NC DHHS COVID-19 Response Updates

January 18, 2022

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

Logistics for today's webinar

Question during the live webinar

Technical assistance

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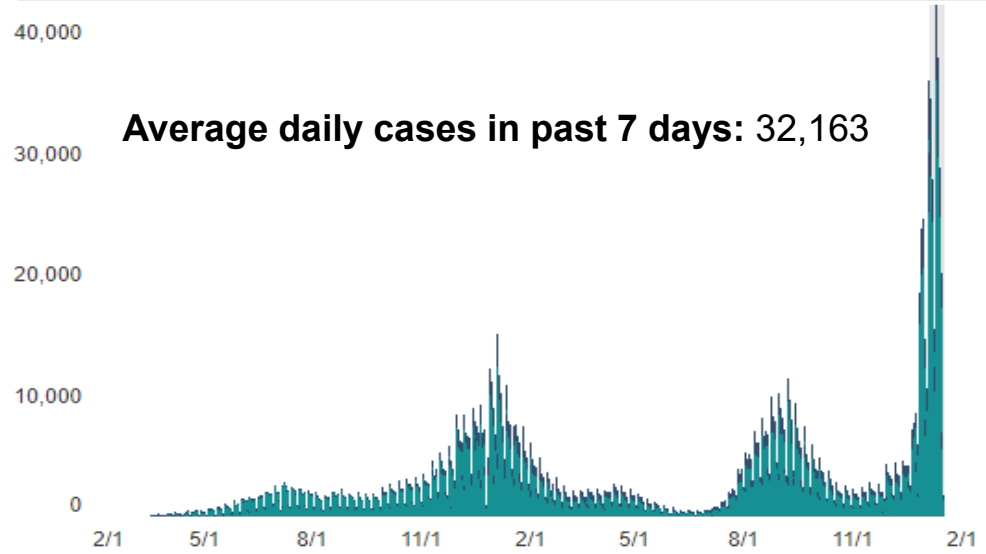
AGENDA

1. **Statewide COVID-19 Updates and Data Trends**
2. **Guidance changes**
   a) Face Masks
   b) Isolation and Quarantine Guidance Changes
   c) Strong Schools Toolkit and Child Care Update
3. **Vaccination Update**
   a) Updated Booster Eligibility
   b) Vaccination Trends
   c) NCIR/CVMS upgrades
4. **Testing**
5. **Therapeutics**
   a) Available COVID Treatment Overview
   b) Allocation Timeline
6. **Med Surge Efforts**
   a) State Medical Surge Levers
7. **Comms Updates**

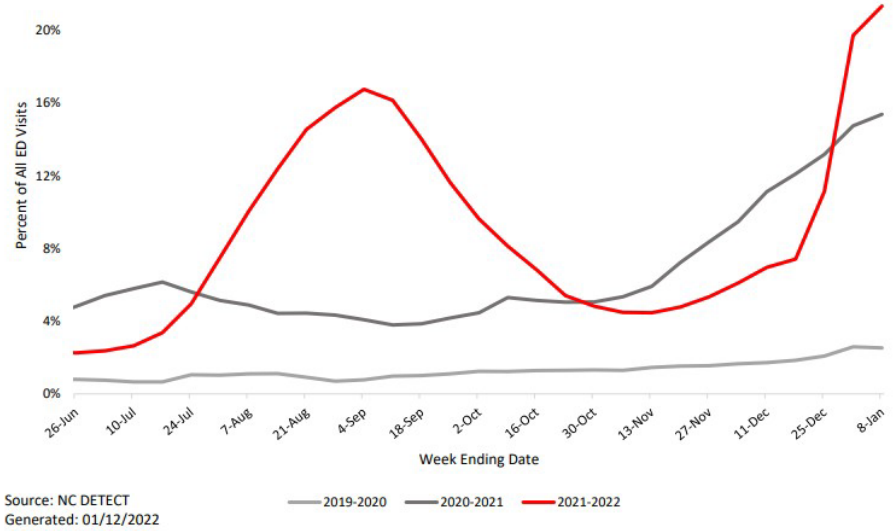
Statewide COVID-19 Updates and Data Trends

FOUR KEY METRICS- ALL AT HIGH LEVELS AND RISING

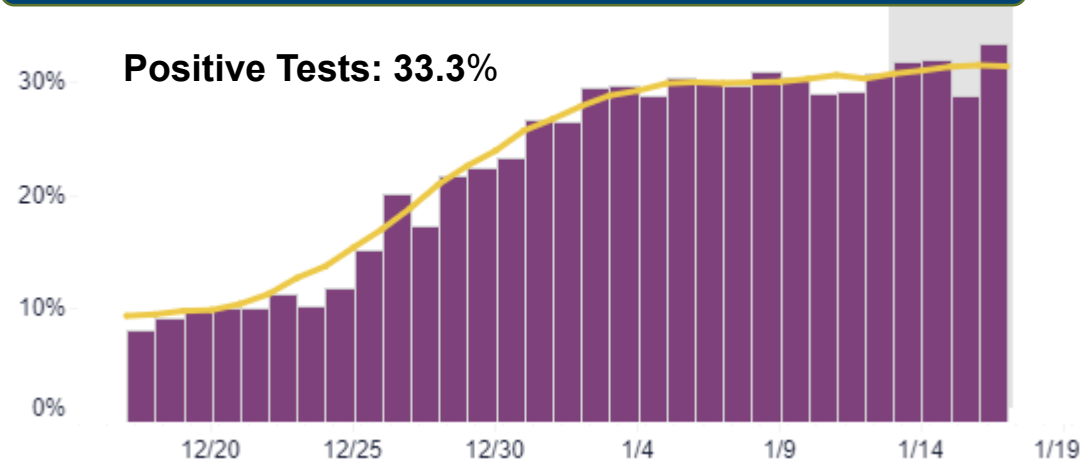
Daily Lab Confirmed Cases by Date Reported



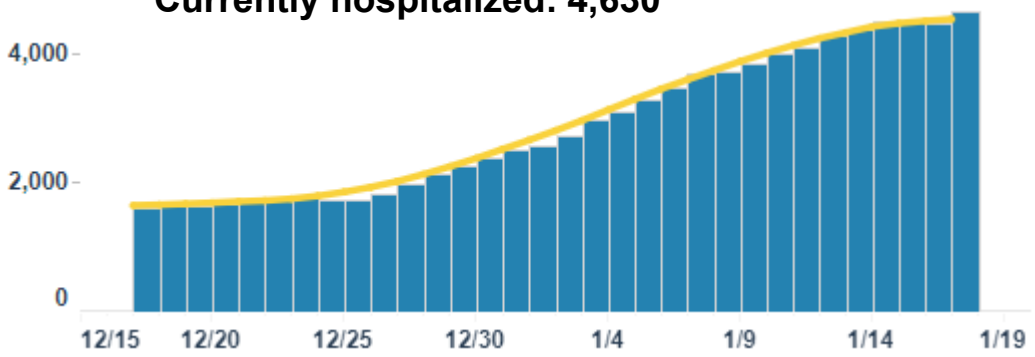
What Percentage of ED Visits this Season are for COVID-like Illness Compared to Previous Seasons?



Positive Tests as a Percent of Total Tests



Daily Number of People Currently Hospitalized

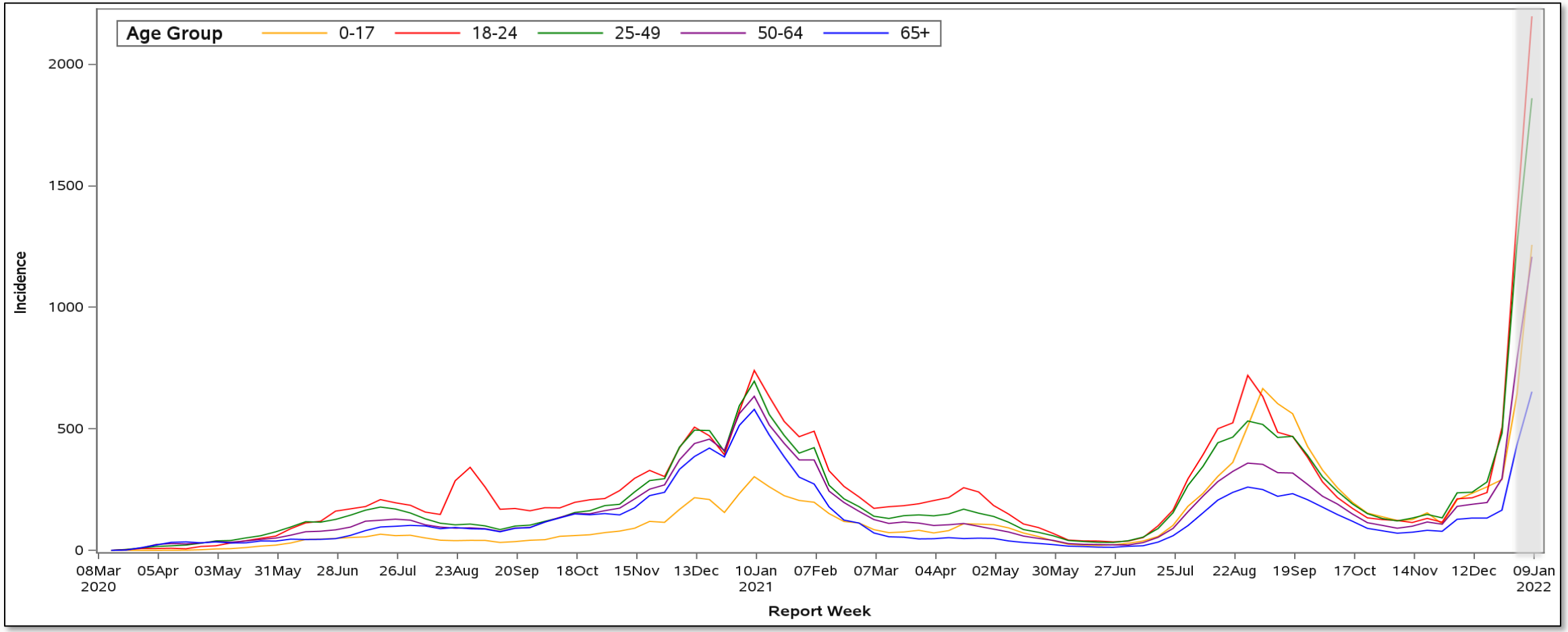


CASE RATES CONTINUE TO INCREASE FOR ALL AGE GROUPS

Case rates are highest among young adults (ages 18-24) and lowest among older populations (ages 65+), potentially due to higher vaccination rates and lower exposure risks among older adults.

COVID Cases per 100K Population by Age Group and Report Date

Data through January 9, 2022

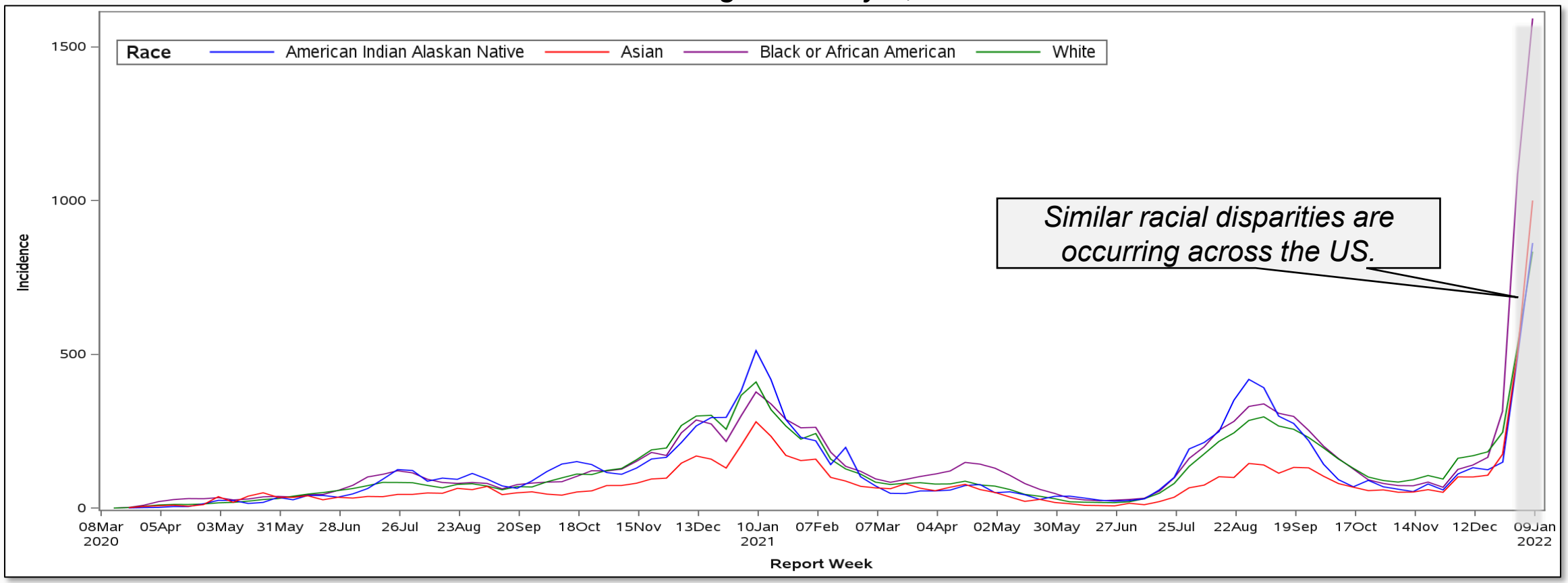


RACIAL DISPARITIES CONTINUE TO GROW

Case rates among Black/AA population have increased disproportionately compared to other races.

COVID Cases per 100K Population by Race and Report Date

Data through January 9, 2021

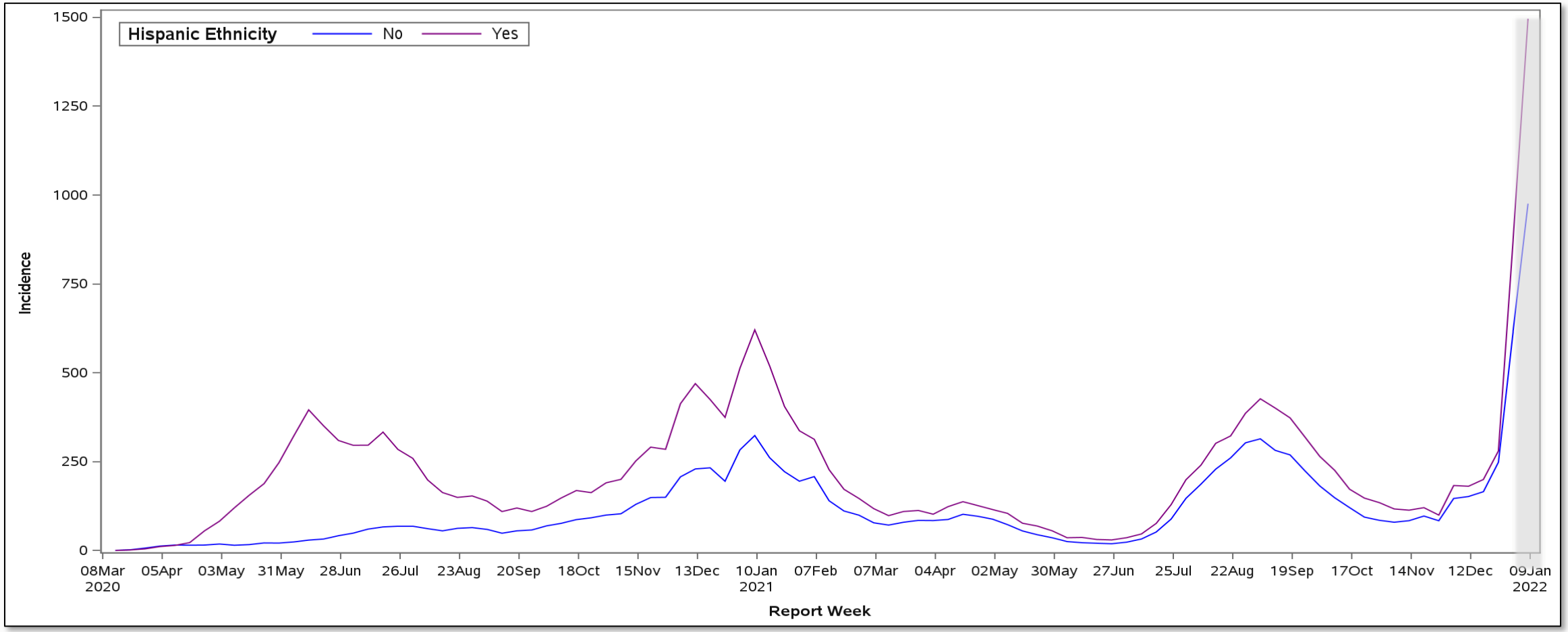


ETHNIC DISPARITIES CONTINUE TO WIDEN

Case rates among the Hispanic population are ~1.5x higher than rates among the non-Hispanic population.

COVID Cases per 100K Population by Ethnicity and Report Date

Data through January 9, 2021



OMICRON VARIANT SPREADING RAPIDLY

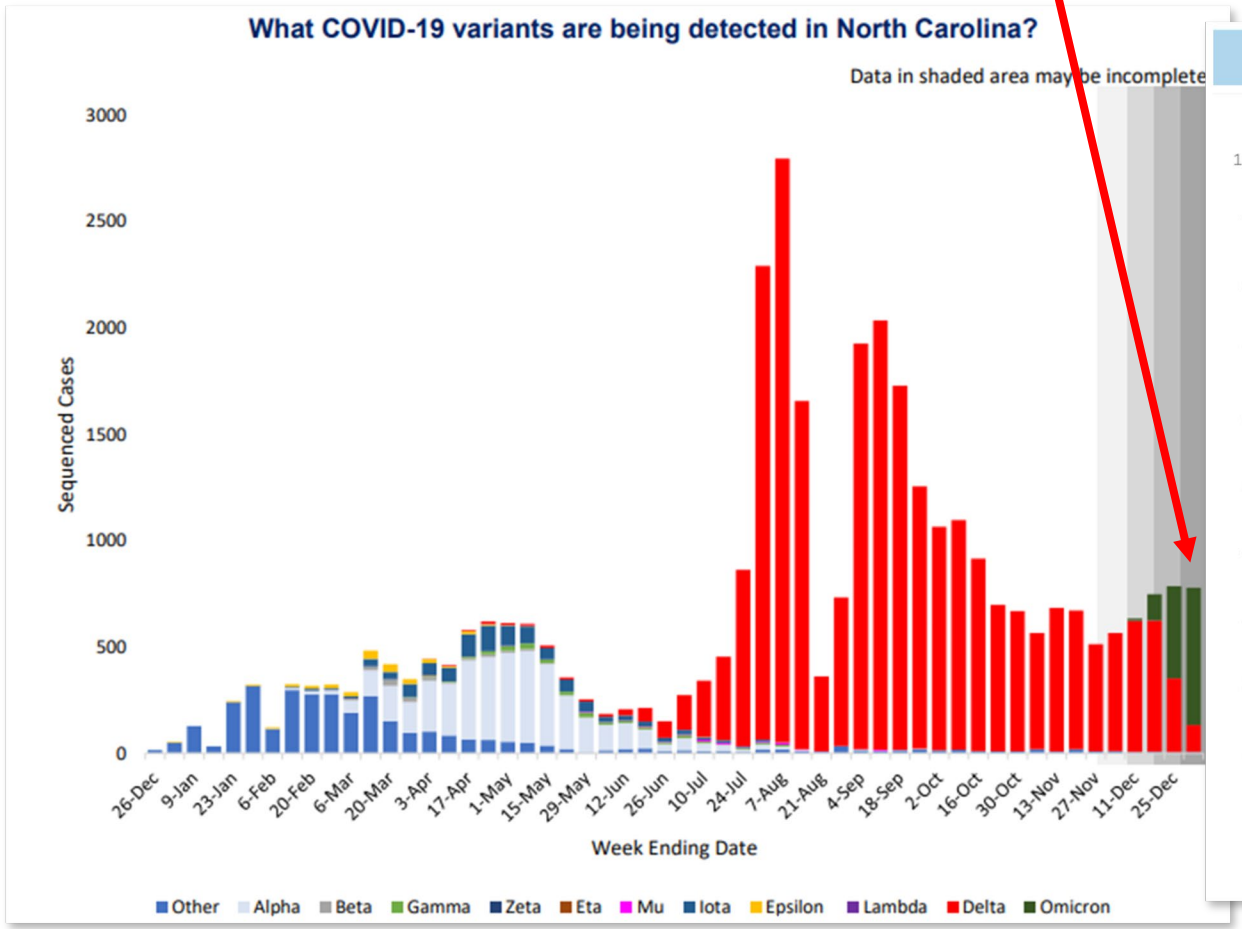
Impact on Infection and Clinical Illness

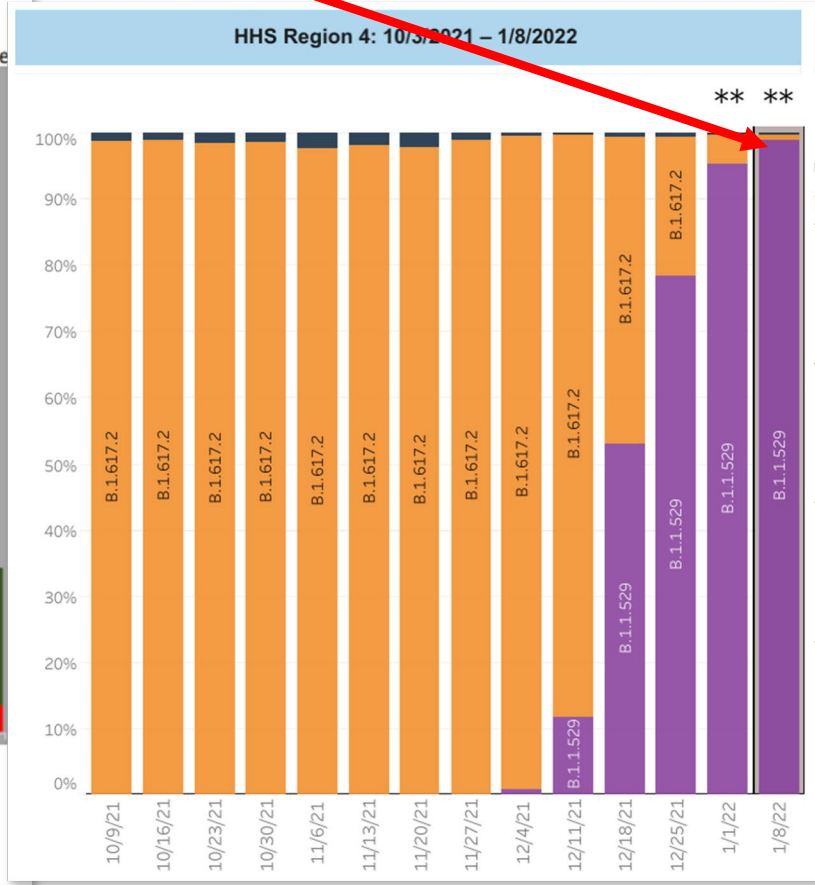
- Highly transmissible. Likely at least two-three times as contagious as Delta
- Rapidly spreading
- Preliminary data suggests less severe disease – Affects upper respiratory track (nose and throat) more than lower respiratory tract (lungs)

Impact on Vaccines and Therapeutics

- **Decreased protection from primary series of vaccination or past infection**.
- **Boosters provide increase protection against infection.** Preliminary data suggest vaccine booster dose restores vaccine effectiveness against infection to 75%. Boosters reduce risk of hospitalization by 81%+.
- **Decreased protection from some therapeutics:** Decreased effectives of monoclonal antibodies, except Sotrovimab. Other Antivirals (remdesivir, molnupiravir, and PAXLOVID™) still appear to be effective.

RAPID EMERGENCE OF OMICRON





HHS Region 4: 1/2/2022 – 1/8/2022 NOWCAST

Region 4 - Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee

WHO label	Lineage #	US Class	%Total	95%PI
Omicron	B.1.1.529	VOC	99.0%	98.1-99.5%
Delta	B.1.617.2	VOC	0.9%	0.5-1.9%
Other	Other*		0.0%	0.0-0.0%

* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.

** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates

AY.1-AY.127 and their sublineages are aggregated with B.1.617.2. BA.1, BA.2 and BA.3 are aggregated with B.1.1.529.

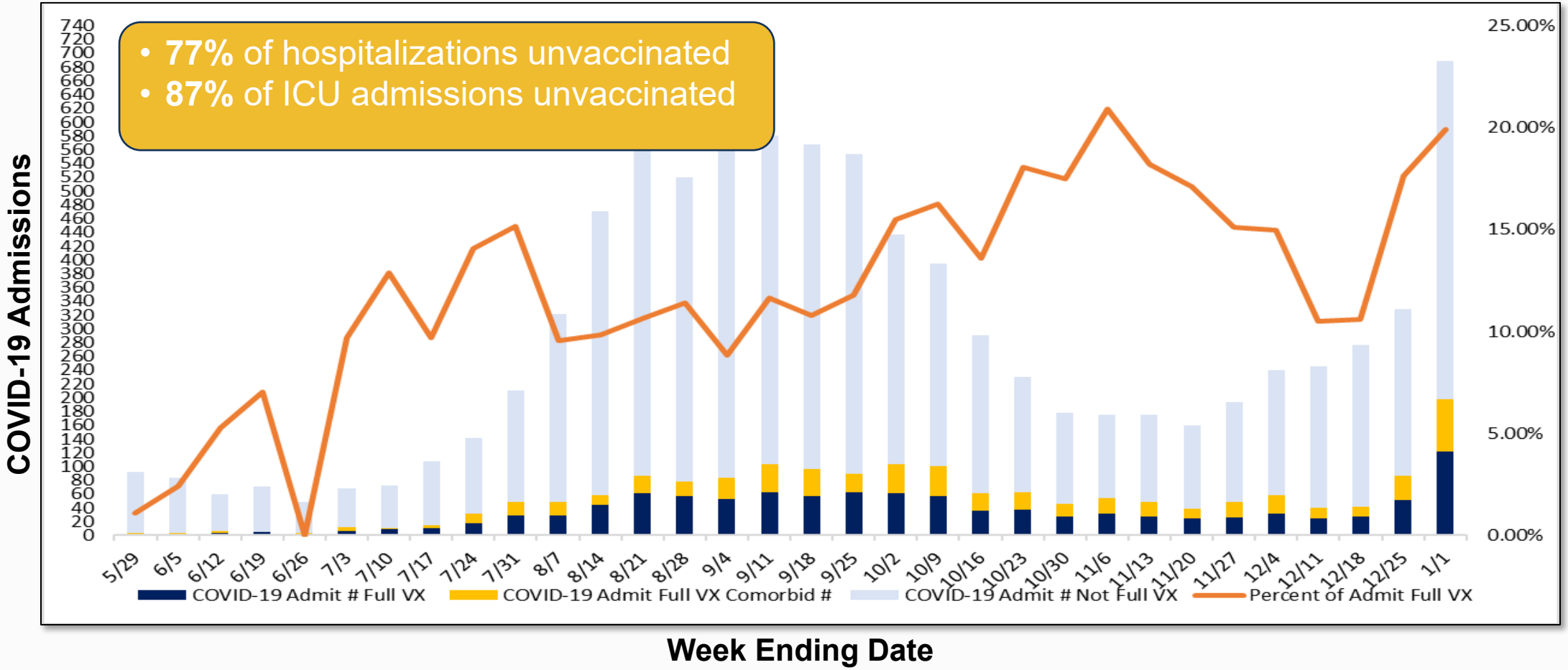
- Sequencing data from NC https://covid19.ncdhhs.gov/media/380/open
- NOWCAST modeling from CDC https://covid.cdc.gov/covid-data-tracker/#variant-proportions

COVID-19 ADMISSIONS AND VACCINATION STATUS

COVID-19 Admissions Mostly Among Unvaccinated

COVID-19 PHE Admissions by Vaccination Status

Data through January 1, 2022



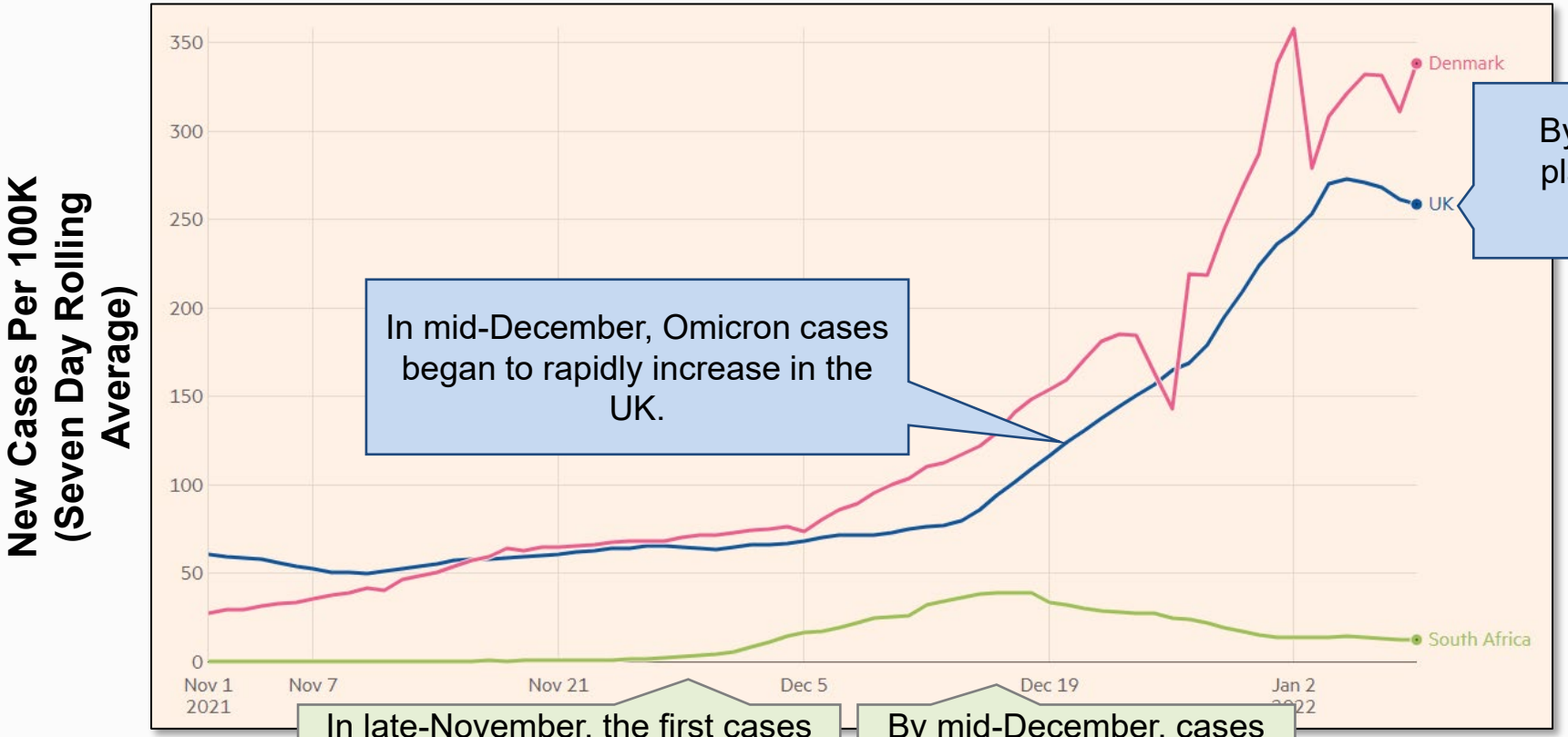
- Source: NC Public Health Epidemiologist (PHE) Program Surveillance

OMICRON CASE RATES NOW DECLINING IN SOUTH AFRICA AND UK

Early evidence suggests that the Omicron surge has already peaked in South Africa and the UK, two countries that were earliest affected by the new variant.

New Confirmed COVID-19 Cases in Select Countries

Data through January 11, 2022



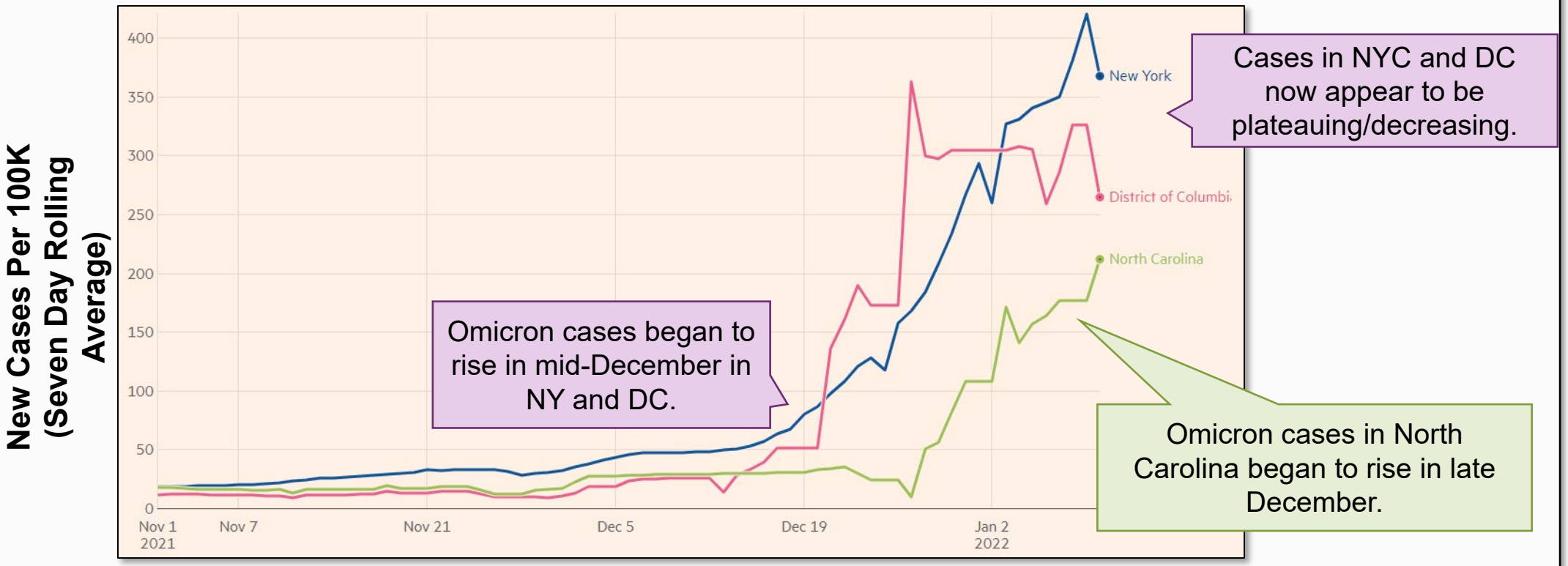
- **Source: Financial Times analysis of data from Johns Hopkins CSSE, World Health Organization, and UK Government coronavirus dashboard**

OMICRON ALSO MAY HAVE PEAKED IN SELECT US CITIES

COVID-19 cases in New York and the District of Columbia appear to have begun to plateau.

New Confirmed COVID-19 Cases in Select U.S. Localities

Data through January 11, 2022



- **Source:** [Financial Times analysis] **of data from Johns Hopkins CSSE, World Health Organization, and UK Government coronavirus dashboard**

Guidance Changes

UPDATED CDC GUIDANCE ON MASKS

Complete CDC guidance can be found here: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/masks.html

- People should wear a multi-layer mask that fits well and is comfortable.
- Wearing a higher-grade mask like a surgical or procedural mask or KN95 and N95 offer more protection, if they fit well and are tolerated.

Guidance on website include:

- Your Guide to Masks-How to Select, Properly Clean, and Store Masks
- Improve How Your Mask Protects You
- Types of Masks and Respirators

QUARANTINE AND ISOLATION GUIDANCE

Protect Yourself and Others

If you test positive for COVID-19:

Limit contact with others for 5 days

THEN

Wear a mask for an additional 5 days

If you test positive for COVID-19 and have symptoms:

Limit contact with others until you are fever-free and your symptoms are improving

(This should be at least 5 days since your symptoms began.)

THEN

You should wear a mask until it has been a total of 10 days after your symptoms began

If you are exposed to COVID-19:

Limit contact with others for 5 days

THEN

Wear a mask for an additional 5 days

UNLESS

If you are up-to-date on vaccines – including boosters if eligible OR have tested positive in the last 90 days THEN wear a mask for 10 days.

Recommend test on Day #5 after exposure

Always wear a mask in public places indoors

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https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html

K-12 Schools and Child Care

CONSISTENT GUIDANCE IN STRONGSCHOOLS NC TOOLKIT

Data continues to support importance of two key prevention strategies:

1. Vaccination and Boosters

2. Masking

https://covid19.ncdhhs.gov/media/164/download

UPDATED GUIDANCE ON EXCLUSION CRITERIA IN STRONGSCHOOLS TOOLKIT

Based on evolving data on COVID-19 and the Omicron variant, CDC revised isolation and quarantine guidance.

High Level Major Changes

- **People with COVID-19 -** Excluded from school for at least 5 full days and wear a mask for an additional 5 days.

- **People exposed to COVID-19 -** Excluded from school for 5 days and wear a mask for an additional 5 days. Should get tested on Day #5 after exposure. Exemptions in all school settings
  - People vaccinated against COVID-19. For adults, this includes boosters.* Should get tested on Day #5.
  - People who tested positive for COVID-19 in past 90 days.
  - When both people were consistently masked during the exposure.

*To allow time for students to catch up with the latest recommendations and to minimize disruption to in-person learning, schools may consider forgoing quarantine for students ages 12-17 years who completed their primary vaccine series but have not yet received all eligible boosters.

NEW GUIDANCE ON TEST TO STAY BASED ON DATA FROM ABC SCIENCE COLLABORATIVE

- **In mask required school settings only**, individuals not otherwise exempt from exclusion after exposure, do not need to be excluded from school after an unmasked exposures (e.g. during lunch or extracurricular).
  - Individuals should get tested on the day of notification of exposure and as close to 5 days as possible after exposure and wear a mask in school settings.
  - If tests are limited, exposures during athletics should be prioritized
  - This applies to exposures in or out of school but does not apply to in-home exposures.
  - Outside of school, individuals should stay home, not attend non-school activities and wear a mask anytime they leave the house.

- Will continue to monitor data with Omicron spread.

- ABC collaborative has enrolled 7 mask optional school districts in the next phase of the pilot. Can consider change in guidance for those settings based on forthcoming data.

Key updates to exclusion to child care guidance:

People with COVID

- Excluded from childcare for at least 5 days and wear a mask for an additional 5 days.
- If unable to wear a mask- including children under 2- they must be excluded for 10 days.

Exposure to COVID-19

- Excluded from childcare for 5 days after exposure and wear a mask for an additional 5 days. Should get tested on Day #5 after exposure.
- If unable to wear a mask- including children under 2- must be excluded for 10 days.
- Exemptions from exclusion
  - •People vaccinated against COVID-19. For adults, this includes boosters.* Should get tested on Day #5.
  - •People who tested positive for COVID-19 in past 90 days.
  - •When both people were consistently masked during the exposure.

*To allow time for students to catch up with the latest recommendations and to minimize disruption to in-person learning, schools may consider forgoing quarantine for students ages 12-17 years who completed their primary vaccine series but have not yet received all eligible boosters.

State Vaccine Update

FDA, CDC EXPAND RECOMMENDATIONS FOR PFIZER AND MODERNA VACCINE

The FDA and CDC have expanded their recommendations for:

Pfizer:

- Expand the use of a single Pfizer-BioNTech booster dose to include use in individuals 12 through 15 years of age.
- Shorten the time recommended between the completion of primary vaccination of the Pfizer-BioNTech COVID-19 vaccine and use of a booster dose to five months.
- Allow for a third Pfizer-BioNTech primary series dose for certain immunocompromised children 5 through 11 years of age. **Please note: Only the Pfizer-BioNTech COVID-19 vaccine is authorized and recommended for children ages 5-11.**

Moderna:

- Shorten the time recommended between the completion of primary vaccination of the Moderna COVID-19 vaccine use of a booster dose to five months.

Please reference the updated Pfizer-BioNTech EUA and Moderna EUA fact sheets.

DHHS Actions

- All standing orders have been updated and executed
- Press release and provider communications have been sent out

IMMUNOCOMPROMISED INDIVIDUALS NOW ELIGIBLE FOR FOUR DOSES

Update:

- **Some** moderately or severely immunocompromised people who received THREE (3) doses of the Pfizer-BioTech or Moderna primary series may now be eligible for a booster dose.
- Everyone 12 years and older, including immunocompromised people, should get a booster shot. If you are eligible for an additional primary shot, you should complete all three doses first before you get a booster shot.

Connecting the dots:

- According to recently released recommendations by the CDC, **some immunocompromised individuals** can get what would amount to a fourth dose (booster shot) of the COVID-19 vaccine **as early as this coming week due to the shortened wait period of 5 months.**
  - **This dose would be a booster dose of the Pfizer/Moderna vaccine,** beyond the third additional dose that was originally authorized for immunocompromised individuals in August of 2021
  - **This does NOT apply to individuals who received a Johnson & Johnson primary vaccine**

For more information, please see the booster qualification chart on the next slide

FDA COVID-19 VACCINE BOOSTER QUALIFICATION

Which primary vaccine series did you complete?	Pfizer-BioNTech	Moderna	Janssen (J&J)
You should get a booster if:	It's been at least 5 months since completing the primary series AND you are:	It's been at least 5 months since completing the primary series AND you are:	It's been at least 2 months since completing the primary series AND you are:
	Age 12+	**Age 18+**	**Age 18+**
If eligible, you can get a booster of:	✓ Pfizer BioNTech* ✓ Moderna ✓ Janssen (J&J) *Only Pfizer-BioNTech can be used as a booster in those age 12-17	✓ Moderna ✓ Pfizer BioNTech ✓ Janssen (J&J)	✓ Janssen (J&J) ✓ Pfizer BioNTech ✓ Moderna
If eligible for a booster shot according to the guidelines above: A booster for immunocompromised individuals who obtained an additional dose is available for:	Booster qualified people age 5+ who are **moderately or severely immunocompromised** and have received an additional third dose	Booster qualified people age 18+ who are **moderately or severely immunocompromised** and have received an additional third dose	*No additional primary dose has been authorized at this time, therefore a fourth dose is not applicable for this brand*

STATEWIDE VACCINATIONS SUMMARY

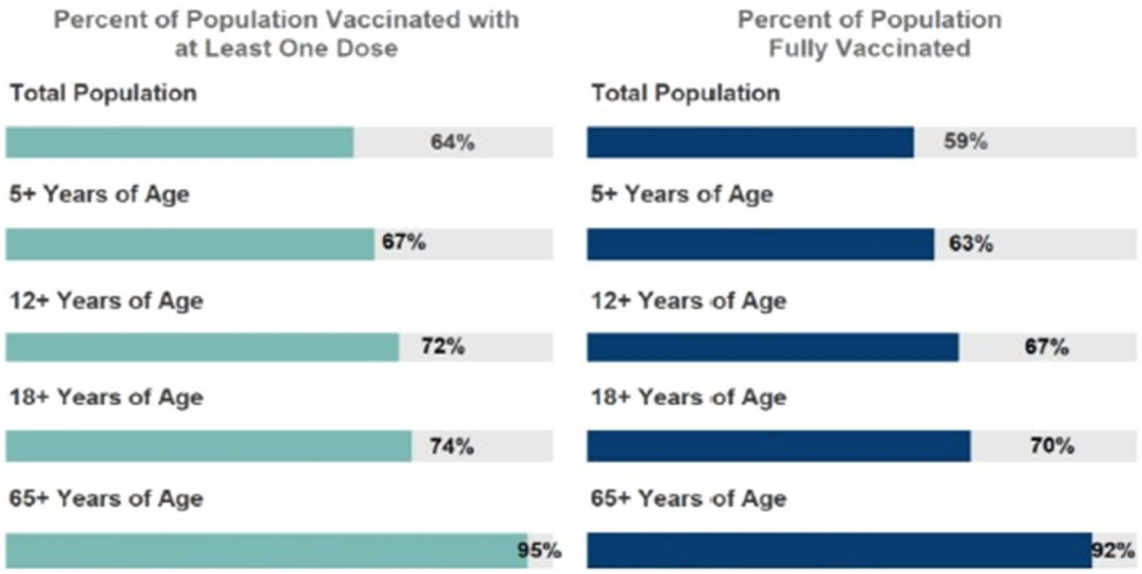
Statewide Vaccinations Summary

New First + Second Doses Reported Since Last Update

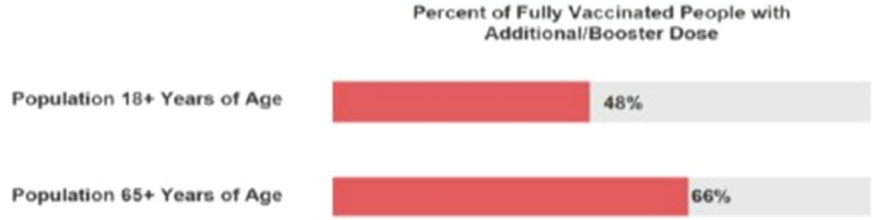
NC Providers	Federal Pharmacy Programs	Federal Entities
10,713	0	801

Vaccinations Summary

First of 2 Doses Administered	Second of 2 Doses Administered	Single Shot Doses Administered	Additional/Booster Doses Administered
6,191,718	5,751,639	473,187	2,776,964



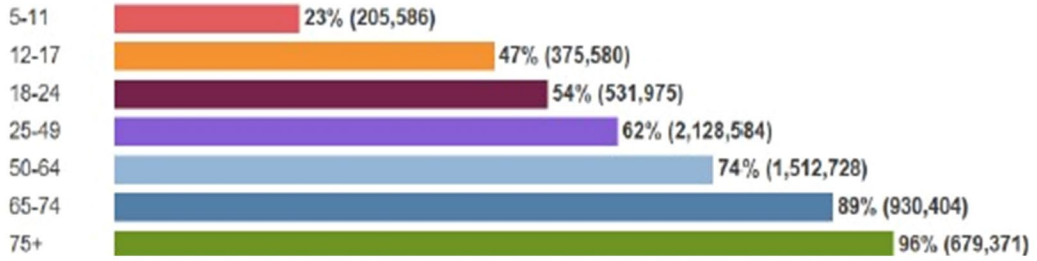
Additional/Booster Dose Summary



Total Doses Administered

	NC Providers	Federal Pharmacy Programs	Federal Entities
First of 2 Doses	4,045,050	1,861,044	285,624
Second of 2 Doses	3,759,324	1,750,500	241,815
Single Shot Doses	343,134	118,234	11,819

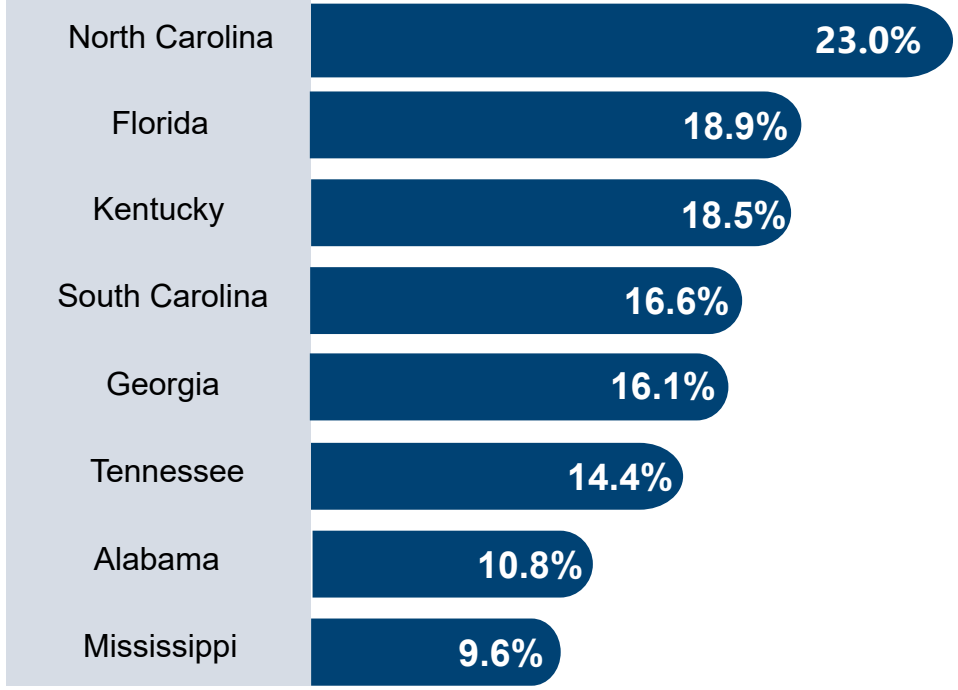
Percent of Population Vaccinated with at Least One Dose by Age Group



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

PEDIATRIC VACCINATION RATES

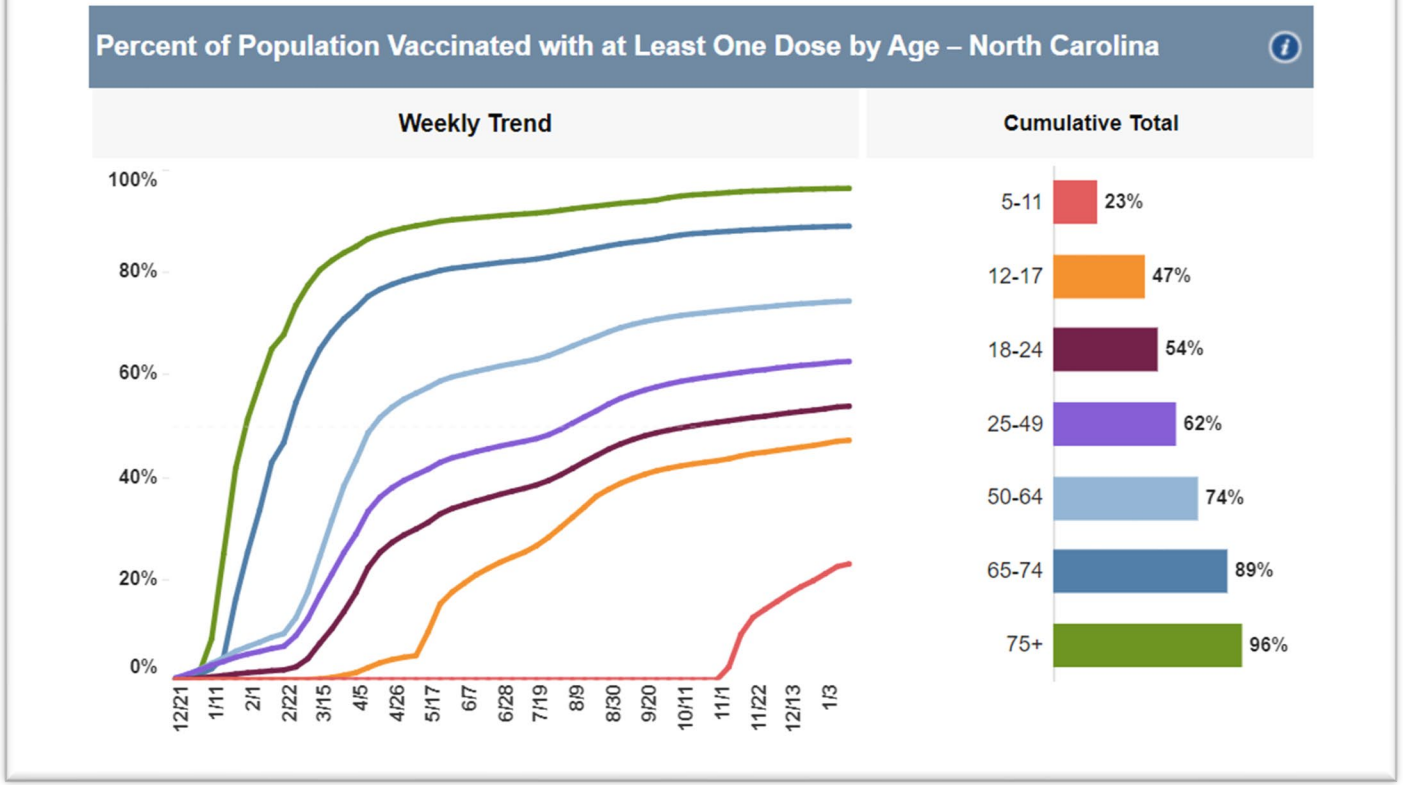
North Carolina has the highest pediatric vaccination rate of FEMA IV States



Source: All metrics are from 1/13/22 ASPR Report

Note: FEMA IV states shown are states with comparable vaccine programs.

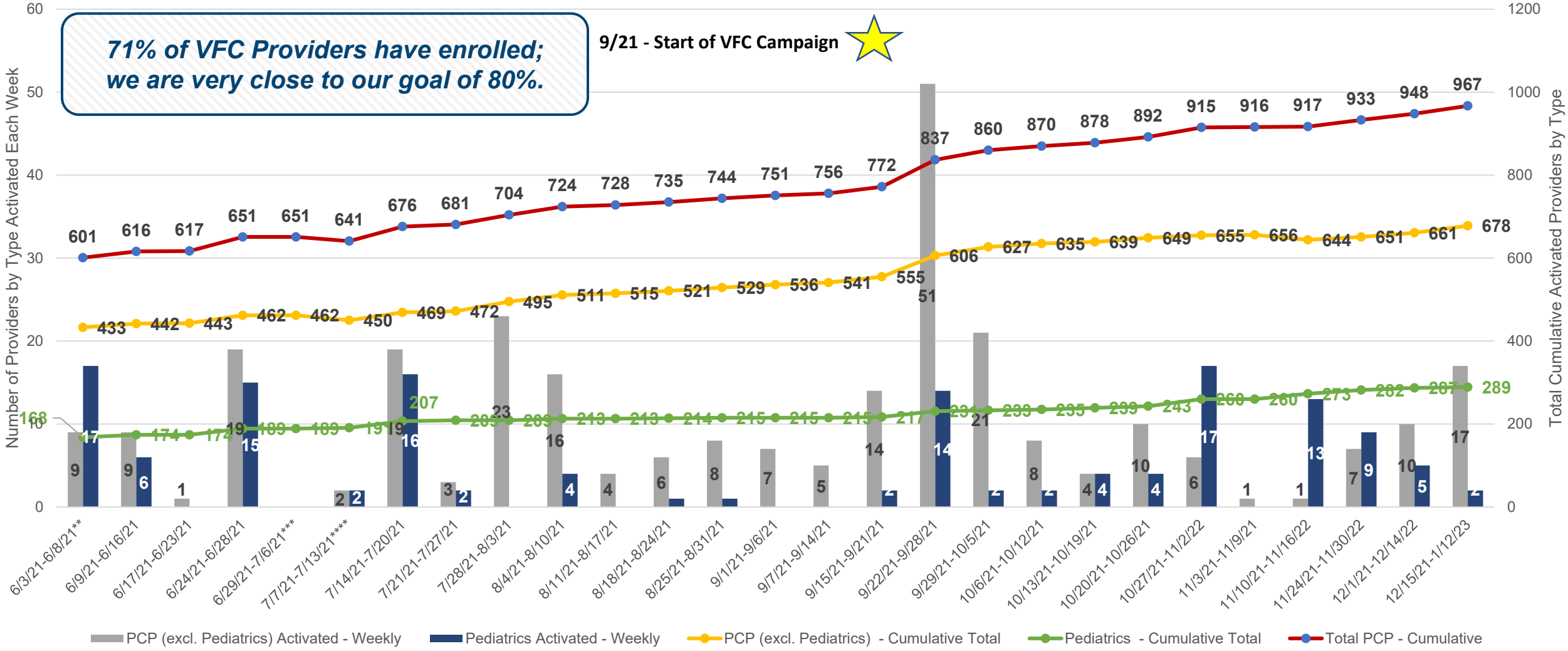
% of Population Vaccinated with at Least One Dose by Age



Source: NC Covid Dashboard as of 1/18.

PCP AND PEDIATRIC ACTIVATION – CUMULATIVE INCREASE FROM 5/27 (AS OF 1/12/21)

Great progress has been made in onboarding PCPs to be COVID-19 providers particularly after VFC Campaign Launch



*Data from 5/24 – 5/26; new cadence of Wednesday to Wednesday data pull going forward, adjusted to clean up deactivated providers
** Adjustment made to move specialty PCP to 'Other' category no longer captured in total PCP number
*** No data for week 6/29-7/6
****14 PCP locations were deactivated during this period decreasing overall cumulative count

NCIR-CVMS INTEGRATION UPDATE

We have implemented technological improvements that enable the planning and operationalization of pediatric vaccinations and improve provider engagement and vaccination coverage

Providers are able to...

	Oct	Nov	Dec	Jan	Strategic Impact:
Release A	**Access all vaccination records (including COVID) in one system** 10/8: Non-pharmacy records available for query 10/20: All COVID-19 records available for query in NCIR				As of 10/20, NCIR contains a **consolidated immunization record** that enables providers to **assess patient needs** on vaccines (including COVID-19), and conduct **outreach and counseling**
Release B	**Document COVID vaccine administration in one system** 11/8				As of 11/8, providers can **administer and document all vaccines** for which an individual is eligible **at the same visit,** which increases the probability that individuals are **up to date on recommended vaccines** (MMR, flu, COVID, etc)
Release C	**View and manage vaccination data from a single recipient record in CVMS** 1/18				As of today, CVMS providers can **access both state and federal pharmacy COVID-19 vaccination records** through the CVMS Patient Portal and recipients can **generate their COVID-19 Information PDF**

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

Testing

INCREASING TESTING ACCESS IN NC

Vendor

- Contracted with 2 additional vendors – MAKO and Radeas – for a total of 14 vendors with statewide support.
- Vendors available to all LHDs to support one-time and ongoing testing events. Also can be used to aleviate pressure of people coming to EDs for testing. Submit requests via the event request form)

Staffing

- Available upon request to LHDs to support testing-related activities

Federal

- NCDHHS exploring federal support options in the following areas for mass testing events:
  - Registration system
  - Medical personnel
  - PCR tests
  - Specimen processing
  - Result notification

Supplies

All available for request via online form. Orders are fulfilled as supplies become available. Email on Tuesday confirm ordering for the week.

Point-of-Care Tests: *All inventory allocated for distribution*

- 550K+ on their way; arriving on a staggered basis over the course of the next month.
- Providing these to LHDs, K12, and other high-priority facilities (e.g., LTC, Corrections)

At-home Tests: *All inventory allocated for distribution*

- 450K+ on their way; arriving on a staggered basis over the course of the next month.
- Distributing these to partners for community distribution, including Healthier Together and Community Health Workers

Bulk testing supplies: 2.5M NP swabs, 2.9M VTM media

- Ample swabs and media available for request

Specimen collection devices: *High inventory*

- Fulfilled and processed by SLPH. Full requirements available on NCDHHS website

HOW TO FIND TESTING

All testing information can be found at: ncdhhs.gov/gettested, but the five main ways to get tested are:

1. **No-Cost Community Testing Events**
   - *Plan ahead and look for appointments at a variety of locations.*
   - *Don't go to the Emergency Department for testing.*
   - *Many sites provide both PCR and rapid testing.*

2. **Test Site Finder**
   - *Note, some locations may charge a fee*

3. **No-Cost LabCorp Pixel Home Collection Kits** directly shipped to your home
   - *https://www.ondemand.labcorp.com/nc*

4. **Pick up an At-Home Testing Kit**
   - *https://covid19.ncdhhs.gov/about-covid-19/testing/approved-covid-19-home-tests*
   - *At a Pharmacy*
   - *Direct ship via the Federal Program: https://www.covidtests.gov/*

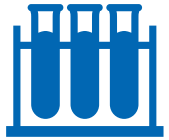
5. **Insurance now covers costs of at-home COVID-19 tests.**
   - *Different processes for different payors*
   - *For people covered by Medicaid, can go to pharmacies and have test be billed to Medicaid Standing Order in place to support that https://covid19.ncdhhs.gov/media/3733/download?attachment*

ANTIGEN TESTING ACCURACY

1. **Antigen tests have always been less sensitive than molecular tests, like PCR.**
2. **Antigen tests remain more specific than sensitive**.
   - A positive result is truly a positive and no additional test is needed. The individual should isolate.
   - A negative result should be followed by a PCR if the individual is symptomatic and strongly considered if a close contact exposure.
3. **Antigen tests remain an important testing tool when used correctly.**
   - Data is emerging about differences in sensitivity for some variants, like omicron; however, early data conflicts and these differences are still being studied.
4. **Antigen tests should be used as intended and authorized by the FDA.**
   - Some tests require certain frequency (i.e. 2 tests 24 to 48 hours apart).
   - Some should only be used within a specific time from symptom onset (i.e. 1 to 5 days).
   - Antigen tests currently authorized use nasal swabs or nasopharyngeal (NP) swabs, not throat (OP) swabs. Tests must be used with the authorized specimen type. Using other specimens increases the risk of false positive or false negative results.

K12 TESTING PROGRAM

NCDHHS through federal funding is providing support for school-based testing.



State Contracted Vendor		Independent Testing		Staffing Support*
NCDHHS vendor available to support testing program at school/district: screening plus PCR or antigen diagnostic testing	OR	NCDHHS provides free tests that schools may request to perform antigen screening and/or diagnostic testing**	+	NCDHHS provides funds for LEAs/charters to hire clinical staff
Available to all schools		Available to all schools		Available to LEAs and charters who participate in testing (opt in)

Districts will define their own testing programs or may choose not to participate in K-12 testing program for 2021-2022.
StrongSchoolsNC K-12 Testing Program Guidance

**Staffing support is a program that LEAs and charters can take advantage of in addition to state contracted vendor or independent testing*
***Schools interested in implementing Test to Stay can opt-in to the Independent Testing Program*

PROGRAM CURRENT STATE – TESTING STATUS AS OF JANUARY 13TH

3,537 total schools in North Carolina

2,283 (65%) schools have opted in (89 LEAs of 115 in NC)

1,253 (35%) schools have not opted in

1,705 (81%) schools participating in state vendor program

Stage 1 → Stage 2 → Stage 3 → Stage 4

	Including
245 are developing their plan	10 LEAs (213 schools)
327 are onboarding	11 LEAs (143 schools)
0 has a planned go-live date	0 LEAs (0 schools)
1,133 are live[1]	46 LEAs (1,023 schools)
770 diagnostic +/- screening	35 LEAs (697 schools)
340 rapid on-site antigen	11 LEAs (323 schools)
363 screening only	11 LEAs (326 schools)

578 (19%) schools participating in independent testing

	Including
323 schools in planning stage	12 LEAs (310 schools)
255 schools requested 98.5K antigen tests	10 LEAs (216 schools)

[1] Increase of 20 schools from prior week; includes 31 Wake County schools

K12 TESTING PROGRAM SUPPORTING SCHOOLS THROUGH THE OMICRON SURGE

Testing in K12 schools remains a critical mitigation strategy

1. **Schools can still opt-in to the StrongSchoolsNC Testing Program.** Options include vendor pooled screening, vendor PCR diagnostic, independent antigen diagnostic (including Test-to-Stay)
2. To strengthen our testing supply during nationwide shortage, **NCDHHS has identified additional suppliers of antigen tests,** which began shipping on 1/10/22.
3. **Antigen test "conservation" and "flexibility" strategies may be warranted**

All schools should consider onboarding to vendor PCR diagnostic to supplement, when necessary, current screening or antigen testing

Schools will need to update CLIA waivers to use new types of tests (testing contacts being sent details)

For schools in the independent testing program, when supply is low and prioritization decisions must be made, NCDHHS recommends using antigen tests for diagnostic rather than screening

Schools should limit their ordering to ensure they are only ordering for more immediate needs of 2-3 weeks.

Therapeutics Update

MONOCLONAL ANTIBODIES - OVERVIEW

Monoclonal antibodies, or mAbs, are antibodies made in a laboratory to fight a particular infection. The Food and Drug Administration (FDA) has issued **Emergency Use Authorization (EUA)** for the use of monoclonal antibody therapies for adult and pediatric patients aged 12 and older (bam/ete authorized for all ages). mAbs are given to patients with an infusion, subcutaneous injection, or intramuscular injection. They are used for treatment or prevention. There are four types of mAbs that have been authorized for use for COVID-19:

mAbs Generic Name	Also known as	Authorized Indication	Route of Administration	Dosing Regimen	Authorized Patient Population	Standing Order?	Variant Efficacy	Allocation Estimates
Casirivimab / imdevimab	**REGEN-COV**	Post-exposure Prophylaxis, Treatment within 10 days of symptoms	Subcutaneous Injection; Intravenous Infusion	600 mg of both	Patients aged 12 years and older	Yes, revised January 5th	Reduced efficacy against Omicron	~1,000 per week
Bamlanivimab / etesevimab	**Bam/Ete**	Post-exposure Prophylaxis, Treatment within 10 days of symptoms	Intravenous Infusion	Dosage varies with weight	Patients of all ages, including neonates	Yes, revised January 5th	Reduced efficacy against Omicron*	~1,000 per week
Sotrovimab	**Sotrovimab**	COVID-19 Treatment within 10 days of symptoms	Intravenous Infusion	500 mg of Sotrovimab	Patients aged 12 years and older	Yes, revised January 5th	Retained efficacy against Omicron*	~1,000 per week
Tixagevimab / cilgavimab	**Evusheld AZD7442**	Pre-exposure prophylaxis (PrEP)	Intramuscular Injection	Two simultaneous IM injections every 6 months	Patients aged 12 years and older who are immunocompromised or have a contraindication for COVID-19 vaccines	No – per FDA/HHS.	Retained efficacy against Omicron	~2,000 per week

**Bam/Ete and Sotrovimab data is preliminary, have not published official studies yet regarding efficacy*

ORAL ANTIVIRAL - OVERVIEW

Generic Name	Also known as	Authorized Indication	Route of Administration	Standing Order	Administration Requirements	Dosing Regimen	Authorized Patient Population	Variant Efficacy	Allocation Estimates
Molnupiravir	**MK-4482, Merck**	Treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and for whom alternate treatment is not accessible or clinically appropriate	Oral	No per FDA/HHS	Must start within 5 days of symptom onset Not recommended during pregnancy	800 mg twice-daily for five days	Adult (18+)	30% effective in preventing hospitalizations or deaths within 5 days of symptom onset. Expected to maintain effectiveness across all variants.	~10,000 per two-week cycle
Paxlovid	**Nirmatrelvir / Ritonavir, Pfizer**	Treatment of mild-to-moderate COVID-19 in adults and pediatrics (12+) who are at risk for progressing to severe COVID-19	Oral	No per FDA/HHS	Must start within 5 days of symptom onset Dosage adjustment for moderate renal impairment Drug interactions list	300mg of nirmatrelvir and 100 mg of ritonavir twice-daily for five days	Adult and Pediatric (12+)	88% effective in preventing hospitalizations or deaths within 5 days of symptom onset. Expected to maintain effectiveness across all variants.	~2,500 per two-week cycle

THERAPEUTIC ALLOCATION & PROVIDER PRIORITIZATION

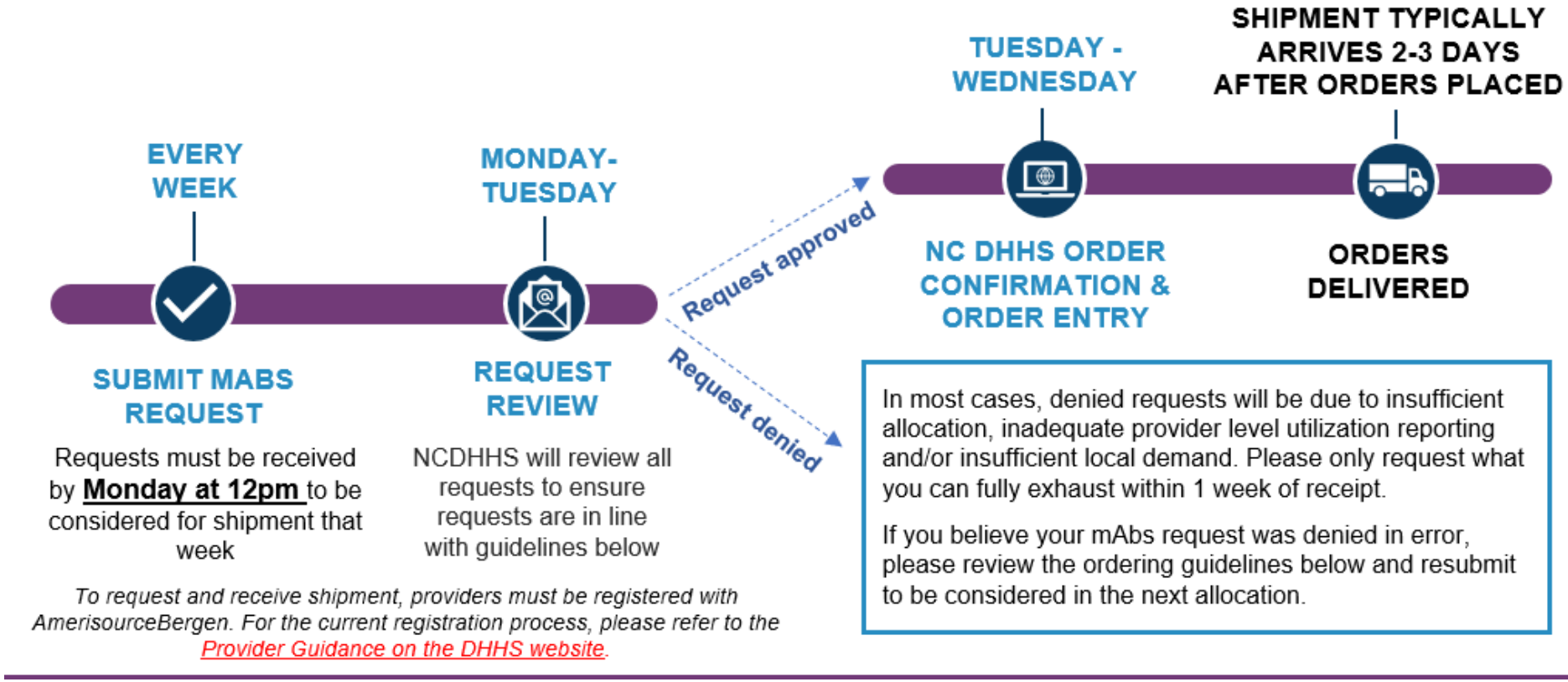
Federal Allocation & Provider Prioritization Criteria by Product			
Product Name	**Product Type**	**Federal Allocation Cycle**	**Provider Selection Prioritization**
Molnupiravir (Merck)	Antiviral Pill	Bi-weekly beginning 1/10	1. Equitable 'Flu Region' distribution taking into account population, access to mAbs, provider capacity, and provider location
Paxlovid (Pfizer)	Antiviral Pill	Bi-weekly beginning 1/10	1. Equitable 'Flu Region' distribution taking into account population, access to mAbs, provider capacity, and provider location
Evusheld (Astra-Zeneca)	Long-Acting Antibody	Weekly	1. Initial allocation prioritized to hospitals/specialty providers who routinely see the immunocompromised populations this drug intended for. 2. Supply is currently greater than demand for this product. We now have an open request link, that providers can use to order supply as needed based on their use history.
Casirivimab + Imdevimab (Regen-Cov)	Monoclonal Antibody	Weekly	1. Providers have capability to identify a potential case of the Omicron variant AND can administer that product within 48 hours 2. If providers' local indicators point to omicron not being the predominant variant
Bamlanivimab + Etesevimab (Bam/Ete)	Monoclonal Antibody	Weekly	1. Providers have capability to identify a potential case of the Omicron variant AND can administer that product within 48 hours 2. If providers' local indicators point to omicron not being the predominant variant
Sotrovimab	Monoclonal Antibody	Weekly	1. Equitable 'Flu Region' distribution taking into account population, access to mAbs, provider capacity, and provider location 2. Providers who are able to administer intravenously

Current **weekly** federal allocation for all COVID therapies effective against Omicron is 7,846 courses/1121 per day (Sotrovimab, Paxlovid, and Molnupiravir). (32,163 cases per day; supply sufficient for ~3% of cases)

NEW REQUEST PROCESS FOR MONOCLONALS

Monoclonal Antibody Process

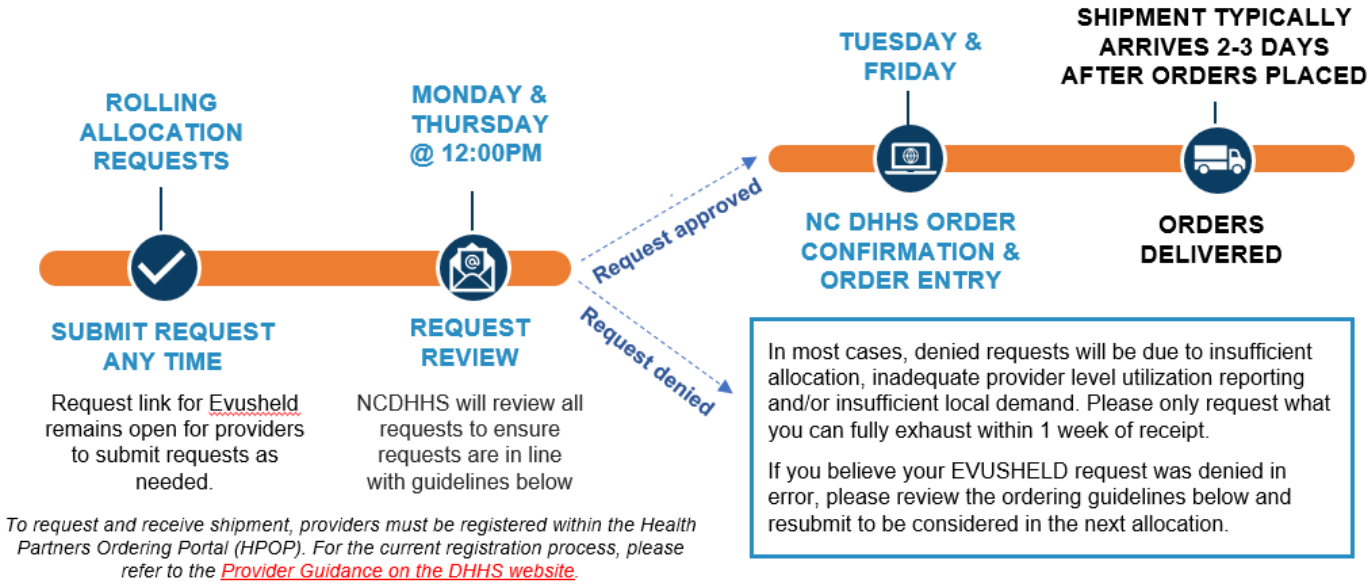
Link to request forms:
REGEN-COV and Bam/Ete Requests
Sotrovimab Requests



NEW REQUEST PROCESS FOR EVUSHIELD AND ORAL ANTIVIRALS

Evushield Process

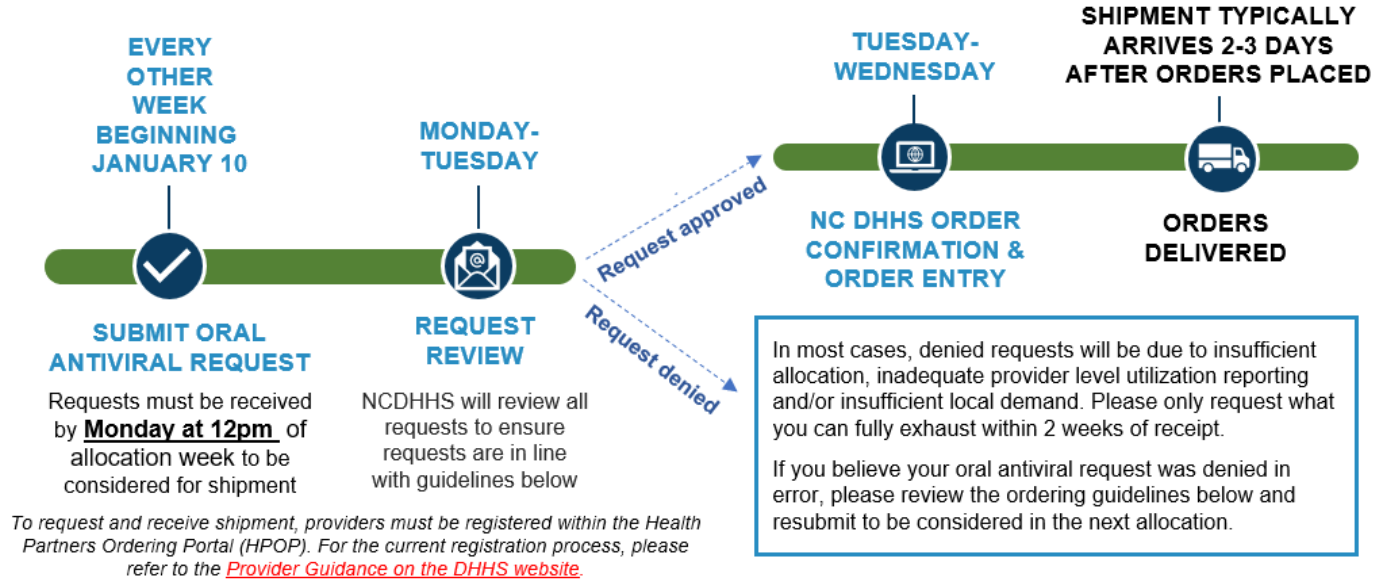
Link to request form:
EVUSHELD Requests



To request and receive shipment, providers must be registered within the Health Partners Ordering Portal (HPOP). For the current registration process, please refer to the Provider Guidance on the DHHS website.

Oral Antiviral Process

Link to request forms:
Molnupiravir Requests
Paxlovid Requests



To request and receive shipment, providers must be registered within the Health Partners Ordering Portal (HPOP). For the current registration process, please refer to the Provider Guidance on the DHHS website.

UPDATED PHYSICIAN DISPENSING GUIDANCE FOR COVID-19 ORAL ANTIVIRALS

All physicians, advanced practice registered nurses and physician's assistants with active licensure in good standing with their respective governing bodies can prescribe and dispense from their office for treatment of COVID-19 in accordance with the EUA if the following conditions are met:

1. There is absolutely **no charge to the patient for the drug or act of dispensing**, including seeking reimbursement of dispensing fees through 3rd party payors.
2. Products are **labeled in accordance with State and Federal dispensing laws**. Details from the NC Board of Pharmacy on what information must be included on a prescription label can be found here.

Physicians who wish to dispense oral antivirals for the treatment of COVID-19 (or any other medication) for a fee must be registered with the NC Board of Pharmacy as a dispensing physician.

Nurse Practitioners and Physician Assistants who wish to dispense medications other than COVID-19 therapeutics (whether a fee is charged or not) or who wish to dispense COVID-19 therapeutics for a fee must register with the Board of Pharmacy as dispensing PAs or NPs.

For more information on becoming a dispensing physician, nurse practitioner, or physician assistant please visit the NC Board of Pharmacy Dispensing Physician, Physician Assistant and Nurse Practitioners Registration Requirements.

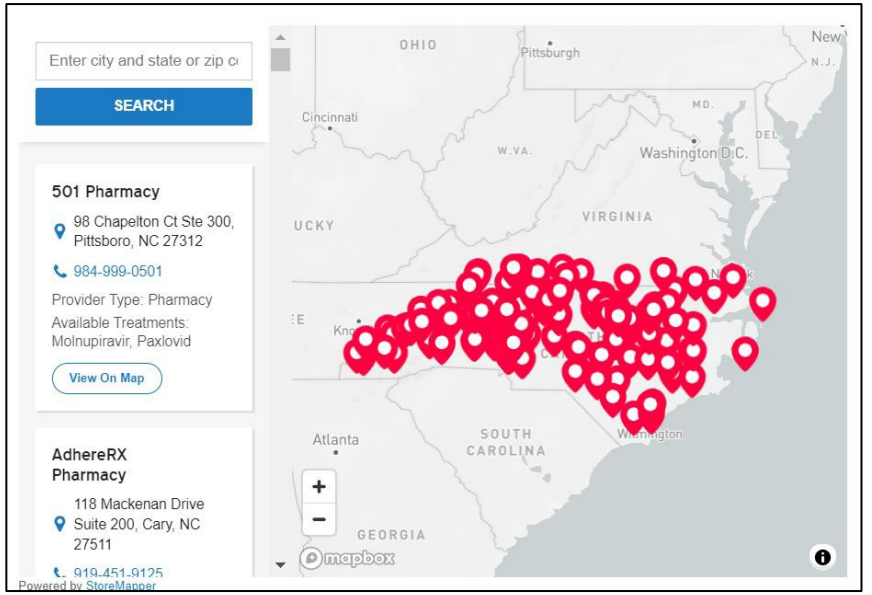
Providers interested in dispensing COVID-19 oral antivirals can complete this new provider enrollment survey.

RECIPIENT WAYFINDING IMPROVEMENTS

Wayfinding Improvements

- The ‘Find COVID-19 Treatment’ section on the NC DHHS website includes an updated ‘Site Finder’ tool that enables recipients to:
  - Search for nearby treatment sites
  - Discover available treatments each site offers for administration
  - Find resources to schedule an appointment (phone numbers, websites)
  - Offers a list view option that allows for sorting by available product
- The ‘Information For Individuals at Higher Risk’ section on the NC DHHS website includes a ‘Site Finder’ tool specifically for EVUSHELD treatment locations.

Site Finder Tool on NC DHHS Website



Site Name	Available Products	Provider Type	Phone	Address	Website
1237 - Piedmont Healthcare	Molnupiravir, Paxlovid	PCP	336-751-2121	375 Hospital Street, Mocksville, NC 27028	Visit Website
501 Pharmacy	Molnupiravir, Paxlovid	Pharmacy	984-999-0501	98 Chapelton Ct Ste 300, Pittsboro, NC 27312	
AdhereRX Pharmacy	mAbs, Molnupiravir, Paxlovid	Pharmacy	919-451-9125	118 Mackenan Drive Suite 200, Cary, NC 27511	Visit Website
Angel Medical Center	mAbs	Hospital	828-369-4211	120 Riverview St., Franklin, NC 28734	Visit Website
Apex Pharmacy	Molnupiravir	Pharmacy	919-629-7332	904 W Williams St, Apex, NC 27502	Visit Website

NEW PROVIDER GUIDANCE & UPDATED STATEWIDE STANDING ORDER

Patient Prioritization

Due to the limited supply of COVID-19 therapeutics and the emergence of the Omicron variant, the NIH Panel has arranged tiers of patient prioritization. North Carolina is requesting providers prioritize all treatments for patients in Tier 1 & Tier 2:

Tier 1	• Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions below); or • Unvaccinated individuals at the highest risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with additional risk factors).
Tier 2	• Unvaccinated individuals at risk of severe disease not included in Tier 1 (anyone aged ≥65 years or anyone aged <65 years with clinical risk factors)

Drug Prioritization

Due some treatment's reduced susceptibility to the emerging Omicron variant, North Carolina is following the NIH's recommendations to use the following therapeutics (listed in order of preference):

1.	Paxlovid (Pfizer)
2.	Sotrovimab
3.	Remdesivir*
4.	Molnupiravir (Merck)

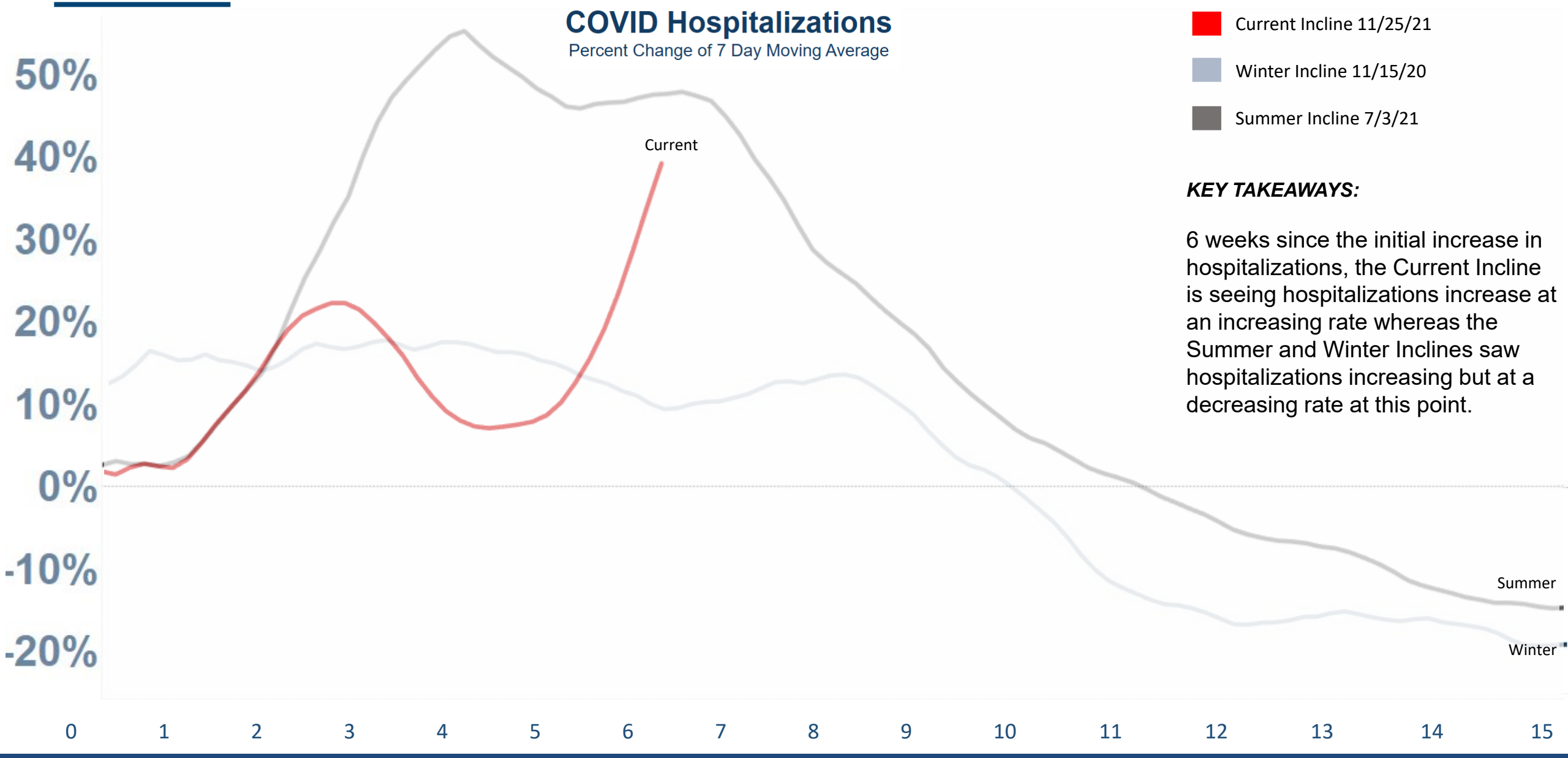
REGEN-COV and BAM/ETE are unlikely to retain activity against the Omicron variant. Providers can only allocate these if: 1) they have capability to identify a potential case of the Omicron variant **AND** can administer that product within 48 hours, or 2) local indicators point to Omicron not being the predominant variant

*Remdesivir is not currently allocated by NC DHHS

Statewide Standing Order: The Standing Order has been revised to provider patient prioritization criteria in the *Specific Assessment* Criteria with the criteria mentioned in Tiers 1 & 2. North Carolina's also updated the Standing Order for BAM/ETE and REGEN-COV (SQ and IV) stating that these can only be administered as a treatment where providers can rule out the Omicron variant.

Medical Surge Efforts

COVID HOSPITALIZATIONS GROWTH RATE SURGE COMPARISON



KEY TAKEAWAYS:

6 weeks since the initial increase in hospitalizations, the Current Incline is seeing hospitalizations increase at an increasing rate whereas the Summer and Winter Inclines saw hospitalizations increasing but at a decreasing rate at this point.

STATE MEDICAL SURGE LEVERS

Type of Lever	Value (Scale 1-5) 5 = High	Lead Time
Statewide Patient Coordination	(2) Support for Rural/Unaffiliated Hospitals and will only support a small number of patients while there is some capacity to support them.	24-48 hours
Staffing Pool for Health Systems to Hire Personnel From	(3) Supports Staffing but has potential administrative barriers – expect this to support larger health systems primarily	7-10 days
Scope of Practice Flexibilities	(3) Supports Staffing but has potential administrative barriers – expect this to support larger health systems primarily	7-10 days
Use of non-traditional staffing resources	(4) Utilizing contracts (CCNC, Starmed etc.) along with unlicensed assistive personnel that would be willing to support efforts within healthcare	
Other State Personnel Resources	(3) Limited personnel but would be helpful for large and smaller health systems	14-21 days
Federal Request for Support	(2) Experience has been that it yields little to no support for hospitals and is a lot of administrative work	30 days

Communications

COVID-19 Vaccine Communications: **Vax. Mask. Boost.**

Medical providers remain a trusted source of information on the COVID-19 vaccine

- The unvaccinated ranked talking to a nurse or doctor as a top factor to make them more likely to get vaccinated[1]
- 77% of parents say they trust their child's pediatrician to provide reliable information on vaccines for children[2]
- Vaccine counseling from a medical provider increases the likelihood that Medicaid beneficiaries for all age groups will make the decision to get vaccinated[3]

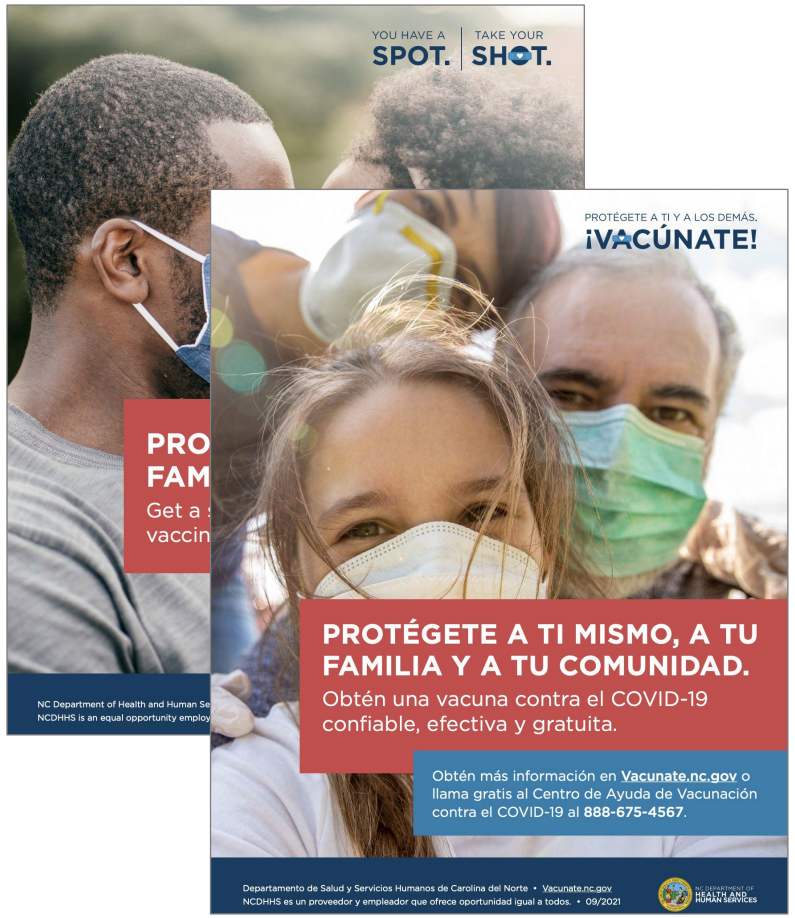
1.KFF COVID-19 Vaccine Monitor: Winter 2021 Update On Parents' Views Of Vaccines For Kids
2.Neimand Collaborative, November 2021 Benchmarking Research & Analysis: Wave 4 Parent Focus
3.NCDHHS: 2021 NC Medicaid Internal Analysis of Claims and Vaccination Data

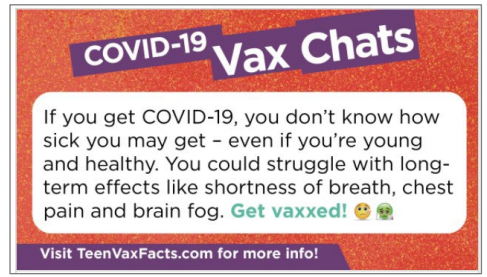
COVID-19 Vaccine Communications

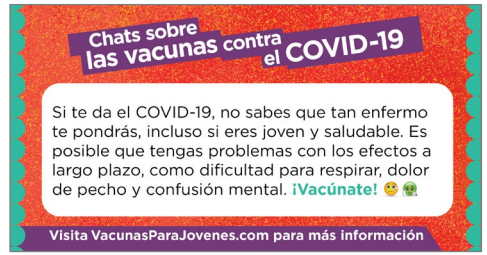
Resources Available for Medical Provider

COVID-19 Vaccine Communications Toolkit

- covid19.ncdhhs.gov/vaccines/covid-19-vaccine-communications-toolkit
- Download these easy to use and frequently updated materials.
- Includes flyers, social media posts, graphics, and more!
- Materials in English and Spanish







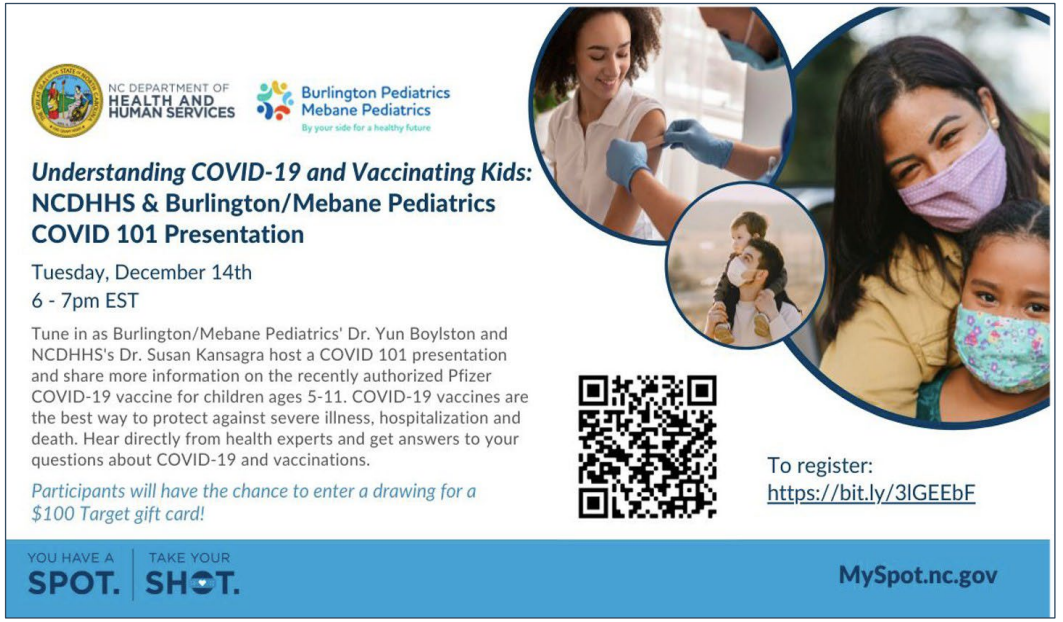
COVID-19 Vaccine Communications

NCDHHS is partnering with healthcare providers to talk to their local communities about staying healthy with vaccinations, boosters and masks

- **COVID-19 101 Webinar:**
  We make the process easy for providers. We have the presentation and customize it to local needs, plus provide technical assistance.

- **Vaccine Event Support:**
  If you are hosting a vaccination event we can provide materials, social media graphics, and make automated calls to invite your community.

Will you partner with NCDHHS and host a webinar on vaccines?
Contact kelly.wright@dhhs.nc.gov



Recent Presentation: Hosted by Dr. Yun Boylston, Pediatrician, Mebane/Burlington Pediatrics and Dr. Susan Kansagra, NCDHHS Section Chief for Chronic Disease and Injury

Q & A

Appendix

UPDATED SCIENCE BRIEF: COMMUNITY USE OF MASKS TO CONTROL THE SPREAD OF SARS-COV-2

- https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/masking-science-sars-cov2.html

- **Updated review on data on masks**

- Summarize findings **of 21 different studies that showed benefit of masks.**

- Including new study among eight public K-12 school districts in Massachusetts
  - 70 schools (with >33,000 enrolled students) during the 2020–21 school year
  - Secondary attack rate of 11.7% for unmasked versus 1.7% for masked interactions.

NC REPORTED K-12 CLUSTERS (OCTOBER 10 – DECEMBER 7, 2021) ACCORDING TO FACE MASK POLICIES

- **21 of 46 districts (45%) with optional mask policies** reported a cluster during this time frame, compared with **6 of 65 districts (9%) with mandatory mask policies**
- Among counties that reported a K-12 clusters during this period, there was an average of **7.2 clusters/100 schools** in **mask optional** counties **(n=21) and 2.4 clusters/100 schools** in masks required counties **(n=6)**
  - This represents a **3-fold difference** comparing counties by school mask policy
  - 71 counties did not report a cluster during this time period; 2 were excluded due to changes in policy

Notes:

1. *This analysis is based solely on K-12 clusters reported to public health during an 8-week period. Jurisdictions were considered mask optional if they had a mask optional policy for at least one week during the 8-week timeframe.*
2. *This analysis does not account for other factors that could affect cluster occurrence or reporting – e.g., incidence rates among school-age cases or vaccine uptake.*
3. *This data also includes private schools that may have different mask policies than the district.*

TEST TO STAY PILOTS

- CDC reported data on test to stay pilots in two school districts (CA, IL)
  - Limited to universally masked settings with fully masked exposures for both person with infection and person exposed
  - Secondary attack rate 0.7-1.5%. No increase in transmission in test to stay environments

- NC – ABC collaborative Test to stay research pilot.
  - Over six weeks, enrolled 367 participants from five North Carolina school districts and one charter school. Data through December 13, 2021
  - All masked required schools. Test to stay for brief unmasked exposures in mask required settings (e.g., lunch, athletics)
  - In-school secondary transmission rate 1.7%. No documented transmission from study participant to another person
  - While still low, exposure during athletics higher risk than other exposures
    - Most exposures occurred during lunch (39%). Only 13% of exposures occurred during athletics; however, these exposures accounted for 50% of all individuals with positive tests.