

NC DHHS COVID-19 Vaccination Update

Provider Webinar

March 2, 2021



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

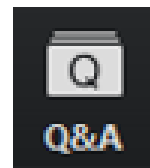
RCC (Relay Conference Captioning)

Participants can access real-time captioning for this webinar here:

<https://www.captionedtext.com/client/event.aspx?EventID=4722700&CustomerID=324>

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>

AGENDA

Welcome

Quick Hits

Updates on Distribution / Trends/ Allocations

Group 3 Frontline Essential Workers

Equity Story

CVMS Upgrades

Communication tools

Updates on Provider Enrollment, Activation, Receiving allocations

Clinical Info on J&J's Janssen Vaccine

Distribution / Allocation Updates

Distribution Status

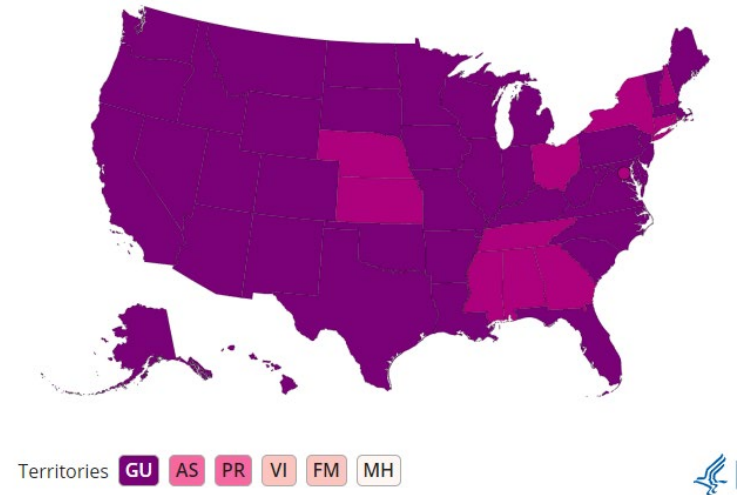
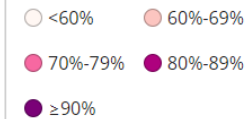
Total Doses Administered	NC Providers		Federal Long-Term Care Program	
2,524,531	2,320,066		204,465	
Vaccinations Summary – NC Providers				
	Allocated by the Federal Government	Arrived in North Carolina	Total Doses Administered	Percent of Arrived Doses Administered
FIRST DOSES	1,695,800	1,475,370	1,464,631	99%
SECOND DOSES	1,045,825	870,575	855,435	98%
TOTAL DOSES	2,741,625	2,345,945	2,320,066	99%

Vaccinations Summary – Federal Long-Term Care Program				
	Allocated by the Federal Government	Arrived in North Carolina	Total Doses Administered	Percent of Arrived Doses Administered
FIRST DOSES	145,900	145,900	121,590	83%
SECOND DOSES	145,900	145,900	82,875	57%
TOTAL DOSES	291,800	291,800	204,465	70%

<https://covid19.ncdhhs.gov/dashboard/vaccinations>



Percent of Delivered First Vaccine Doses Administered



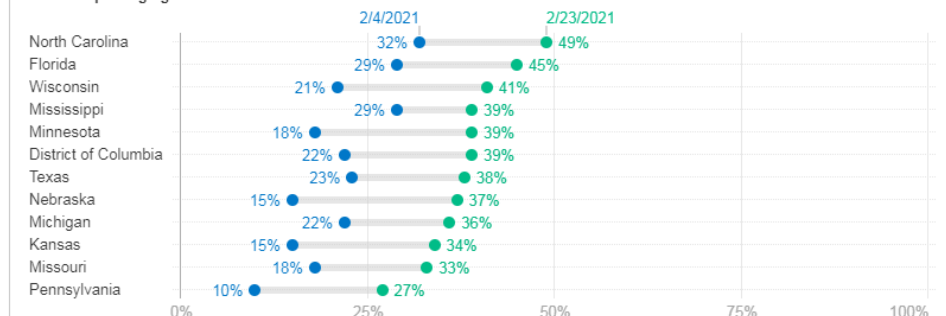
<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/distributing/first-doses.html>

Figure 3

The Share of Older Adults Who Have Received At Least One COVID-19 Vaccine Dose Has Increased Across States

Among states consistently reporting the number of older state residents who have received at least one COVID-19 vaccine dose, as of 2/23/2021

States reporting age 65 and older

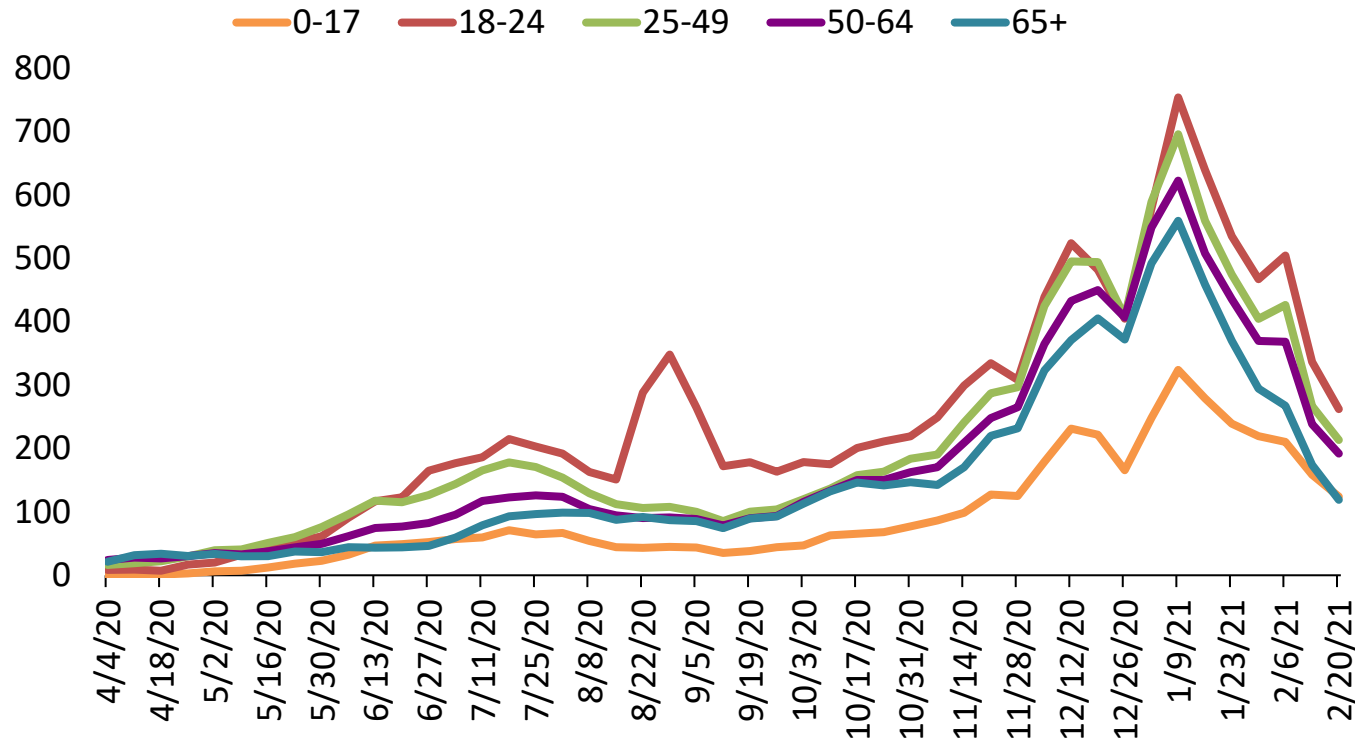


<https://www.kff.org/coronavirus-covid-19/issue-brief/vaccinating-older-adults-in-the-us-against-covid-19-a-work-in-progress/> 5

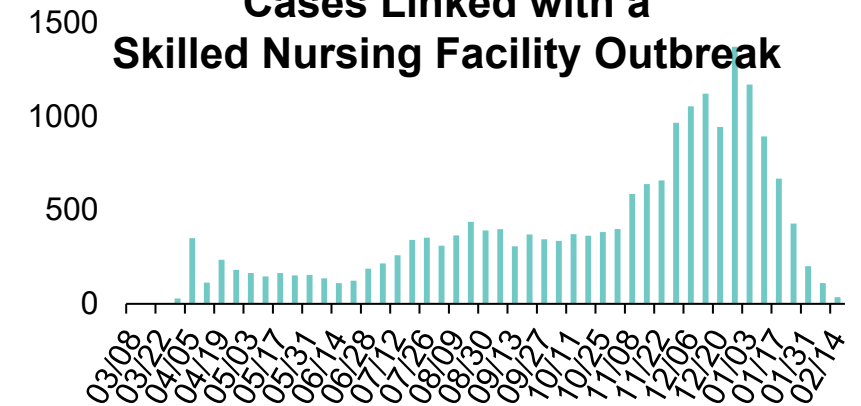
Case Rates and Outbreaks are Declining

Case rates for the 65+ age group the lowest among all age groups for the first time since June 2020 as vaccination rates continue to rise.

NC COVID-19 Cases per 100,000 Population by Age



Cases Linked with a Skilled Nursing Facility Outbreak



ALLOCATION UPDATE - SUPPLY IS INCREASING, BUT STILL LIMITED

- Overall, **168k more first doses arriving over the weeks of 2/22 and 3/1 than we had been receiving** with Moderna and Pfizer allocation increases to the state, the Federal Retail Program, and the addition of the J&J/Janssen vaccine
- 324,070 first doses arrived to NC providers the week of 2/22
 - Included vaccine allocations for the week of 2/15 that were delayed due to weather and arrived in the week of 2/22
 - 5% increase in doses of Moderna in week of 2/15 that arrive in week of 2/22
 - 15% increase in Pfizer doses in week of 2/22 allocation
- 304,030 first doses will arrive in week of 3/1
 - 83,700 doses of J&J/Janssen arriving a week before we expected them
 - 15% increase in Pfizer doses from week of 2/22
 - 5000 first doses returned from CVS federal LTCF program
- In the weeks of 2/22 and 3/1 about 100k first doses will be in Walgreens and a few CVS locations
 - These are federal allocations above the NC allocation and is twice that of previous weeks
- FEMA and NC will open a new administration site the week of 3/8 with additional doses from the federal allocation.
- About 15 NC FQHC locations will also receive federal vaccine allocations.

Prioritization Updates

Your best shot at stopping COVID-19.

YOU HAVE A **SPOT.** | TAKE YOUR **SHOT.**



PRIORITIZATION UPDATES

- **Group 1 - The definition of long-term care has been updated to include:**
 - people receiving long- term home care for more than 30 days including Home and Community Based Services for persons with intellectual and developmental disability, private duty nursing, personal care services, and home health and hospice.
 - [Deeper Dive Group 1: Health Care Workers and Long-Term Care Staff and Residents](#).
- **Group 3 - Additional Frontline Essential Workers will be eligible for vaccine beginning on Wednesday, March 3 instead of March 10th.**
 - [Deeper Dive Group 3: Frontline Essential Workers](#)
 - Please be sure to share our video with Frontline Essential Workers talking about why they plan to take their shot ([English](#) / [Spanish](#)) and our video with Agricultural Workers ([Spanish](#))
- **Group 4 - We will plan to move to Group 4 starting March 24th**
 - First phase - people who have a high-risk medical condition, people experiencing homelessness or living in a homeless shelter and people in a correctional facility, such as jail or prison.
 - Next phase – people living in other group settings (e.g, students in congregate housing) and other essential workers
 - Define high-risk medical conditions to include Intellectual and Developmental Disabilities, including Down Syndrome, and neurologic conditions, such as dementia and schizophrenia. [Deeper Dive Group 4: Adults at Higher Risk of Exposure and Increased Risk of Severe Illness \(Higher-Risk Conditions and Additional Congregate Settings\)](#).

The COVID-19 Vaccine Equity Story

A COMMITMENT TO EQUITY IN COVID-19 VACCINATION

Earn Trust in Historically Marginalized Communities

COMMUNICATION EFFORTS:

- **Research:** Continued partnership with ACCORD from NCCU to understand evolving HMP perspectives.
- **Vaccine 101 Presentations:** Offered weekly for to general public and soliciting requests for presentations in English or Spanish. Recent presentations: Greek Life NAACP, Duke Healthcare Preparedness Coalition (Spanish), Good Hope Missionary Baptist Church
- **Video PSAs:** Growing library featuring trusted messengers from HMP communities
- **Misinformation toolkit** with HMP Advisory Group

COMMUNITY-BASED ORGANIZATION ENGAGEMENT:

- **Partner with CBOs:** Toolkit and survey for CBOs developed to support vaccine education and operations. >200 organizations interested in hosting vaccine events.
- **Older adults:** Partnership with AARP to reach older adults, particularly from HMP

Embed Equity in Vaccine Operations

USE EQUITY DATA TO DRIVE ACTION

- Allocation method prioritization based on HMP
- E.g., WakeMed & Wake County LHD partnered with churches & community centers. With ~150 volunteers, they vaccinated almost 1,800 people, 91% Black.

REMINDER ON PROVIDER EXPECTATIONS

- Vaccinations should match local demographics. Provider allocation is at risk if not meeting equity expectations.

VACCINE SITE SELECTION

- Deploying DHHS-directed testing & vaccination vendors to zip codes with high numbers of HMPs & HMPs >65 years old.
- Directing FEMA mobile vaccination clinics to underserved, high HMP communities
- NCA&T and UNC-Pembroke vaccination site open all semester. More HBCUs planned.

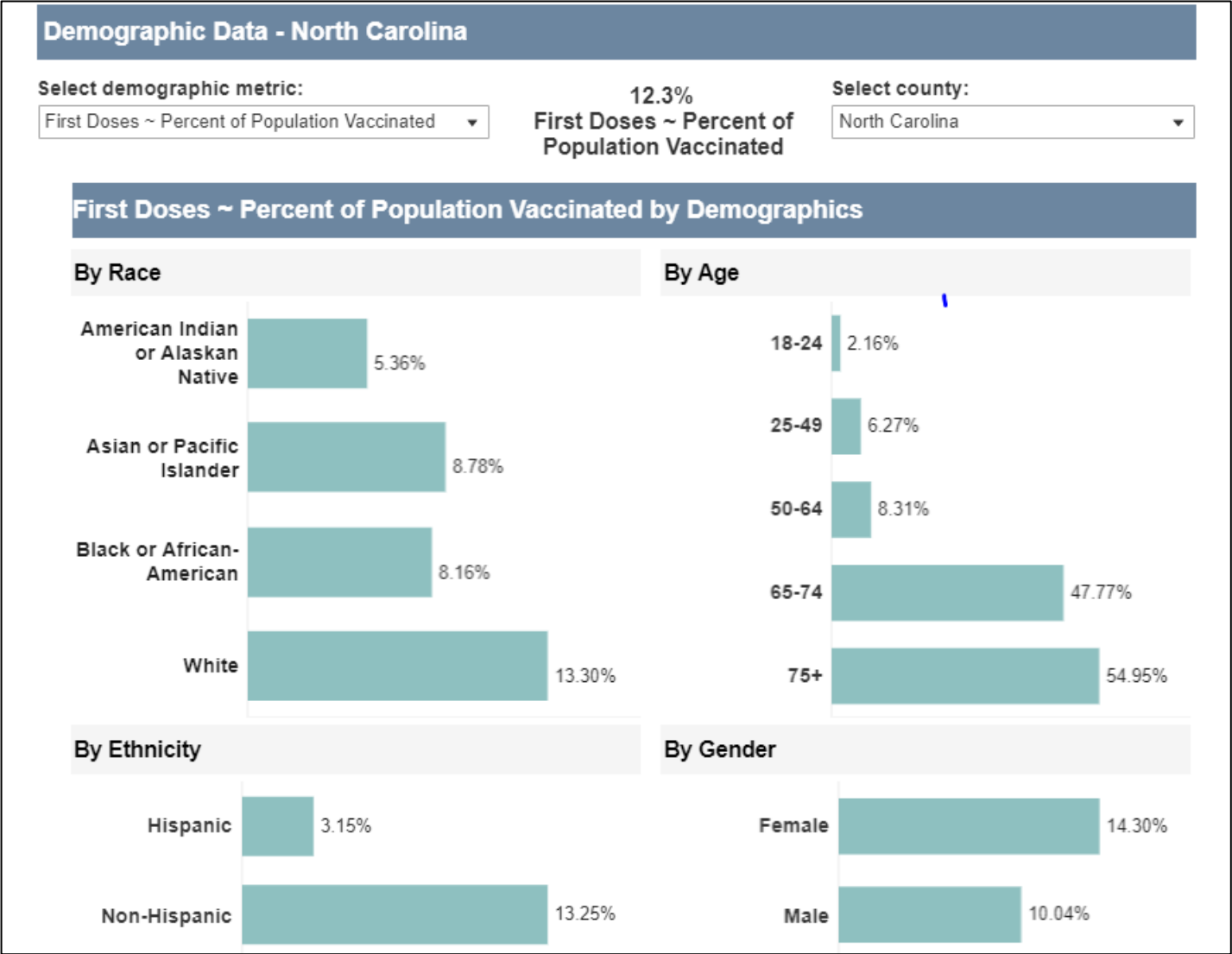
VACCINE PROVIDER SUPPORT

- 232 CHWs in 39 counties dedicated to vaccine work with vaccine registration, scheduling, and education

TRANSPORTATION SUPPORT

- \$2.5M to local transportation agencies for vaccine rides

PROMOTE ACCOUNTABILITY THROUGH DATA



Bloomberg News just rated NC as being best in nation for data quality, reporting race/ethnicity data for nearly 100% of people vaccinated in the state.

Percent of the population by race, ethnicity, age, and gender that has received a first dose.

Weekly reports to each provider on their race/ethnicity vaccination rates

MAKING PROGRESS AND MORE WORK TO DO

- For the past three weeks, **more than 20%** of first doses administered in the state have gone to our Black/African American population. The Black/African Americans population is **22.2% of the state's total population**.
- Starting to see some progress in Latinx/Hispanic population. For the week ending February 21st, **3.7%** of first doses administered in the state went to our Hispanic/LatinX population, **up from 1.8%** for the week ending January 17th. The Hispanic/Latinx population is **9.8 percent of the state's total population**

CVMS Updates

CVMS RELEASE 5 – KEY HIGHLIGHTS

R5 will now be split into 3 releases to accommodate immediate needed CVMS functionality

- ▶ **Release 5.0** (Tuesday, March 2)
 - ▶ One dose vaccine product support for Johnson & Johnson (Janssen)
 - ▶ Non-state vaccine allocation inventory identification to support FQHC and FEMA federal vaccine allocations
- ▶ **Release 5.1** (Friday, March 5)
 - ▶ Spanish translation of COVID-19 Vaccine Portal for recipients
 - ▶ Recipient Portal User Interface updates, including removal of CVMS priority tiering for recipients aligning with all recipients using the online 'Find My Group' tool
- ▶ **Release 5.2** (Sunday, March 14):
 - ▶ Implementation of Scheduling Capability for participating providers:
 - ▶ Enable Recipients to schedule and cancel appointments for 1st and 2nd doses for providers who have chosen to use the scheduling function for their site
 - ▶ Enable Healthcare Location Managers to manage appointment slots
 - ▶ Enable CVMS Provider Location master data integration with the VAX FINDER /myspot.nc.gov application
 - ▶ Ability for CVMS to have multiple accounts with same email to accommodate multiple recipients using a single email address.
 - ▶ Provider Enrollment (PE) enhancements

HIE Integration

NC DHHS and the NC HIEA are partnering to leverage the existing infrastructure in place at provider organizations and the NC HealthConnex health information exchange (HIE) to submit vaccine records to the COVID-19 Vaccine Management System (CVMS).

- This solution will utilize flat-file extracts of demographics and vaccine administration data to populate CVMS.
- It will eliminate the need for registration of patients in CVMS and reduce the need for manual re-entry of EHR documented vaccine administration data into CVMS.

Goals

1. Increase vaccination rate by reducing dual documentation steps.
2. Improve user experience in CVMS by de-duplicating patient records using the NC HealthConnex master patient identifier (MPI).
3. Provide more timely and accurate reporting.

Steps

1. Establish secure connectivity with NC HealthConnex.
2. Create and send daily files adhering to the NC COVID Vaccine Reporting (NCVR) specification.
3. Receive and remediate errors reported for rejected records.

For more information, contact hiea@nc.gov.

Provider Enrollment, Onboarding, Activation, Allocation

CVMS ENROLLMENT / ONBOARDING PROCESS FOR NON-FEDERAL PARTNERS

Provider Enrollment

686 Provider Organizations Approved
1,483 Provider Location Sites Approved

Provider Enrollment Process

1. Provider receives training (live or recording)
2. Provider completes application in CVMS
3. DHHS provider enrollment approval process:
 - a. Review CMO and provider licensure matches
 - b. Review storage & handling unit
 - c. Update NCIR and Vtrcks with required information
 - d. CVMS sends auto-generated provider approval email to provider

Enrollment Complete



Hospitals and Local
Health Departments
(LHDs)

Completing Enrollment



**Remaining
provider enrollment**
Pharmacies, FQHC's,
Rural Health
Centers, Free and
Charitable Clinics,
primary care practices,
occupational health

Activated to Receive Vaccine



Activated Locations

FQHC's 146

PCPs 167

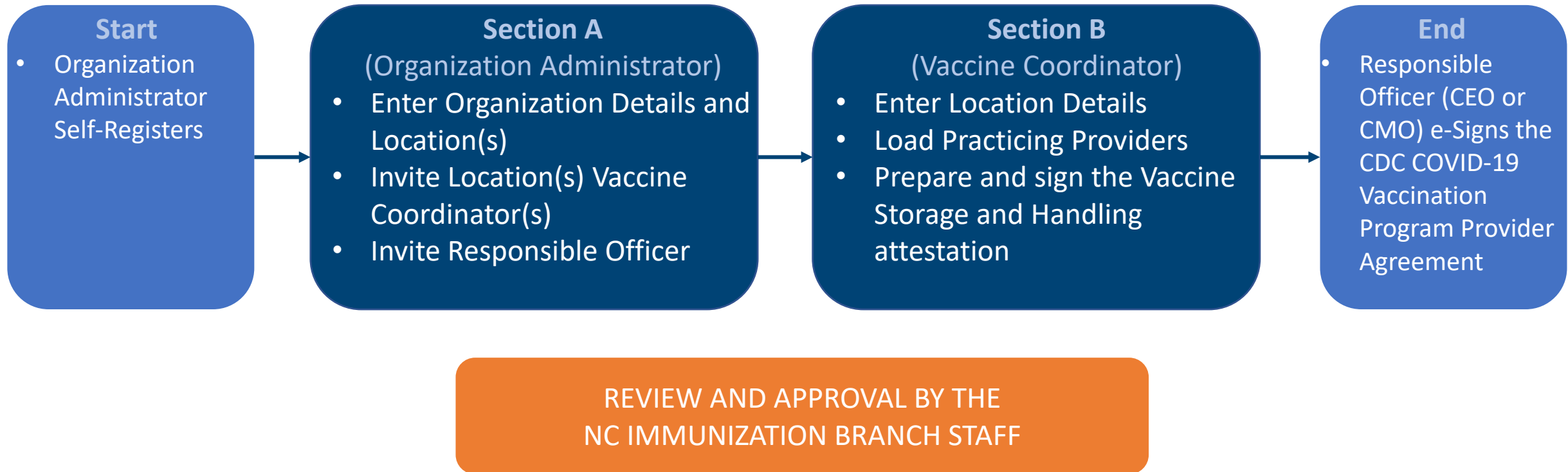
Independent
Pharmacies 203

Occupational Health 29

**Data updated as of 3/2 @ 3pm EST

CVMS PROVIDER ENROLLMENT PROCESS OVERVIEW FOR NON-FEDERAL PARTNERS

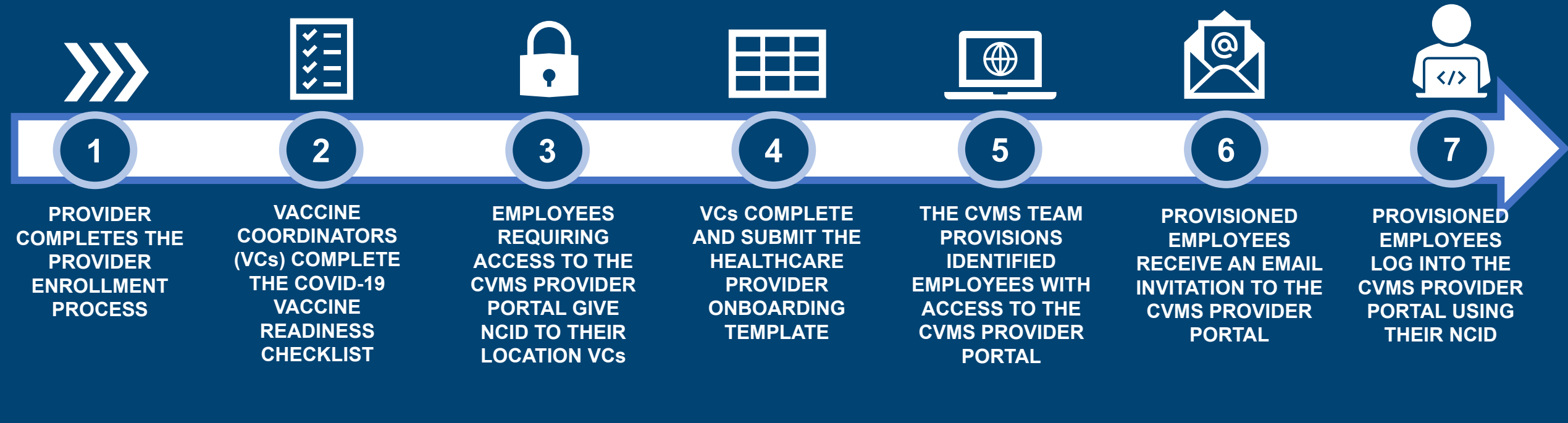
The Provider Enrollment Process is **NOT** complete until **BOTH Section A** and **Section B** (for all Locations) are complete *and* the NC Immunization Branch Staff has reviewed and approved the submitted agreement.



Provider Enrollment Approval is not the same as gaining access to the CVMS Provider Portal. Vaccine Coordinators will need to complete and submit the Healthcare Provider Onboarding Template to have their employees provisioned for access to the CVMS Portal.

ONBOARDING TO THE CVMS PROVIDER PORTAL

While Provider Enrollment is an important step in the onboarding process, it is not the *only* step. This process will take a few days to complete and is dependent on the volume of providers onboarding at the time of submission.



As the Provider Enrollment process is running, Vaccine Coordinator(s) should begin working through the COVID-19 Readiness Checklist for their location(s), including completing the Healthcare Provider Onboarding Template.



To learn more about the Onboarding Process, check out the Onboarding User Guide found here:

<https://immunize.nc.gov/providers/ncip/training/CVMS%20Provider%20Enrollment%20Account%20Registration%20and%20Password%20Reset%20User%20Guide> 01 08 2021.pdf

ENROLLED, ACTIVATED...AND AWAITING AVAILABLE VACCINE ALLOCATION

1

CVMS Activation Complete

Provider completed all required onboarding activities and their CVMS account is activated

No set day

2

Provider turns on "Allocations Button"

Turning this button on signifies the provider is ready to receive vaccine

No set day

3

Selected for Allocation

Provider is selected to receive vaccine allocation for the next week

Monday - Wednesday

4

Provider added to CM Master List

New providers are added to master list and assigned a CM based on alignment (type, region, capacity)

Wednesday

5

Case Manager Introduction

Case managers contact provider to introduce themselves and provide support

Wednesday

6

Provider Sent ReadyOp Form

Provider sent survey with allocation information and must respond and accept vaccine allocation

Thursday

AVAILABLE TO RECEIVE ALLOCATION BUTTON

The “**Available to Receive Vaccine Allocation**” field can be found on the Account Record (Location) page in CVMS (screen shots below). If you indicate ‘**Yes**’, that means your location is **able to receive COVID-19 vaccine** inventory that week if allocated. Note being *able* to receive vaccine by selecting “Yes” does not guarantee you will *receive* vaccine. If you indicate ‘**No**’ because you do not have storage or capacity to administer, your location **will not be allocated vaccine**.

Step 1

Home Recipient Appointments Bulk Registration Reports Vaccine Inventory More ▾

Account TestCarmel (Loc 1)

Change Allocation Availability

Available to Receive Vaccine Allocation No

Instructions (Available to Receive Vacs)

Please ensure field 'Available to Receive Vaccine Allocation' is correct each week. 'Yes' means the site does not wish to receive vaccine or is not able to receive and administer additional vaccine at that time if allocated and the site will not be considered for allocation. This value can be changed at any time, so if you wish to skip one week for any reason (i.e. sufficient supply planning that week. If you would like to be considered for allocation, you should have the value set at 'yes' by 10AM on Mondays. The value will STAY in place until a site adjusts it (i.e. if you select 'No,' it will remain 'No' until the site moves it to 'Yes.')

Step 2

Change Allocation Availability

* Available to Receive Vaccine Allocation ⓘ

Yes ▾

Instructions (Available to Receive Vacs) ⓘ

Please ensure field 'Available to Receive Vaccine Allocation' is correct each week. 'Yes' means the site is able to receive and administer additional vaccine if allocated. A value of 'No' means the site does not wish to receive vaccine or is not able to receive and administer additional vaccine at that time if allocated and the site will not be considered for allocation. This value can be changed at any time, so if you wish to skip one week for any reason (i.e. sufficient supply planning that week. If you would like to be considered for allocation, you should have the value set at 'yes' by 10AM on Mondays. The value will STAY in place until a site adjusts it (i.e. if you select 'No,' it will remain 'No' until the site moves it to 'Yes.')

Cancel Save

Step 3

Step 4

UPDATED SURVEY INFORMATION AND DEADLINES

Key Information

Allocations Survey

- Weekly survey to give providers the opportunity to accept/decline allocations
- Any provider who does not complete the digital acceptance form, agree to the expectations, and **accept by the deadline will have their allocation forfeited and the vaccine will be allocated elsewhere.**
- There will not be follow up on missed survey responses

Events Survey

- Bi-weekly survey for providers to submit large-scale community vaccination events (>500 first doses administered per day)
- These are requests, not guarantees, and will be evaluated based on readiness, equity focus, and community partnerships
- Only submit one form if you are partnering with other providers, and you DO NOT need to submit every time for recurring requests

Deadlines

Each week, an email with the Allocations Survey link will be sent on Thursday afternoon, and providers must respond by:

12:00pm EST every Friday

An email with the Events Survey link will be sent by EOD Thursday and providers must respond by:

12:00pm EST every Monday

Johnson & Johnson (Janssen): Allocation – Use case

- 83,700 doses of J&J/Janssen arriving week of March 2 allocated as vaccine event set-asides.
- All allocated doses that arrive between March 2 and March 4 need to be administered and recorded no later than March 14.
- No additional J&J/Janssen vaccine expected in weeks of 3/8, 3/15, or 3/22

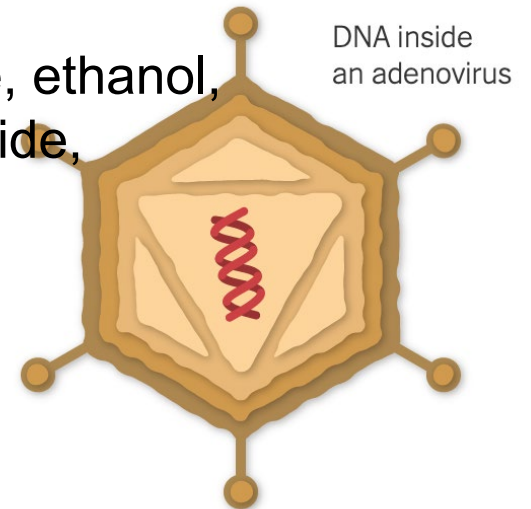
Vaccine event requests

- <https://nc.readyop.com/fs/4d8U/edbe>
- Vaccine providers can submit additional event allocation requests by **Monday, March 8 at 12pm EST**.
 - Requests will be for events in the weeks of March 15, 22, and 29
- Due to limited supply, the State is only able to support a limited number of events or efforts per week.
- Not all proposed events can be supported in a given week.
- Current supply levels do not allow for week-after-week support of any large events or efforts.
- The State is currently rotating geographically around the state to support these efforts for one week at a time, to ensure geographic access.

Information on Johnson and Johnson (Janssen) Vaccine

JOHNSON AND JOHNSON (JANSSEN) VACCINE – BASICS OF THE VACCINE

- Like the Pfizer and Moderna vaccines, scientists **built on decades of previous work** on similar vaccines to create the Johnson & Johnson one-shot vaccine.
 - Ebola vaccine and experimental HIV and Zika vaccines
- Instead of mRNA (like Pfizer and Moderna), **DNA for SARS-CoV-2 spike protein** inserted in a **replication-incompetent** adenovirus vector
 - After entering a cell, it produces the spike protein antigen which triggers immune response without virus replication
 - You cannot get an adenovirus infection or COVID-19 from the vaccine
 - Inactivated (not live) virus
- **Other inactive ingredients:** Citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl- β -cyclodextrin, polysorbate 80, sodium chloride, sodium hydroxide, hydrochloric acid. **No preservative. No animal derived proteins**
- 1-dose schedule



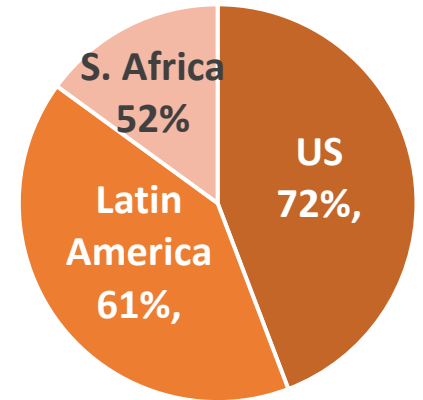
JOHNSON AND JOHNSON (JANSSEN) VACCINE – CLINICAL TRIALS

- Phase 3 trial included over 43,783 participants
- 45% female
- 18 – 100 years old, 20% were \geq 65 years old
- 40% with at least one co-morbidity (e.g., obesity, hypertension, diabetes, cancer, heart disease, lung disease, sickle cell anemia)
- 62% white, 17% Black/AA, 8% Native American, 4% Asian, 5% multi-racial
- 45% Hispanic/Latino
- 47% from US, 17% Brazil, 13% South Africa, 23% other Latin American Countries
- Similar distribution of demographic characteristics between vaccine and placebo group
- 9.6% of vaccinated participants had evidence of prior infection with SARS-CoV-2 infection

JOHNSON AND JOHNSON (JANSSEN) VACCINE – EFFECTIVENESS

- 1 dose, protection starts at 14 days after vaccination and increases after 28 days

Efficacy in preventing moderate to severe disease



- **Effectiveness 28 days after vaccination**

- 66% effective overall in preventing any symptomatic disease
 - 66% effective in preventing moderate to severe illness
 - 72% in the US
 - 84% effective overall in preventing severe disease
 - 100% effective in preventing the need for medical intervention, hospitalization, ICU and death
 - Similar across age, race, ethnicity, co-morbid chronic conditions
-
- Still learning about effectiveness of preventing asymptomatic infection and ability to spread
 - No significant safety concerns.

JOHNSON AND JOHNSON (JANSSEN) VACCINE – ADMINISTRATION

- Each dose is 0.5mL, given as singular intramuscular injection
- Each vial contains five doses (do not pool excess vaccine from multiple vials)
- No diluent required
- Colorless to slightly yellow, clear to very opalescent suspension
 - Visually inspect vials and each dose in dosing syringe for particulate matter and discoloration prior to administration and if present do not administer
- Before withdrawing each dose of vaccine, carefully mix contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. **Do not shake.**
- Does not contain a preservative. Record the date and time of first use on the vial label. After the first dose has been withdrawn, use within 6 hours (refrigerated) or 2 hours (room temperature). Discard if vaccine is not used within these times.

COVID-19 VACCINATION GUIDANCE, INCLUDING JOHNSON AND JOHNSON (JANSSEN) VACCINE

- **Any COVID-19 vaccine can be used when indicated, no product preference**
- Persons may receive any ACIP-recommended COVID-19 vaccine and are encouraged to receive the earliest vaccine available to them.
- The Janssen COVID-19 vaccine is not interchangeable with other COVID-19 vaccine products
- There is no information on the co-administration of the J&J/ Janssen COVID-19 Vaccine with other vaccines; COVID-19 vaccines (including Janssen) should be administered alone with minimum interval of 14 days before or after administration of other vaccines.
 - A shorter interval may be used in situations where benefits of vaccination outweigh potential unknown risks (e.g. tetanus toxoid vaccine for wound management, etc) or to avoid barriers or delays to vaccination

COVID-19 VACCINATION GUIDANCE, INCLUDING JOHNSON AND JOHNSON (JANSSEN) VACCINE

- Limited data suggests individuals can be re-infected with SARS-CoV-2; **Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection**
- **Viral testing for current infection, or serologic testing for prior infection, is NOT recommended** for vaccine decision-making purposes
- **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**
- Current evidence suggests reinfection uncommon in the months after initial infection and thus while vaccine supply remains limited, **persons with documented infection may choose to temporarily delay vaccination**
 - Risk of reinfection, and need for vaccination, might increase with time following initial infection

COVID-19 VACCINATION GUIDANCE (INCLUDES JOHNSON AND JOHNSON (JANSSEN) VACCINE)

- **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**
 - Does not apply to persons receiving antibody therapies not specific to COVID-19 treatment
- **Persons with underlying medical conditions**
 - **Any currently authorized COVID-19 vaccine can be administered to persons with underlying medical conditions who have no contraindications to vaccination, including:**
 - Immunocompromised persons
 - People with autoimmune conditions
 - People with history of Guillain-Barré syndrome, Bell's palsy, dermal filler use
 - Clinical trials demonstrate similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to persons without comorbidities

COVID-19 VACCINATION GUIDANCE (INCLUDES JOHNSON AND JOHNSON (JANSSEN) VACCINE)

Immunocompromised Persons

- Any currently authorized COVID-19 vaccine can be administered to immunocompromised persons who have no contraindications to vaccination, including:
 - Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19
- All currently authorized vaccines are inactivated vaccines
- Individuals should be counseled about:
 - Unknown vaccine safety and efficacy profiles in immunocompromised persons
 - Potential for reduced immune responses
 - Need to continue to follow current guidance to protect themselves against COVID-19

COVID-19 VACCINATION GUIDANCE (INCLUDES JOHNSON AND JOHNSON (JANSSEN) VACCINE)

- **Pregnancy**

- Increased risk of severe illness with COVID-19 (ICU admission, mechanical ventilation and death), might be an increased risk of adverse pregnancy outcomes such as preterm birth
- Currently limited data on safety of COVID-19 vaccines in pregnant people
 - No concerns demonstrated in animal developmental and reproductive toxicity (DART) studies
 - J&J/ Janssen adenovirus vector platform previously used for other clinical development programs that included pregnant people, including a large-scale Ebola vaccine trial
- Currently authorized COVID-19 vaccines are all inactivated vaccines
- **Pregnant people may choose to receive COVID-19 vaccine when eligible**
 - Conversation between patient and clinical team may assist with decision but not required (conversation should consider level of COVID-19 community transmission, personal risk of contracting COVID-19, risks of COVID-19 to patient and fetus, efficacy and side effects of vaccine, limited data about vaccine during pregnancy)
- Clinical trials to evaluate safety and efficacy of COVID-19 vaccines in pregnant people planned or underway

- **Lactation**

- Risk Summary Data are not available to assess the effects of Janssen COVID-19 Vaccine on the breastfed infant or on milk production/excretion

CONTRAINDICATIONS AND PRECAUTIONS FOR COVID-19 VACCINES

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
<p>History of the following:</p> <ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine[†] Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine[†] <p>Actions:</p> <ul style="list-style-type: none"> Do not vaccinate. Consider referral to allergist-immunologist. Consider other vaccine alternative.[‡] 	<p>Among persons without a contraindication, a history of:</p> <ul style="list-style-type: none"> Any immediate allergic reaction* to other vaccines or injectable therapies[‡] <p>Actions:</p> <ul style="list-style-type: none"> Risk assessment Consider referral to allergist-immunologist 30-minute observation period if vaccinated 	<p>Among persons without a contraindication or precaution, a history of:</p> <ul style="list-style-type: none"> Allergy to oral medications (including the oral equivalent of an injectable medication) History of food, pet, insect, venom, environmental, latex, etc., allergies Family history of allergies <p>Actions:</p> <ul style="list-style-type: none"> 30-minute observation period: persons with history of anaphylaxis (due to any cause) 15-minute observation period: all other persons

[†] See [Appendix C](#) for a list of ingredients. Persons with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).

* Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

[‡] Includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction.

[#] Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. Persons with a contraindication to mRNA COVID-19 vaccines (including due to a known [diagnosed] allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among persons who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). Persons with a contraindication to Janssen COVID-19 vaccine (including due to a known [diagnosed] allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. In patients with these precautions, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.

VACCINATION PROVIDERS

- 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.janssencovid19vaccine.com to obtain the Fact Sheet) prior to the individual receiving the Janssen COVID-19 Vaccine, including:
 - FDA has authorized the emergency use of the Janssen COVID-19 Vaccine, which is not an FDA approved vaccine
 - The recipient or their caregiver has the option to accept or refuse the Janssen COVID-19 Vaccine
 - The significant known and potential risks and benefits of the Janssen 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
- Provide a vaccination card to the recipient or their caregiver
- Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe
- Obtain consent, but that can be verbal or written

COVID-19 Vaccine Safety Monitoring

- ❖ 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.



Vaccine Adverse Event Reporting System (VAERS)



www.vaers.hhs.gov



(800) 822-7967

FDA Emergency Use Authorization

EUA

- ❖ FDA Advisory Committee endorsed 2/26/21, FDA Issued Emergency Use Authorization 2/27/21 for 18 years and older, CDC's ACIP recommended 2/28/21
- ❖ Authorized for use for people 18 years of age and older

Helpful Links

- ❖ [Johnson and Johnson \(Janssen\) data briefing document for FDA](#)
- ❖ [Johnson and Johnson \(Janssen\) 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 Johnson and Johnson \(Janssen\) COVID-19 Vaccine](#)

Communications

Johnson & Johnson (Janssen): Messaging

Key Message for All Vaccines:

COVID-19 vaccines help prevent COVID-19 and are extremely effective in preventing hospitalization and death with no serious safety concerns.

The Johnson & Johnson vaccine is given in one shot and does not require extreme cold storage, so it can be more easily shipped, stored and administered, providing opportunities to increase the number of vaccination sites and make them more convenient.

Having a third safe and effective vaccine will help North Carolina vaccinate as many people as quickly as possible and meet its goals to provide equitable access to COVID-19 vaccinations in every community in the state.

Getting as many people as possible vaccinated quickly will also help stop the spread of COVID-19 variants—and get us back in control of our lives and back to the people and places we love.

New Resources

New materials available

- Top Ten Facts
- Developing COVID-19 Vaccines infographic
- Social media graphics and content
- Community posters

Materials in English and Spanish

YOU HAVE A SPOT. TAKE YOUR SHOT.

10 FACTS YOU SHOULD KNOW ABOUT COVID-19 VACCINES

1. The vaccines are found to help prevent COVID-19 and are effective in preventing hospitalization and death. Millions of people in the U.S. have already received them.
2. COVID-19 vaccines are built on years of work to develop vaccines for similar viruses.
3. You cannot get COVID-19 from the vaccines.
4. There are no serious side effects. You may have temporary reactions like a sore arm, fever, headache or feeling tired and achy for a day or two after receiving the vaccine.
5. The vaccines teach your body how to create a protein that helps you fight COVID-19. The protein and vaccine leave your body after they are finished and cannot be tracked.
- 6.
- 7.
- 8.
- 9.
- 10.

How Safe and Effective COVID-19 Vaccines Come to You

1. **Scientists had a head start.**
 - The COVID-19 vaccines were built upon vaccines for similar viruses.
2. **Vaccines are safe and work to prevent millions of people in the U.S. have.**
 - Trials included diverse participants, including Hispanic/Latino volunteers.
 - Vaccines were found to help prevent COVID-19 in preventing hospitalization and death concerns noted in the clinical trials.
3. **The Food and Drug Administration (FDA) reviews trials and determines if vaccines are safe and effective.**
 - An independent, scientific committee checks the work.
 - Vaccines are authorized and recommended for use.
4. **Companies manufacture vaccines and the federal government distributes them.**
 - High quality vaccines are manufactured for distribution.
 - The federal government ships the vaccines and vaccination supply kits to vaccine providers each week.
 - Supplies are limited—states don't get all the vaccines they need right away.
5. **Safety and effectiveness are continuously monitored.**
 - Like all vaccines, the FDA keeps checking safety through its reporting systems.
 - Health care providers report serious side effects or serious illness.

NC Department of Health and Human Services | YourSpotYourShot.nc.gov
COVID-19 is an equal opportunity employer and provider. | 05/2020

YOU HAVE A SPOT. TAKE YOUR SHOT. YourSpotYourShot.nc.gov

TWO SHOTS are necessary to fight COVID-19

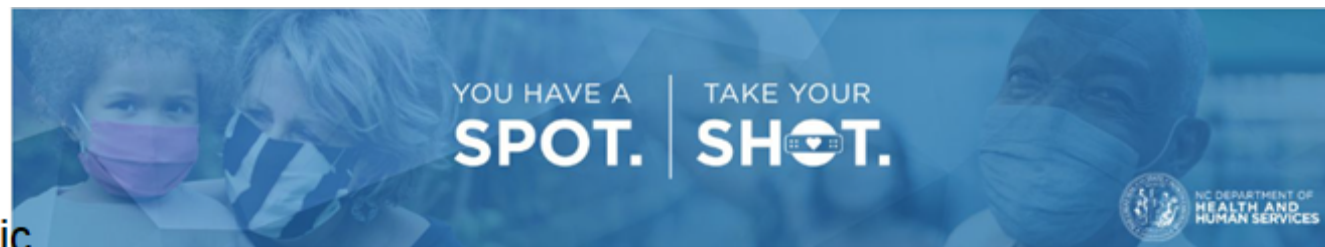
The **SECOND** shot will come **3-4 WEEKS** after the first.

YOU HAVE A SPOT. TAKE YOUR SHOT.

PROTECT YOURSELF, FAMILY AND COMMUNITY.
Get a safe, effective and free COVID-19 vaccine.

Learn more at YourSpotYourShot.nc.gov
COVID-19 Vaccination Help Center
toll-free at 888-675-4567

NC Department of Health and Human Services | YourSpotYourShot.nc.gov
COVID-19 is an equal opportunity employer and provider. | 05/2020



NCDHHS: COVID-19 Vaccine Communications Toolkit

CAMPAIGN

You Have A Spot. Take Your Shot.

DESCRIPTION

This is your spot for ready-made materials to help you communicate about safe and effective COVID-19 vaccines.

Anyone who is sharing information about the COVID-19 vaccine with their community, including health care professionals, team leaders, community and business leaders and non-profit organizations, can use and adapt the resources here to build confidence in the COVID-19 vaccines. This page will be updated frequently with sample social media posts, graphics and other materials for you and your organization to use.

You can help people in your community find their spot and take their shot.

For more information: YourSpotYourShot.nc.gov

Version en español: covid19.ncdhhs.gov/kit-de-herramientas-de-comunicacion-sobre-vacunas-covid-19

HASHTAGS

#FindYourSpotNC | #TakeYourShotNC |
#YourSpotYourShotNC | #BestShot |
#COVID19NC | #COVID19Vaccine |
#StayStrongNC | #StopCOVID19 |
#ThisIsOurShot | #VaccinesSaveLives

Brand Guidelines	Social Media Graphics	Flyers	Post Cards
Presentation/Reports	Website and Newsletter Graphics	Video Library	

FOLLOW THESE GUIDELINES WHEN PRODUCING ANY MATERIALS IN SUPPORT OF THE YOU HAVE A SPOT. TAKE YOUR SHOT. CAMPAIGN

[Brand and Usage Guidelines \(URL\)](#)

[Brand and Usage Guidelines \(PDF\)](#)

New Easy-to-Use Toolkit

Helping People Find Their Spot

Find Vaccine Locations

- Interactive map
- 270k+ users from 2/5-2/21

Vaccine Eligibility Screener

- 267k+ signed up for alerts
- Email and SMS enabled

Vaccine Help Center

- **1-888-675-4567**
- 29,677 calls since launch
- 95% satisfaction rate
- 10 Spanish agents added 2/22

Find A Vaccine Location



Para usar este sitio web en español, seleccione español en el despliegue de la esquina derecha superior.


Find Local Vaccine Providers Near You

Use this tool to find COVID-19 vaccine locations near you in North Carolina. Enter your zip code or search by current location to find the closest vaccine providers.

Vaccine will be available to all who want it, but supplies are currently limited. You may have to wait.

North Carolina is currently vaccinating Groups 1 and 2. Not all vaccine providers may be ready to vaccinate your group yet. Don't know what group you're in? Visit [Find My Vaccine Group](#) to find your vaccination group.

You will likely need an appointment to get vaccinated. You may have to wait to schedule your appointment to get your vaccine. Please contact the provider to find out which groups they are currently vaccinating.



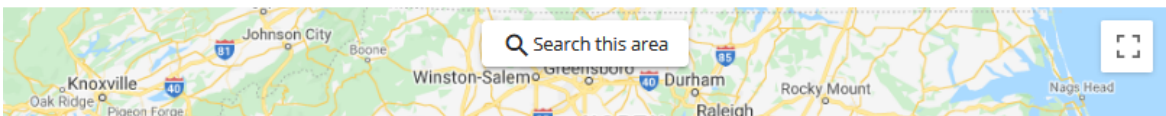
5 Miles

10 Miles

25 Miles

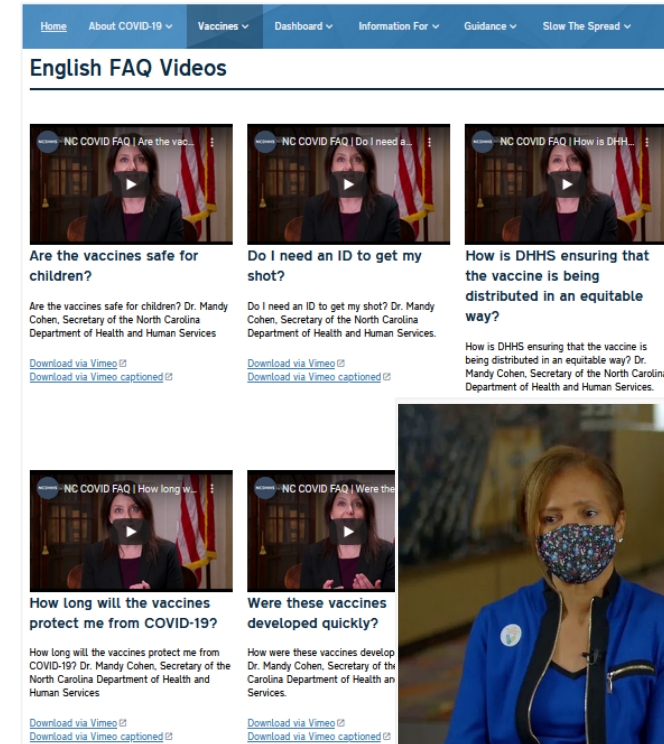
No Limit

Search this area



Outreach and Education: Videos

- **6 short FAQ videos w/Sec. Cohen**
 - Are the vaccines safe for children?
 - Do I need an ID to get my shot?
 - How is DHHS ensuring that vaccines are distributed equitably?
 - How long will the vaccines protect me from COVID-19?
 - Were these vaccines developed quickly?
 - What are the side effects?
- **Essential worker PSA**
- **Chancellor Martin, North Carolina A&T**
- **Up next:**
 - Basketball coaches
 - Western NC with frontline workers



Questions?



Appendix

WHO: FRONTLINE ESSENTIAL WORKERS

Frontline essential workers are people who:

- Must be in-person at their place of work
- Work in one of the eight essential sectors listed below*
- Higher proportion of chronic disease
- High risk of exposure
- Higher proportion of historically marginalized populations

Critical Manufacturing	Education	Essential Goods	Food & Agriculture	Government and Community Services	Health Care and Public Health	Public Safety	Transportation
<p>Including for example:</p> <ul style="list-style-type: none"> • Workers manufacturing medical supplies, medical equipment or PPE • Workers manufacturing products needed for food and agricultural supply chains 	<p>Including for example:</p> <ul style="list-style-type: none"> • Child care staff • K-12 teachers and support staff • College and university instructors and support staff 	<p>Including for example:</p> <ul style="list-style-type: none"> • Workers in stores that sell groceries and medicine 	<p>Including for example:</p> <ul style="list-style-type: none"> • Meat packing workers • Food processing workers • Farmworkers • Migrant farm/fishery workers • Food distribution and supply chain workers • Restaurant workers 	<p>Including for example:</p> <ul style="list-style-type: none"> • U.S. Postal Service Workers and other shipping workers • Court workers • Elected officials • Clergy • Homeless shelter staff 	<p>Including for example:</p> <ul style="list-style-type: none"> • Public health workers • Social workers 	<p>Including for example:</p> <ul style="list-style-type: none"> • Firefighters and EMS • Law enforcement • Corrections workers • Security officers • Public agency workers responding to abuse and neglect 	<p>Including for example:</p> <ul style="list-style-type: none"> • Public transit workers • Division of Motor Vehicles workers • Transportation maintenance and repair technicians • Workers supporting highway infrastructure

*The frontline essential sectors and workers, as categorized by [Cybersecurity and Infrastructure Security Agency \(CISA\)](#) align with federal prioritization guidance from the CDC's Advisory Committee on Immunization Practices (ACIP) recommendations.

EXAMPLE FOR NC'S VACCINATION ALLOCATION AND METHODOLOGY

Sample Week	
Total Allocations to NC	
Moderna	XX
Pfizer	XX
Total	~180,000-200,000
1. Stable Baseline Allocation	XX
Population	XX
HMP/65+ Density Bumps	XX
2. State Set Aside Allocation	XX
Events/Efforts and Further Population Adjustment	XX
People per Dose Corrections	XX
Long-term Care Pharmacies	XX
State Facilities	XX

Methodology Overview

Doses are allocated according to the following priority:

1. Baseline allocations to providers, based on total population per county
2. Additional baseline doses to providers to ensure equity in historically marginalized populations (HMP)
3. Anything remaining is set aside for
 1. State facilities
 2. Long-term care pharmacies
 3. Community vaccination events

Note: the set aside amount is a buffer; if the State's overall allocation decreases, the baseline amounts will remain intact

PRINCIPLES OF PRIORITIZATION

Our overarching provider prioritization strategy is being realigned to our allocation strategy

Prioritize **new providers** in counties with insufficient capacity to administer allocated vaccine:

1. Counties with **lowest relative provider capacity** relative to baseline and HMP bump allocations
2. Counties lagging behind the state with **higher people per dose** allocated

Within those counties, priority criteria below for onboarding and activating new providers; can be a **heterogenic group of providers** (e.g. pharmacies, primary care)



Capacity

1. **Ability to administer and document at least 100 doses per week**
 - a. Validate through case manager prior to allocation receipt
 - b. Confirm commitment through Ready Ops



Operational Readiness

1. **Technical Readiness:** Ease of enrollment and activation in CVMS: providers in the queue and pharmacies.
2. **Provider Readiness:** Does the site have medical staff that can vaccinate? Is the provider mobile?



Equity

Ability to serve priority populations:

- a. Long Term Care population
- b. People over 65
- c. HMP reach

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.



CVMS Help Desk Portal: CVMS Vaccine Support portal will contain a number of Knowledge Articles and FAQs that will provide information such as self-help, troubleshooting and task resolution.

Access ServiceNow at:

https://ncgov.servicenowservices.com/csm_vaccine



Communications: CVMS enhancement updates, training event invitations, and information about new user guides and video demonstrations.

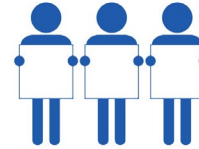
Be on the look out for email from: [vaccineinfo](mailto:vaccineinfo@dhhs.nc.gov) (vaccineinfo@dhhs.nc.gov)



User Guides: Step-by-step instructional guides with screenshots designed to teach users how to CVMS. Screens are annotated with helpful tips and tricks.

Access training at:

<https://immunize.nc.gov/providers/covid-19training.htm>



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.

Access training schedule at:

<https://immunize.nc.gov/providers/covid-19training.htm>

[CVMS Training Session Recordings](#)

- NC Teams site folder where we will continue to upload training session recordings

[Immunization Branch Website](#)

- Public facing website where the latest information on CVMS learning and development is posted, including:
 - Job aids
 - System functionality user guides
 - Previously recorded training sessions
 - Upcoming training schedule
 - ServiceNow Helpdesk information

EXTERNALLY-FACING HCP EXPERIENCE JOURNEY MAP

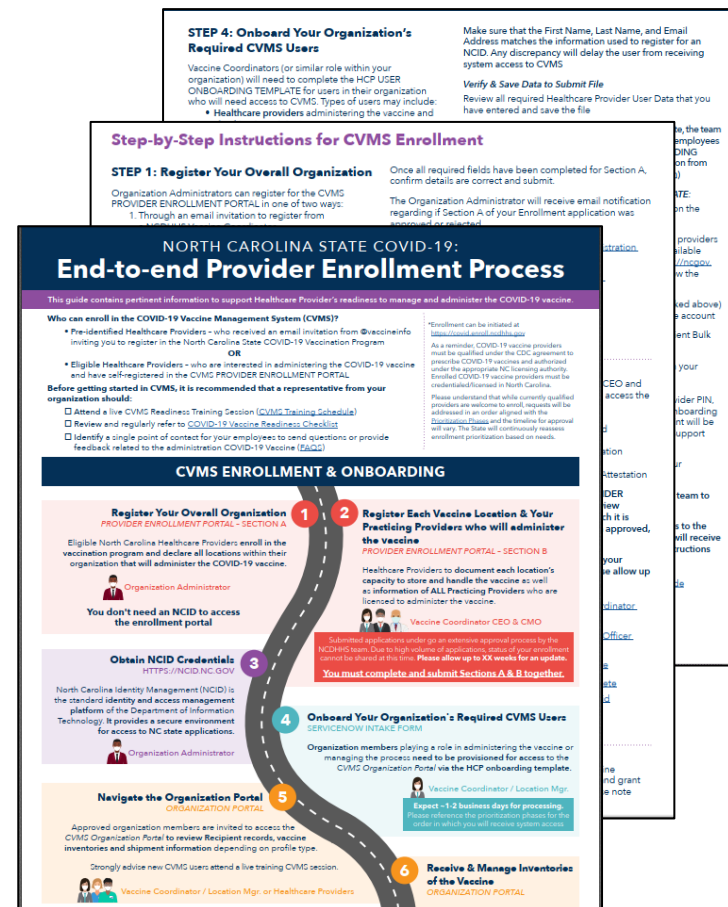
The maps are created as both printable flyers and interactive webpages on the covid19.ncdhhs.gov/vaccines site for healthcare providers to use as a visual aid along their CVMS enrollment journey and vaccine administration process.

Content includes:

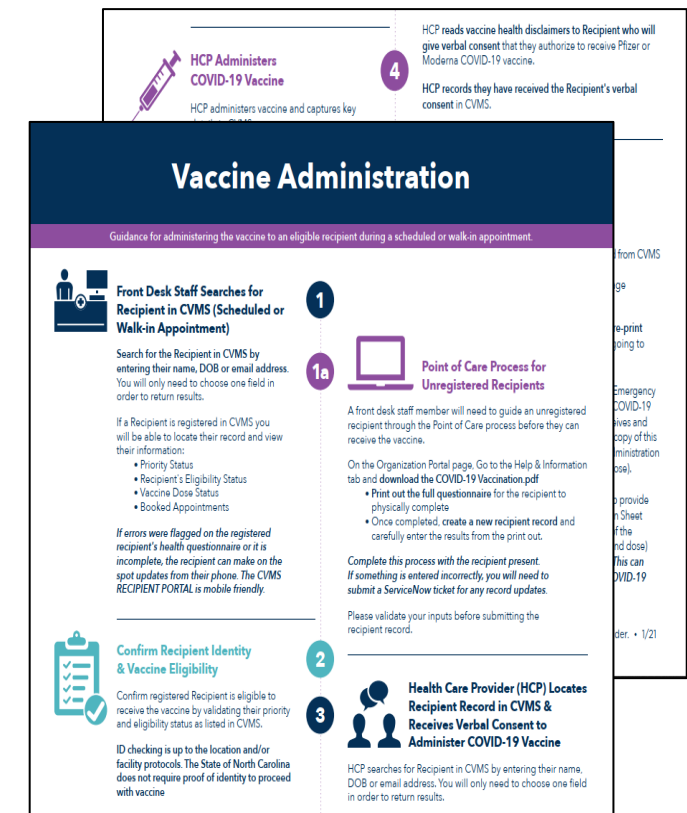
Two sections

- CVMS Provider Enrollment** - Full healthcare provider registration and onboarding process
 - Vaccine Administration** – workflow requirements for administering the vaccine during a scheduled or walk-in appointment
- **Who** from the organization is responsible for each step
 - **Where** each step is executed (i.e., 1 of 4 CVMS portals or via CVMS Help desk Portal)
 - **When** “stop-gates” or approval processes are and tentative timing expectations
 - Bold notations and helpful guidance around specific actions that normally trip users up or cause a lot of confusion

CVMS



Vaccine Administration



Partnering to Host Vaccine Events

Survey for Organizations Wanting to Host/Support Vaccine Events

<https://docs.google.com/forms/d/e/1FAIpQLScqcUN8JiHO-PnZJ3oRftImSN3joiJfAOWxgdgz6ww-MQ7Rog/viewform>

~240 responses since 2/12 launch; shared with vaccine providers to facilitate local partnerships;
14 AME Zion Churches enrolled and 28 pending completion

Toolkit for Partner Organizations Supporting NC's Vaccination Efforts

<https://files.nc.gov/covid/documents/guidance/vaccinations/NCDHHS-Toolkit-for-Partner-Organizations-COVID-19-Vaccines.pdf>