccination. V-safe allows patients to report any side effects after COVID-19 vaccination to CDC in almost real time. It also gives them a convenient reminder to get their second COVID-19 vaccine dose if they need one.
COVID-19 Vaccine Safety Monitoring Website Links and Phone Number

Vaccine Adverse Event Reporting System (VAERS)

www.vaers.hhs.gov

(800) 822-7967
V-safe is a smartphone-based tool only for COVID-19 vaccine that uses text messaging and web surveys to provide personalized health check-ins to vaccine recipients following COVID-19 vaccination and serves as an important active surveillance system for adverse events.

V-safe also provides second dose vaccine reminders.

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

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

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

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

<table>
<thead>
<tr>
<th>First dose</th>
<th>Second dose</th>
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<tbody>
<tr>
<td>$16.94</td>
<td>$28.39</td>
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</table>

### 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.

<table>
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<td>$16.94</td>
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### 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.
- 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.

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**COVID-19 Vaccine Toolkit**
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.

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

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*

1c 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

2 Students and critical industry workers

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

Remaining population

Expected uptake:

207,000 – 238,000
individuals

520,000 – 713,000
individuals

1.18 M – 1.57 M
individuals

574,000 – 767,000
individuals

3.60 M – 4.00 M
individuals

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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 response.

COVID-19 and administering vaccine in initial closed or targeted vaccination clinics

- Population includes: nurses, physicians, respiratory techs, dentists, hygienists, nursing assistants, environmental service 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)

Expected uptake:

207,000 – 238,000
individuals

---

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

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 18+ with 2+ chronic conditions*

384,000 – 650,000
individuals

1.18 M – 1.57 M
individuals

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Expected uptake:

207,000 – 238,000
individuals

520,000 – 713,000
individuals

1.18 M – 1.57 M
individuals

574,000 – 767,000
individuals

3.60 M – 4.00 M
individuals

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Everyone who wants a safe and effective COVID-19 vaccination

Remaining population

Where are people in Phase 1a getting vaccinated?

Health care workers at highest risk for COVID-19 exposure
- Administering vaccine in initial closed or targeted vaccination clinics
- In hospitals or local health departments who have received early shipments of vaccine

Long-Term Care (LTC) staff and residents
- On-site in long-term care facilities in the Pharmacy Partnership for Long-Term Care Program with CVS and Walgreens
- Some will also be vaccinated in local health departments if not with a facility participating in the Pharmacy Partnership program, through other long-term pharmacies, other mobile providers
How will people know if they are in Phase 1a?

Health care workers at high risk for COVID-19 exposure

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

Long-Term Care (LTC) staff and residents

• All long-term care staff and residents qualify in Phase 1a
• LTC facilities will be notified when vaccines will be available to be administered to staff and residents.
<table>
<thead>
<tr>
<th>Planning</th>
<th>Implementation</th>
<th>Adjustment</th>
<th>Transition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Before vaccine is available</strong></td>
<td><strong>Begins when first vaccine doses are allocated to states</strong></td>
<td><strong>Large number of vaccine doses available</strong></td>
<td><strong>Sufficient supply of vaccine doses for entire population</strong></td>
</tr>
<tr>
<td><strong>Populations</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Establish priority groups</td>
<td>• Phase 1 populations</td>
<td>• Continue to move through phased populations as vaccine supply allows</td>
<td>• Offer vaccination to all populations through Phases 3 and 4</td>
</tr>
<tr>
<td><strong>Vaccination Channels</strong></td>
<td></td>
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</tr>
<tr>
<td>• N/A</td>
<td>• Initially through health systems, long term care, local health departments and on-site vaccination clinics</td>
<td>• Require more points of access, mass vaccination clinics, community based, and broad vaccination sites</td>
<td>• Vaccination in established channels</td>
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<td></td>
<td></td>
<td>• Fewer mass, mobile, or community-based clinics</td>
</tr>
<tr>
<td><strong>Enrollment/Ordering/Allotment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Identify/enroll providers</td>
<td>• Continue to enroll providers</td>
<td>• Transition to provider ordering vaccines based on need for population and local demand</td>
<td>• Ordering similar to annual seasonal flu vaccine campaign</td>
</tr>
<tr>
<td>• Expect CDC centralized distribution to providers</td>
<td>• Allocations to state, allotted to enrolled providers</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Shipment minimum of 100 for most vaccines</td>
<td>• Move to high supply/lower demand</td>
</tr>
<tr>
<td><strong>Shipment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• None shipped</td>
<td>• Shipment in increments of 975 for some, 100 for others</td>
<td>• Some require ultra-cold storage &amp; 2-dose series</td>
<td></td>
</tr>
<tr>
<td>• Expect vaccine and anc. supplies procured and distributed by fed gov’t</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Data</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Confirm capability for required functionality, data collection, and reporting</td>
<td>• Data systems for ordering, scheduling, dose tracking, inventory, data collection and reporting requirements</td>
<td>• Data systems for ordering, scheduling, dose tracking, inventory, data collection and reporting requirements</td>
<td>• Data systems for ordering, scheduling, dose tracking, inventory, data collection and reporting requirements</td>
</tr>
</tbody>
</table>
Vaccine Journey

1. CDC/ Operation Warp Speed (OWS) provide pro-rata vaccine allotment to the state.

2. State divides allocation of COVID-19 vaccines across providers based on prioritization, populations served, geography.

3. NC DHHS transmits orders to CDC/ OWS.

4. CDC/ OWS places orders with manufacturer/distributor for vaccines and ancillary kits/supplies.

5. Vaccines are transported by the manufacturer and/or McKesson to enrolled sites as indicated by the orders. McKesson distributes ancillary kits/supplies.

6. Upon receipt, providers store the COVID-19 vaccines in accordance with storage requirements.

7. Providers will organize vaccination clinics. Patients can register on CVMS (COVID-19 Vaccine Management System) and schedule an appointment or schedule with their provider to receive COVID-19 vaccine.

8. Provider administers the first vaccine dose and logs administration in CVMS. Appointments for second doses should be scheduled.

9. Provider monitors and reports adverse events using V-SAFE or VAERS in accordance with Emergency Use Authorization (EUA).

10. Patient receives a second dose reminder and schedules appointment if not already set up.

11. Provider administers the second vaccine dose and logs administration in CVMS. Continues adverse event monitoring.

Federal Responsibility
State Responsibility
Provider Level
Vaccine: Provider enrollment

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

**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

**PROVIDER ENROLLMENT DASHBOARD**

- **117** Hospitals (100%)
- **101** FQHC / RHC / Free & Charitable Clinics
- **100** LHDs (100%)
Vaccine: Federal long-term care pharmacy program

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.

### LTC ENROLLMENT DASHBOARD

<table>
<thead>
<tr>
<th>Adult Care Homes</th>
<th>Skilled Nursing Facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>~498 (79%)</td>
<td>427 (100%)</td>
</tr>
</tbody>
</table>

### KEY PROGRAM DATES

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

**Week of Dec 20-26**

Doses TBD

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

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

85,800 doses (88 increments of 975)

FOR OFFICIAL USE ONLY | NOT FOR DISTRIBUTION
# DRAFT Weekly vaccine allocation by manufacturer

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

*Assumption: serving all for LTC partnership
**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

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**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
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

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.
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

OR

ServiceNow Ticket***

ServiceNow will be live on Dec 15th

NC Helpdesk Personnel

Receives an email with answer

Provider

enduser@provider.com

Find the appropriate answer

**Helpdesk hours of operations**

<table>
<thead>
<tr>
<th>Monday – Friday</th>
<th>Saturday - Sunday</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00 AM to 5:00 PM</td>
<td>10:00 AM to 6:00 PM</td>
</tr>
</tbody>
</table>
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

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

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

https://covid19.ncdhhs.gov/vaccines
New one-page flyer on COVID-19 vaccines to give your patients

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

COVID-19 vaccines 101 deck

Infographic on prioritization
Questions?