NC DHHS Update on COVID-19 Vaccines

August 31, 2021

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

AGENDA

1. COVID and Vaccine Trends

2. Provider Resources for Onboarding CVMS / Vaccination and Counseling Code

3. Vaccine Updates

4. Pfizer FDA Approval
   - Parental Consent for Minors
   - Vaccines Incentives
   - NCIR-CVMS Dual Platform

5. Vaccine Ordering/Storage/Extension

6. Additional doses/booster planning

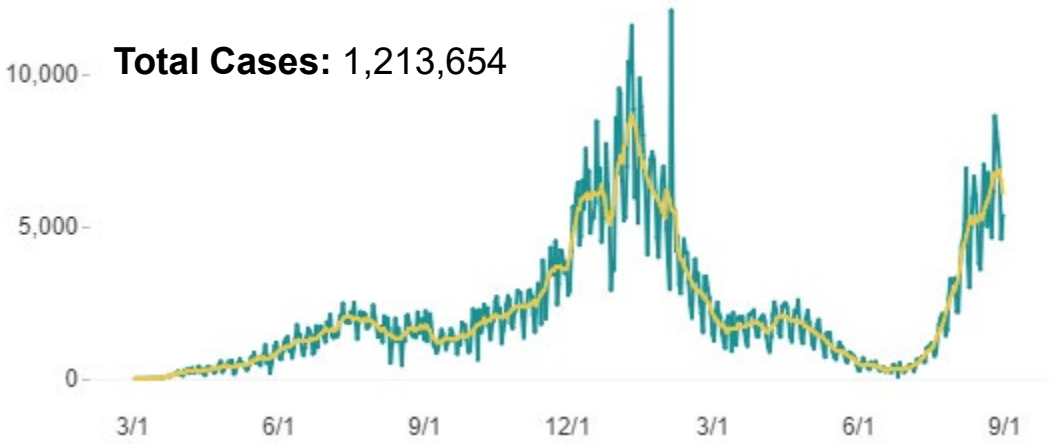
7. Treatment
   - Ivermectin
   - Monoclonal Antibodies Update

8. Testing Q and A

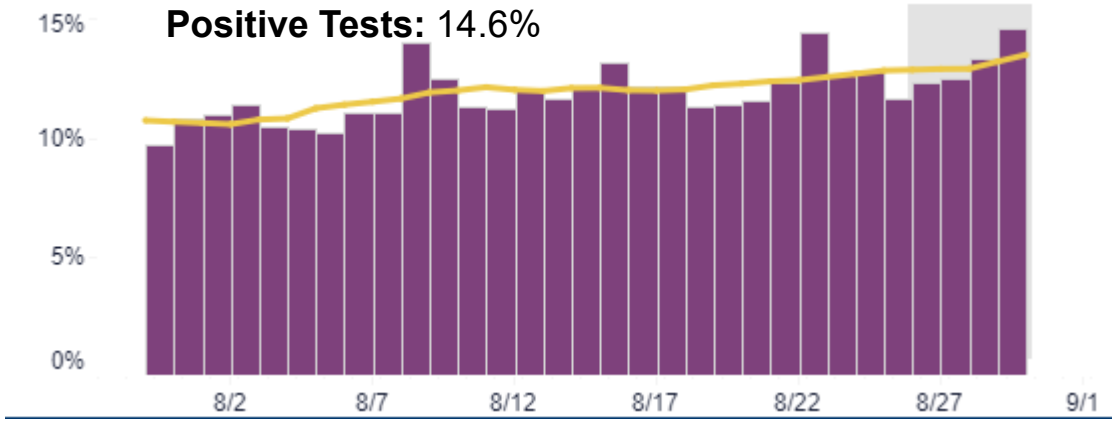
COVID-19 and Vaccine Trends

Four Key Metrics – All Quickly Rising

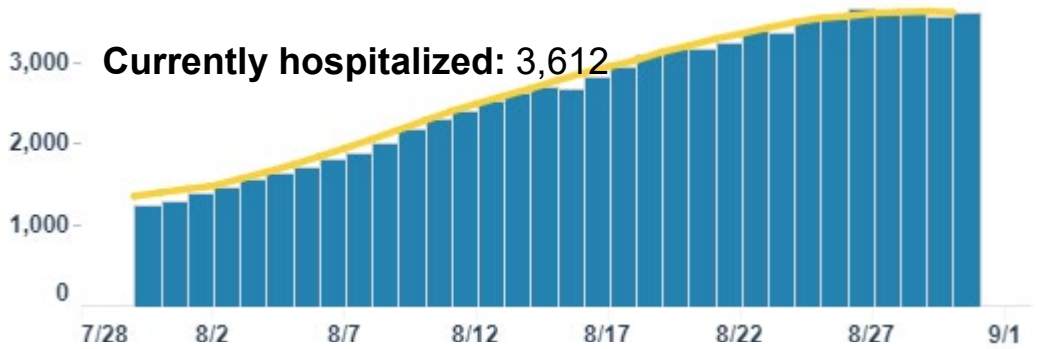
Daily Cases by Date Reported



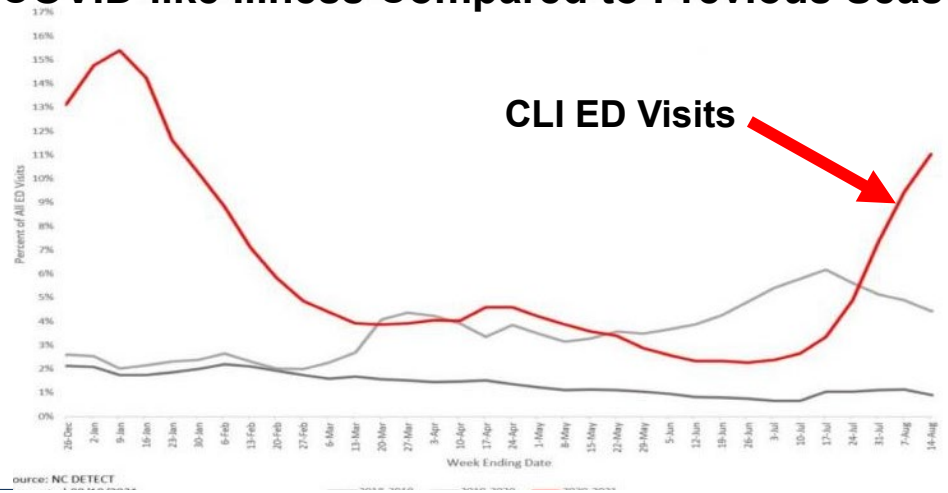
Positive Tests as a Percent of Total Tests



Daily Number of People Currently Hospitalized

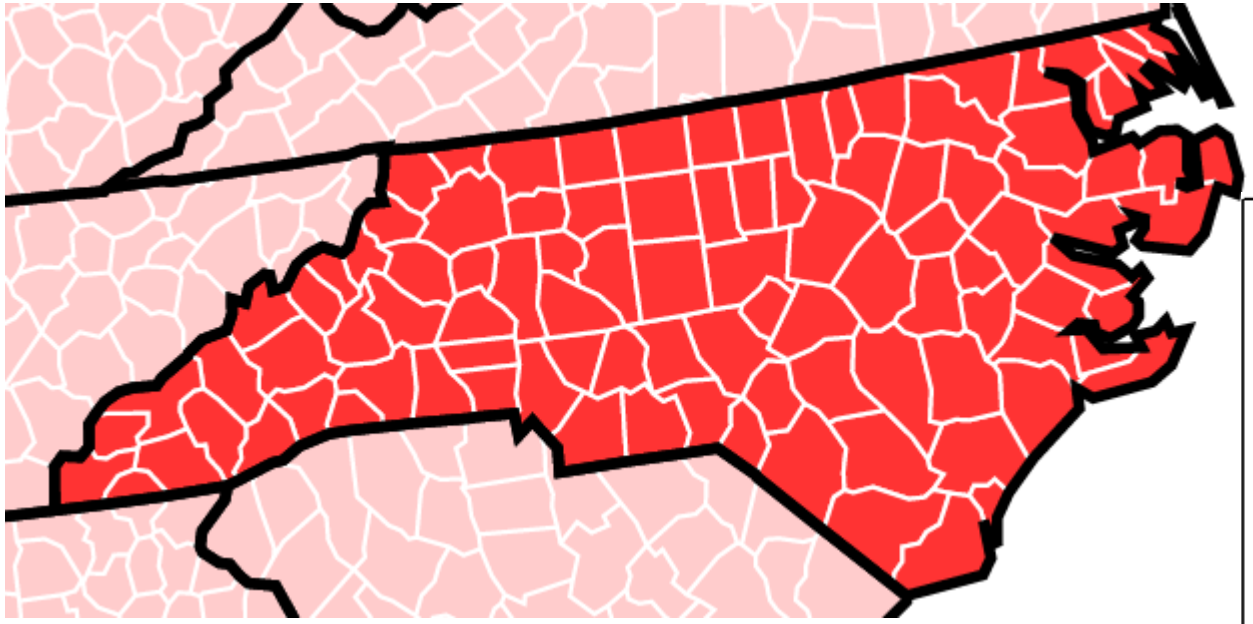


What Percentage of ED Visits this Season are for COVID-like Illness Compared to Previous Seasons?

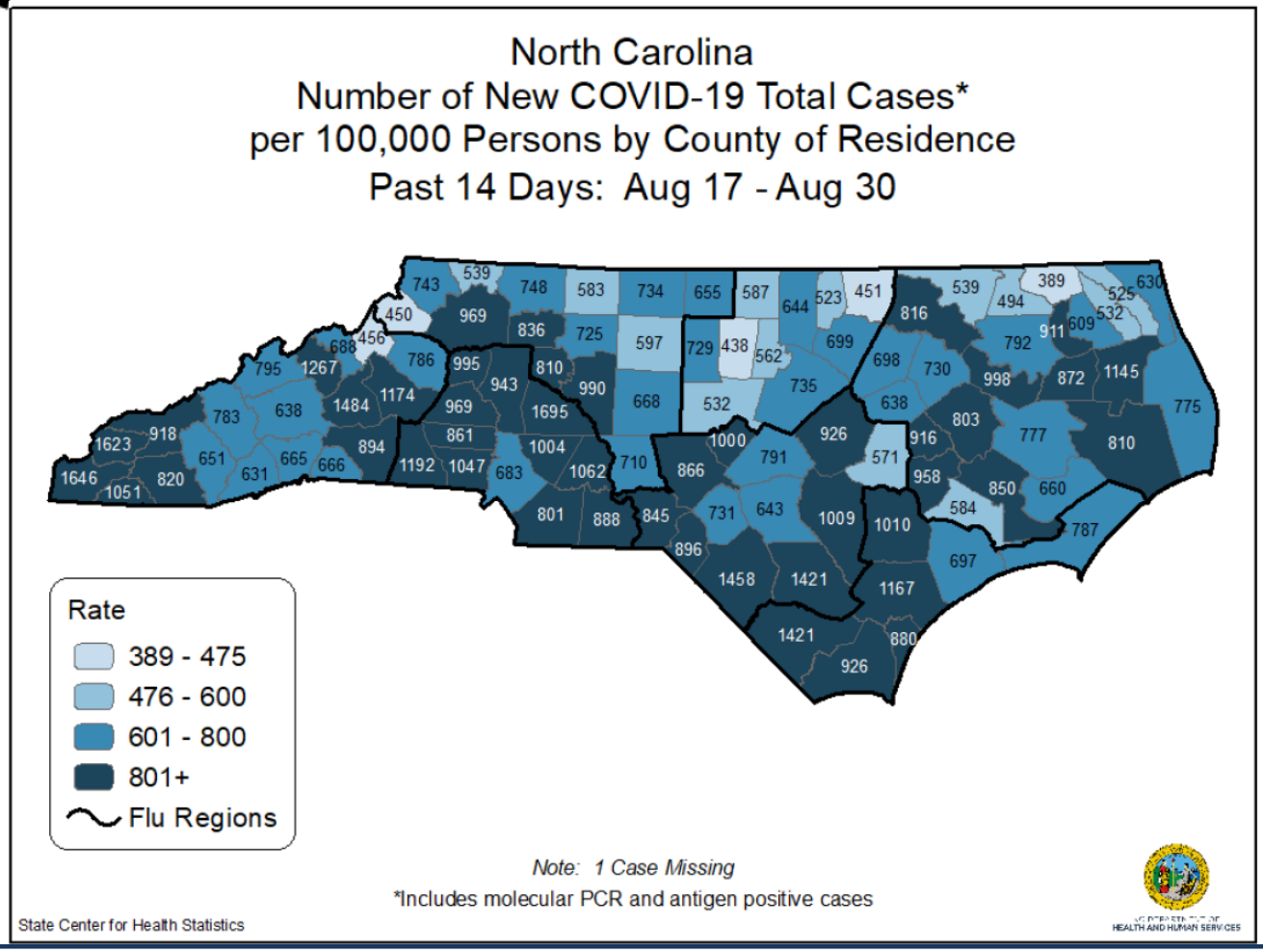


Source: https://covid19.ncdhhs.gov/dashboard

Case Rates Increasing Statewide

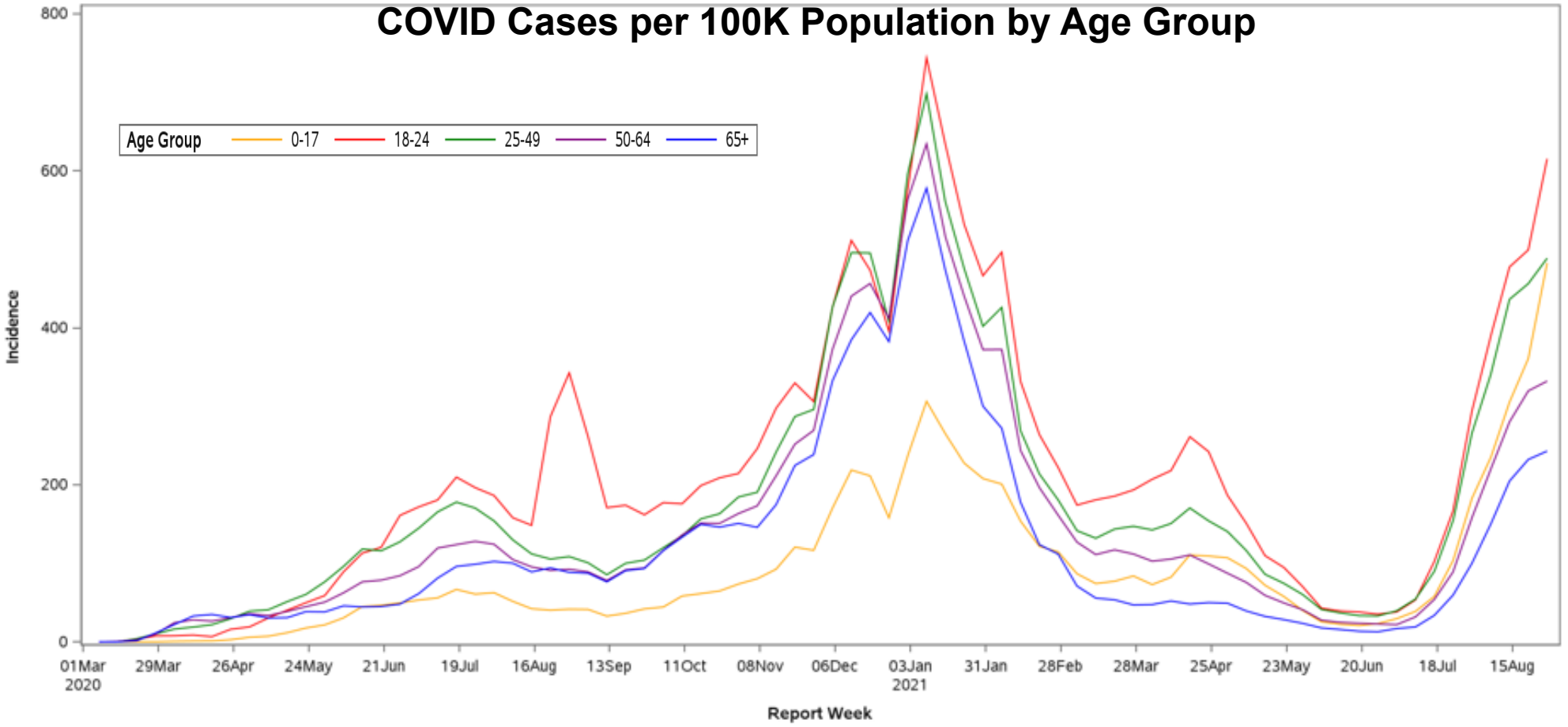


https://covid.cdc.gov/covid-data-tracker/#county-view



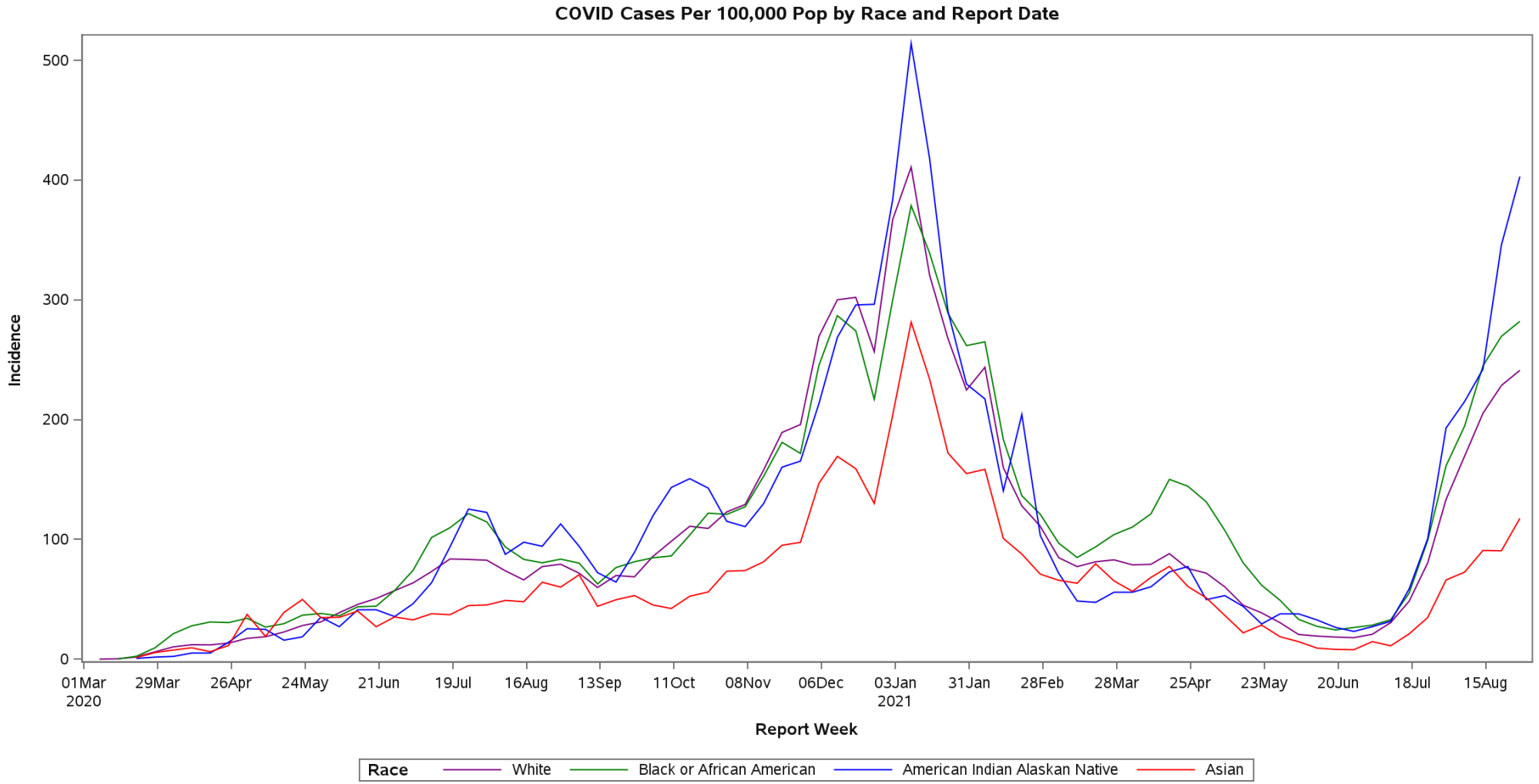
Case Rates Increase Across All Age Groups

Case rates are increasing at the greatest rate among 18 to 24, followed by 0 to 17-year-olds. Case rates for children are higher than January peak levels.

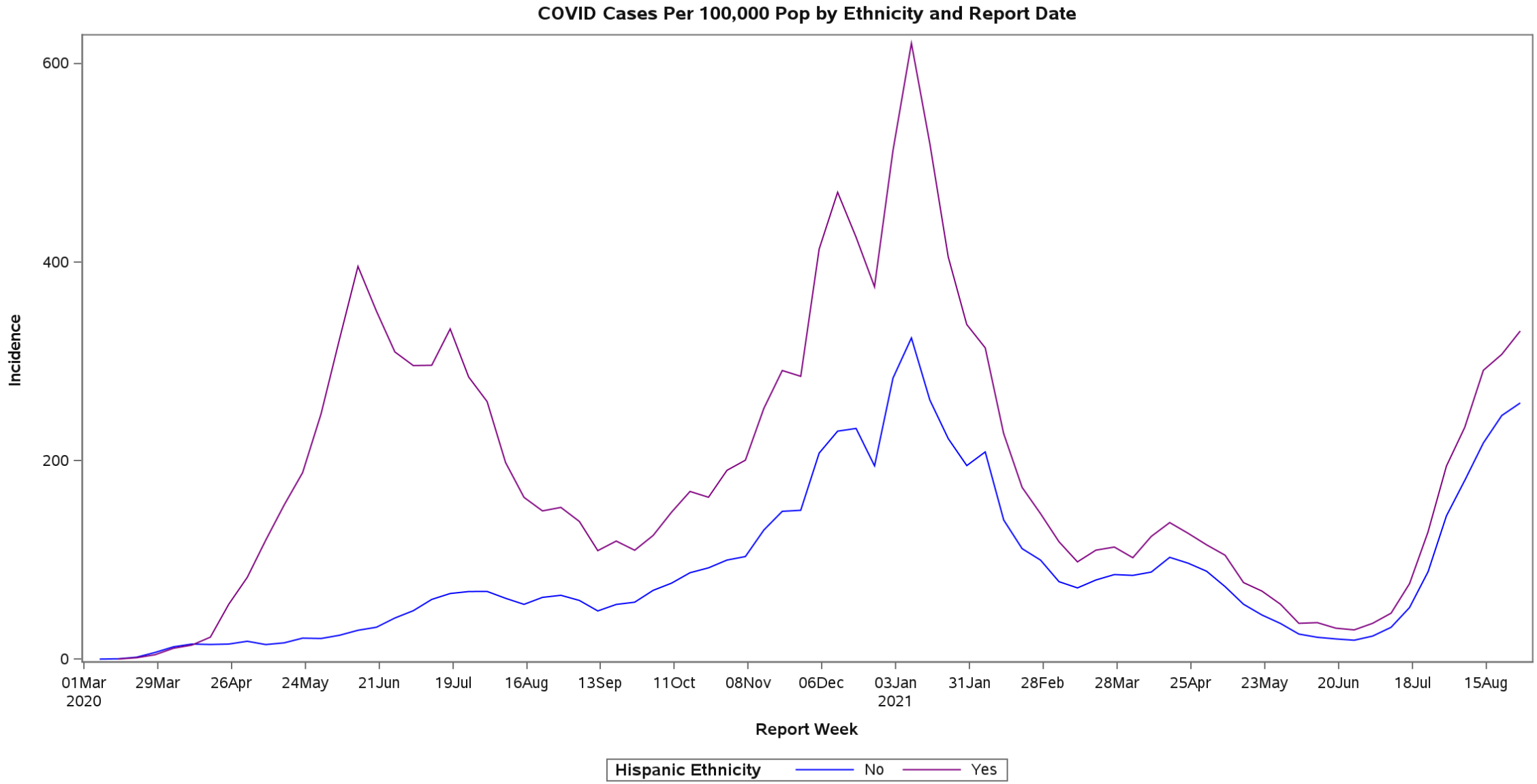


Racial Disparities in Case Rates Widen

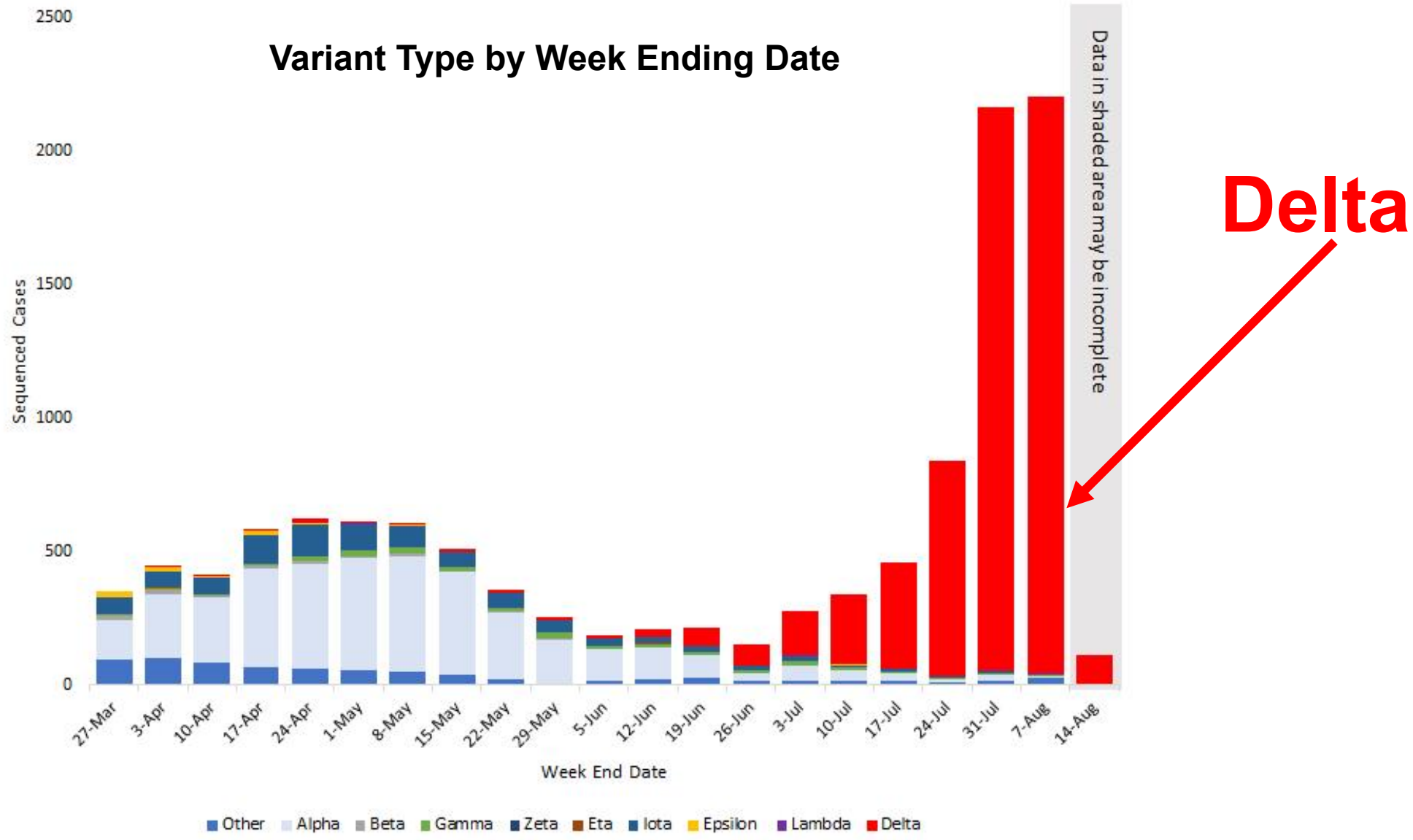
American Indian/Alaskan Native and Black/African American population case rates exceed those for White and Asian populations.



Gap Widens Between Hispanic and Non-Hispanic Population

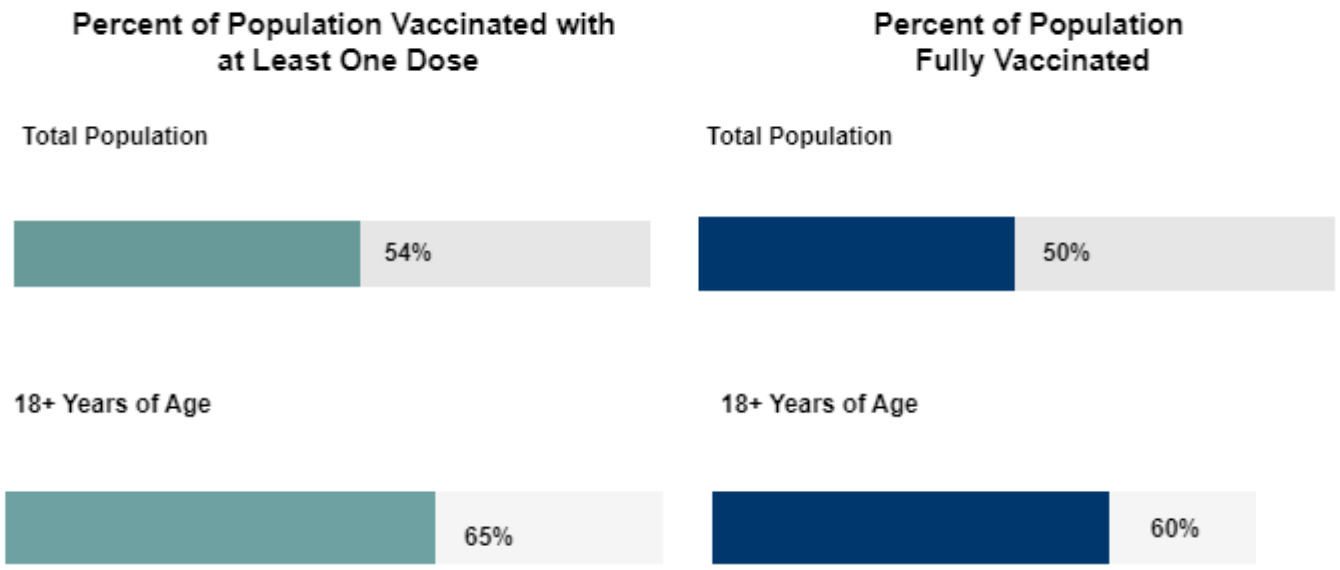


Delta Variant Predominates in North Carolina



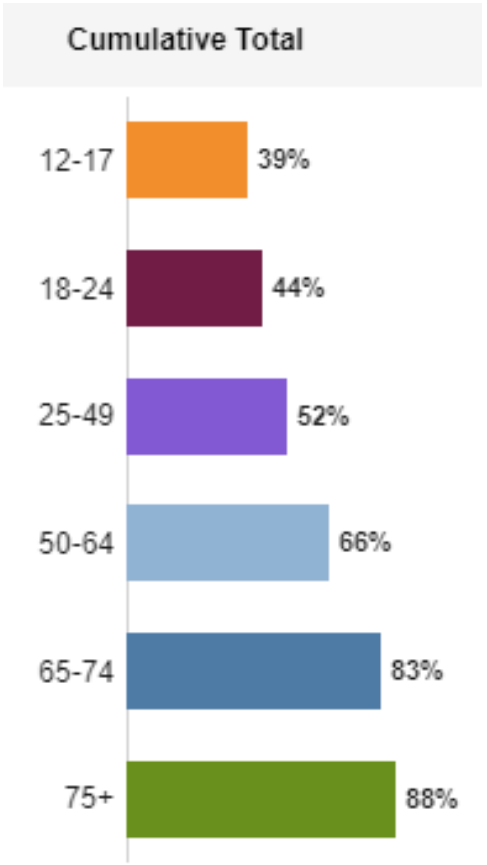
VACCINATION STATUS BY AGE

First of 2 Doses Administered	Second of 2 Doses Administered	Single Shot Doses Administered	Total Doses Administered
5,301,055	4,824,558	388,900	10,514,513



0-12 years – 0%

Not currently eligible for vaccination



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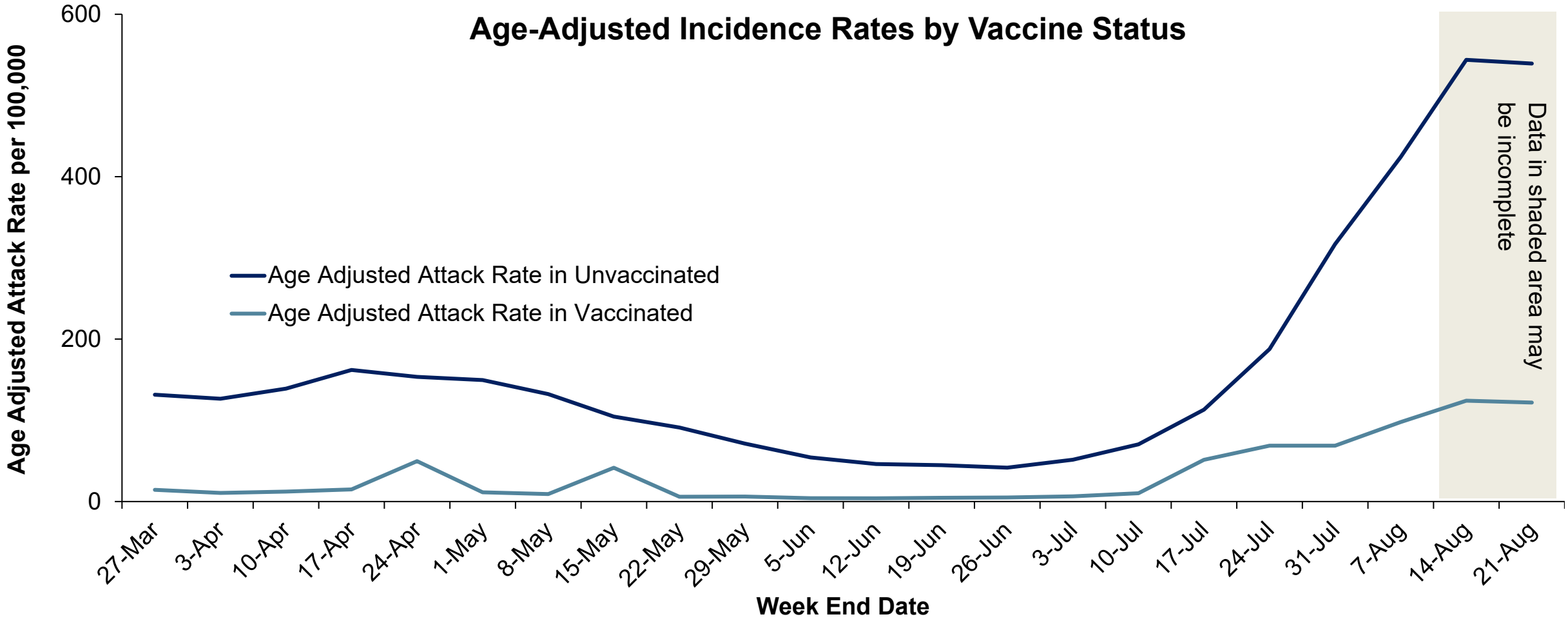
https://covid19.ncdhhs.gov/dashboard/vaccinations

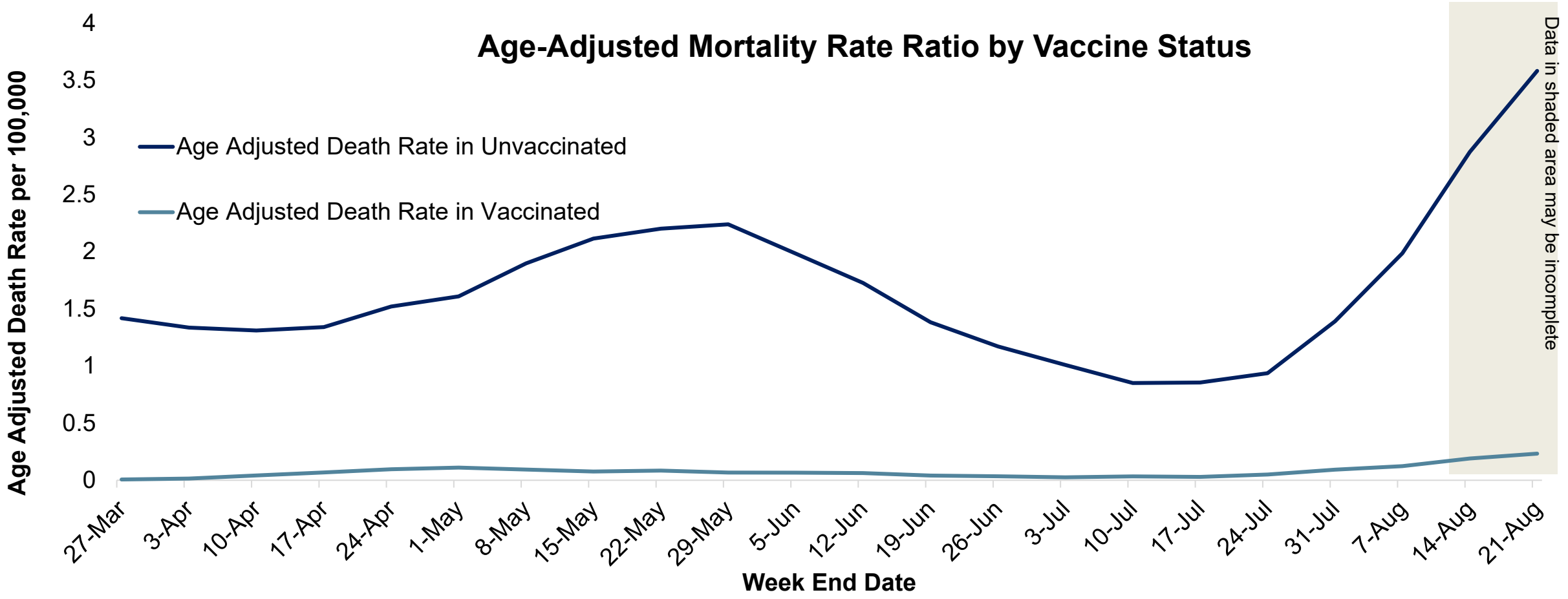
COVID-19 Attack Rate 4.5x Higher in Unvaccinated Individuals

For the week ending August, 21, 2021, the age-adjusted attack rate among unvaccinated individuals was 539 cases per 100,000 unvaccinated population. The age-adjusted attack rate among vaccinated individuals was 121 per 100,000 vaccinated population.



COVID-19 Mortality Rate >15x Higher in Unvaccinated Individuals

For the four-week ending August 21, 2021, the age-adjusted mortality rate among unvaccinated individuals was 3.6 cases per 100,000 unvaccinated population. The age-adjusted mortality rate among vaccinated individuals was 0.23 per 100,000 vaccinated individuals



Among people with an initial infection, unvaccinated individuals are about about 2 and half times (250%) more likely to be re-infected than those vaccinated

Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021

Weekly / August 13, 2021 / 70(32);1081-1083

On August 6, 2021, this report was posted online as an MMWR *Early Release.*

Alyson M. Cavanaugh, DPT, PhD[1,2]; Kevin B. Spicer, MD, PhD[2,3]; Douglas Thoroughman, PhD[2,4]; Connor Glick, MS[2]; Kathleen Winter, PhD[2,5] (View author affiliations)

Summary

What is already known about this topic?

Reinfection with human coronaviruses, including SARS-CoV-2, the virus that causes COVID-19, has been documented. Currently, limited evidence concerning the protection afforded by vaccination against reinfection with SARS-CoV-2 is available.

What is added by this report?

Among Kentucky residents infected with SARS-CoV-2 in 2020, vaccination status of those reinfected during May–June 2021 was compared with that of residents who were not reinfected. In this case-control study, being unvaccinated was associated with 2.34 times the odds of reinfection compared with being fully vaccinated.

What are the implications for public health practice?

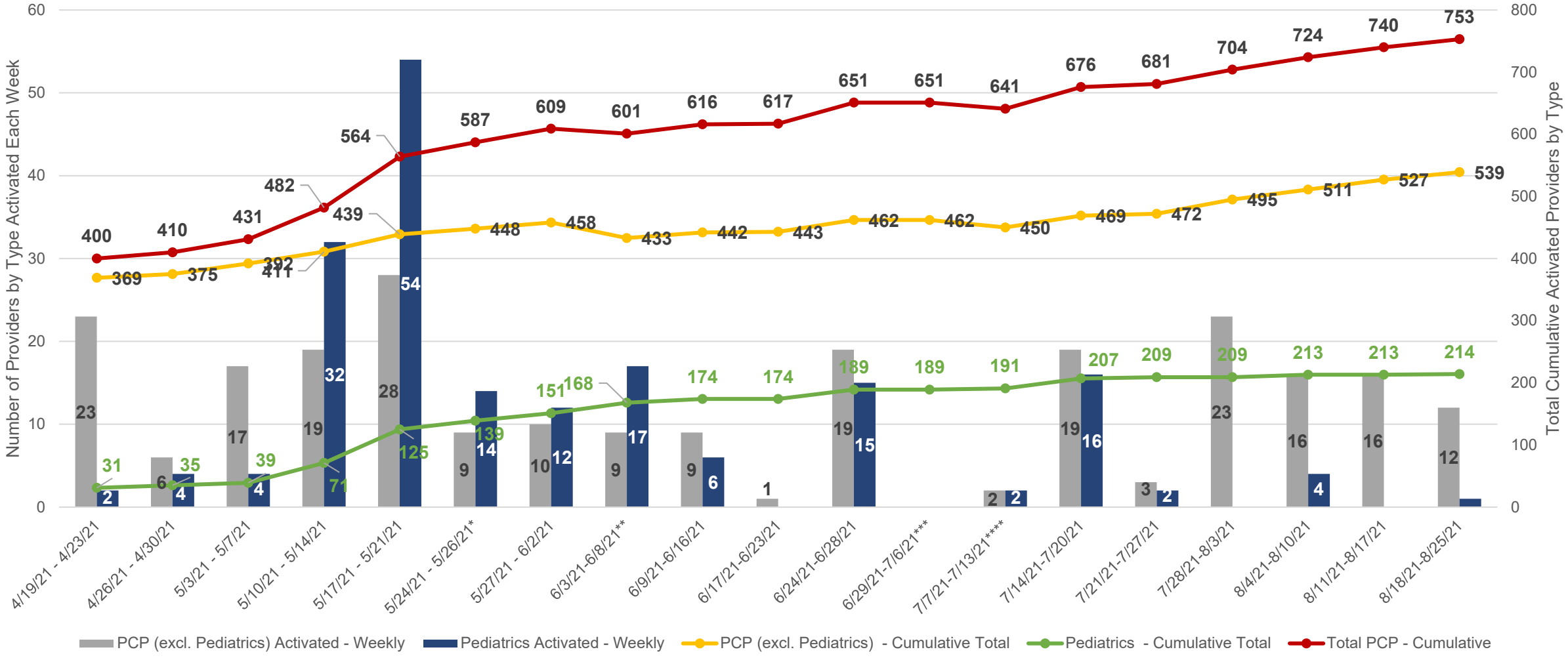
To reduce their likelihood for future infection, all eligible persons should be offered COVID-19 vaccine, even those with previous SARS-CoV-2 infection.

https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm?s_cid=mm7032e1_w

Provider Resources / Vaccination and Counseling Code

PCP AND PEDIATRIC ACTIVATION – CUMULATIVE INCREASE FROM 04/18 (AS OF 8/25/21)

With your support, great progress has been made in onboarding PCPs to be COVID-19 providers



*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

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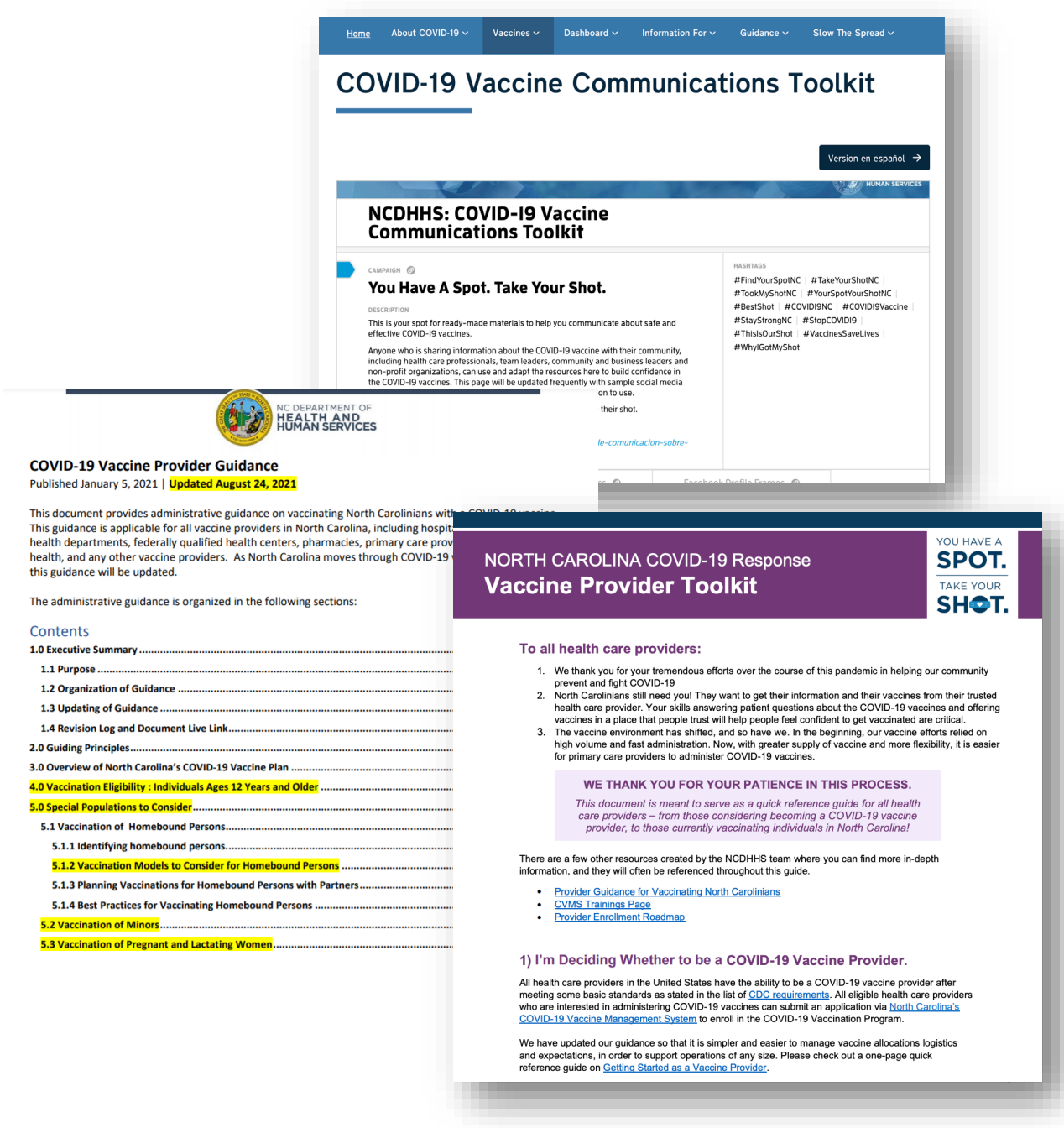
PROVIDER TOOLS

- Getting Started One-Pager
- Provider Toolkit
- Provider Guidance
- Communications Toolkit for your office
- Provider Training Summary
- Discussion guide based in motivational interviewing
- Coding & Billing Resources
  - Medicaid Vaccination Counseling Code: Special Bulletin COVID-19 #170



BILLING FOR COVID-19 VACCINE COUNSELING: 99401 ~6000 CLAIMS IN FIRST MONTH

Purpose: Preventative Code to be used for COVID-19 Vaccine Counseling

Who can utilize code

- Providers Only: MD, DO, NP, PA, CNM
- LHDs, FQHCs, and RHCs can bill for service when counseling completed by above providers

How it can be applied

- May be provided in person, via live audio/video (telehealth), or telephonically
- Parents can be counseled about giving the vaccine to their children age 12 and over
- Parents can be counseled about their getting the vaccine and service filed on child's Medicaid number, however only one code can be billed per day

Additional information

- Time limited coverage, initially 3 months and will reevaluate
  - Ideally through PHE
- Coding criteria will apply
- No quantity limits to billing other than no more than one claim per day
  - Can be billed by multiple providers
  - Can be billed multiple times on different days

Reimbursement Ranges

- Reimbursement is RVU based and ranges from:
  - Facility: $20.68 - $24.54
  - Non-Facility: $32.28 - $38.30

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CMS ENHANCED PAYMENT FOR AT-HOME VACCINATIONS/SMALLER GROUP HOMES

To increasing access to vaccinations and improving health equity, the Centers for Medicare & Medicaid Services (CMS) is expanding opportunities for people to receive COVID-19 vaccinations in their home.

Included At-Home Vaccinations

These opportunities will be expanded for:

- Long-term care facilities
- Group homes
- Other group living situations with less than ten (10) residents

Providers can now receive an increased reimbursement ranging from approximately **$40 to $75** per administered vaccine dose.

The additional payment amount also accounts for:

- The clinical time needed to monitor a beneficiary after the vaccine is administered, as well as
- The upfront costs associated with administering the vaccine safely and appropriately in a beneficiary's home.

The payment rate for administering each dose, as well as the additional in-home payment amount, is geographically adjusted based on where the service is finished

Further details can be found in this press release (Medicare COVID-19 Vaccination for Residents of Small Long-Term Care Facilities)

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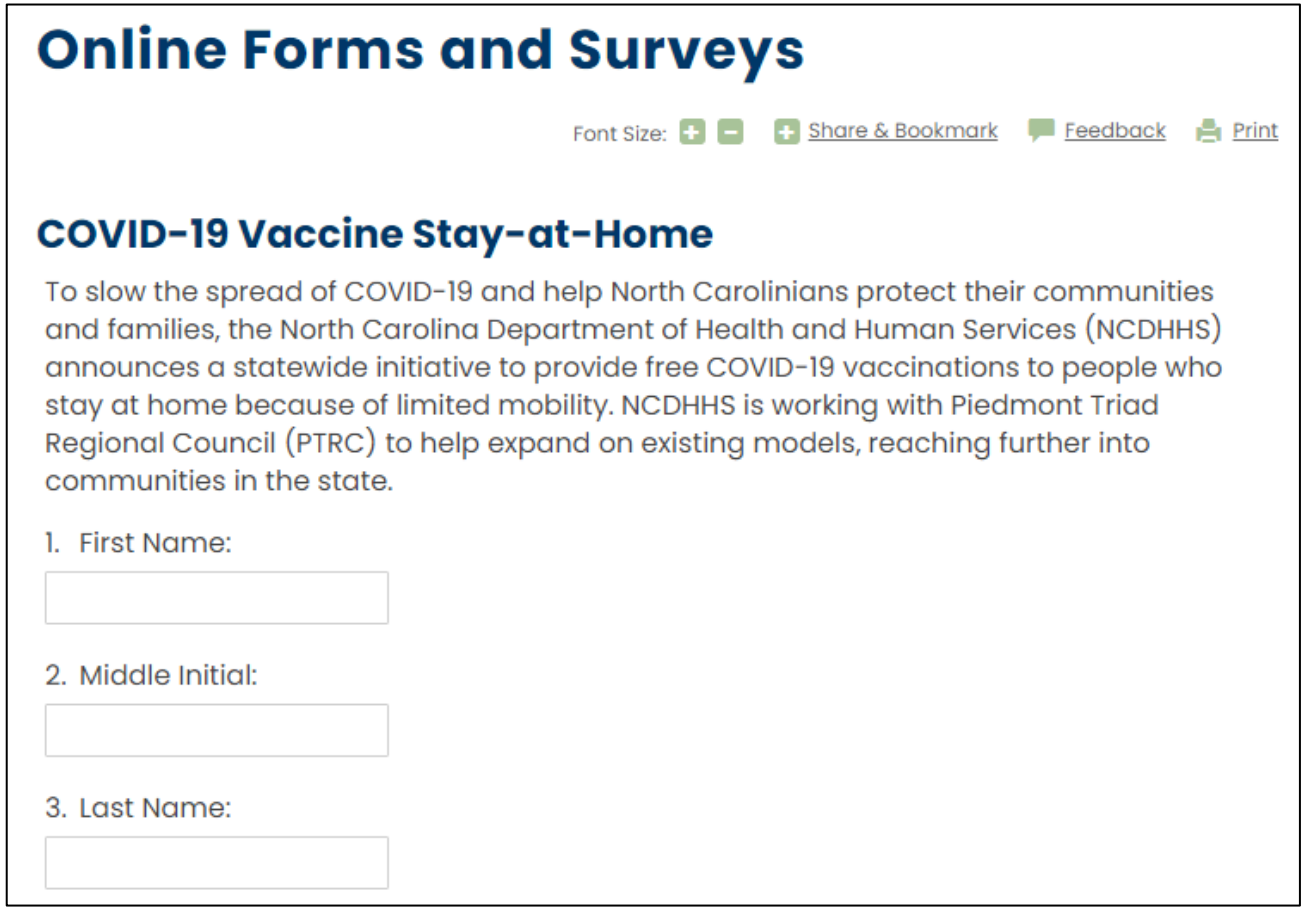
IN-HOME VACCINATION REQUEST PORTAL

[North Carolina in-home vaccination request portal]



Online Forms and Surveys

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COVID-19 Vaccine Stay-at-Home

To slow the spread of COVID-19 and help North Carolinians protect their communities and families, the North Carolina Department of Health and Human Services (NCDHHS) announces a statewide initiative to provide free COVID-19 vaccinations to people who stay at home because of limited mobility. NCDHHS is working with Piedmont Triad Regional Council (PTRC) to help expand on existing models, reaching further into communities in the state.

1. First Name:

2. Middle Initial:

3. Last Name:

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COVID-19 vaccines are available to everyone 12 and older.

Find a Vaccine Location

- [x] Moderna (age 18+)
- [x] Pfizer-BioNTech (age 12+)
- [x] Johnson & Johnson/Janssen (one dose; age 18+)

Zip Code

Go →

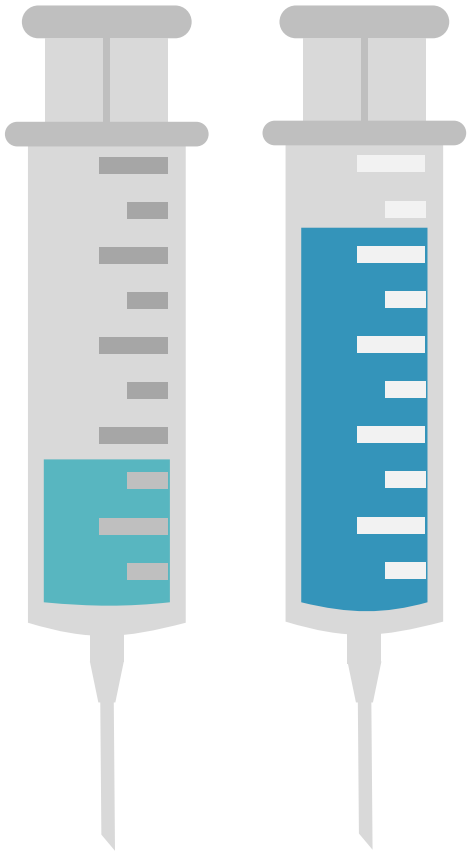
Need to be vaccinated at home?

Need a ride?

YOU HAVE A SPOT. | TAKE YOUR SHOT.

Vaccine Updates

PFIZER FDA APPROVAL



FDA Extends Full Approval to Pfizer Vaccine for Ages 16+

ACIP/CDC Recommendation 8-30-21

*The drug will be marketed as Comirnaty (koe-mir'-na-tee), for the prevention of COVID-19 in individuals **16 years of age and older**. The full press release from the FDA is available HERE.*

12-15 Years of Age remain under EUA

Administration to 12-15 year olds was not included in the EUA until May 2021 – additional time required before approval

Additional Dose Guidance under the EUA

Additional doses for moderately to severely immunocompromised individuals was recently added to the Pfizer-BioNTech EUA for all ages 12+ - and remains under EUA

Pfizer Fact Sheet for Recipients and Caregivers (updated August 23, 2021)
Pfizer Fact Sheet for Healthcare Providers (updated August 23, 2021)

MINOR'S CONSENT CHANGES

Parental Consent for Vaccines Under Emergency Use Authorization

State law (Session Law 2021-110) changed on August 20, 2021 requires health care providers to obtain **written consent** from a parent or legal guardian of a minor prior to administration of ***any vaccine that that has been granted emergency use authorization and is not yet fully approved by the United States Food and Drug Administration*** to an individual under 18 years of age.

- Once a vaccine has full FDA approval, pre-existing minor consent laws apply to consent to vaccination*
- **No other changes to current minor's consent law**

12-15 Years of Age - Initial 2 dose series

Pfizer is available under emergency use authorization for 12-15 year-olds with **written consent from a parent or legal guardian**

16 & 17 Years of age - initial 2 dose series

While expected and typically best practice that parental/guardian consent is obtained for COVID-19 vaccination, adolescents 16 and 17 years of age can consent for the Pfizer-BioNTech COVID-19 vaccine, if they show the decisional capacity to do so.

12-17 Years of Age - Additional doses for Immunocompromised

Pfizer is available under emergency use authorization for additional doses for 12-17 years olds with immunocomprise with **written consent from a parent or legal guardian**

Moderna and J&J COVID-19 vaccines are not currently authorized for individuals under 18 at this time.

Providers should NOT vaccinate anyone 11 or younger – not currently authorized or recommended. Not consistent with COVID-19 Provider Agreement. Studies currently going on in younger populations pertaining to dose, safety, effectiveness

**Minors must demonstrate that they can understand and make decisions about their health.*

COVID VACCINES IN YOUNGER CHILDREN

	16-17 years	12-15 years	5-11 years	6mo - 5yrs
Pfizer	**Full approval on Aug 23, 2021** (after EUA on Dec 11, 2020)	**EUA approved May 10, 2021.** Additional time required before approval	**Started March 2021, expect EUA submission in Sept**	**Started March 2021, ongoing**
moderna	**EUA requested Jun 10 (96% effective, safe)**	**EUA requested Jun 10 (96% effective, safe)**	**Started March 2021, expect EUA submission in fall**	**Started March 2021, ongoing**
Johnson & Johnson	**Announced in April 2021, ongoing**	**Ongoing**	**Planned**	**Planned**

- **Pfizer**: Dose-escalation study evaluating safety, tolerability, and immunogenicity in a two-dose schedule in 3 age groups: 5-11 years, 2-5 years, and 6 months-2 years. Expected enrollment of ~4,500 children.
- **Moderna**
  - TeenCOVE: 3,732 participants 12-17 years old. 0 cases in vaccinated arm. Similar safety, tolerability profile as in adult study.
  - KidsCOVE: Expected enrollment ~12,000 children age 6 months to 12 years
- **Dosing**: Anticipate smaller dose (e.g., 10 vs 30 micrograms) in 5-11 yr olds due to size & stronger immune response
- AAP urges FDA to authorize COVID-19 vaccines for children <12 as soon as possible

Vaccines Incentives

$100 Summer Cards

- Anyone 18+ who got their first dose of a COVID-19 vaccine at a participating location received a $100 Summer Card*. Anyone who drove someone to get their first dose at a participating location received a $25 Summer Card* through **August 31.**

- 133,000+ Summer Cards distributed since May 26, with a sharp increase in distribution after switch to $100 in early August.

- CDC authorization expires today (August 31). Looking towards creating a new program accessible to more providers.

NCIR-CVMS Dual Platform Update

COMING SOON: NCIR OR CVMS

This Fall, opportunity to co-administer COVID-19 and flu vaccines and need to check for COVID-19 booster eligibility

Document both COVID-19 and influenza vaccines in one system and enable provider access to COVID-19 vaccine status

Option to use their preferred system ("no wrong door") for COVID-19 vaccine documentation

Creating one consolidated vaccine record in NCIR for querying

Value to NC Providers

- ✓ **Enable co-administration of COVID and flu vaccines through NCIR, decreasing provider burden**
  *The most common setting for flu vaccination among both adults and children was a doctor's office (children: 67.6%; adults: 34.3%)**
- ✓ **Improved provider access to COVID-19 vaccine status and consolidated immunization information**
  *All **4714** NCIR providers will have access to recipient COVID vaccination history*
- ✓ **Offer provider choice with existing COVID-19 providers**
  ***275** surveyed providers rank consolidated immunization information and simplified workflows as their top priority †*
- ✓ **Open existing functionality such as clinical decision support, reminder recall, and bidirectional data exchange with EHRs**
  ***35%** of NCIR providers used reminder recall in last 2 months*

End Goal
Improve vaccination rates and prevent illness and death

Value to Recipients

- ✓ **Can get vaccinated at their 'trusted medical professional'**
  ***44%** of the unvaccinated would feel most comfortable getting vaccinated at their doctor's office ‡*
  ***83%** of people have a good or fair amount of trust in their doctor for reliable vaccine information §*
- ✓ **Continued recipient access to COVID immunization information through CVMS Recipient Portal**
  ***2,643,632** active recipient accounts in CVMS Recipient portal*

* https://www.cdc.gov/flu/fluvaxview/nifs-estimates-nov2018.htm
† Survey detail in Appendix
‡ Source: Neiman Collaborative survey conducted May 2021, detailed data in Appendix
§ Source: KFF Vaccine Monitor, June 2021

Vaccines Ordering/Storage/Extension

PFIZER SHELF-LIFE EXTENSION – APPROVED!

The **FDA** has authorized a 3-month extension **of the shelf-life for the Pfizer COVID-19 vaccine when stored at ultra-cold temperature**.

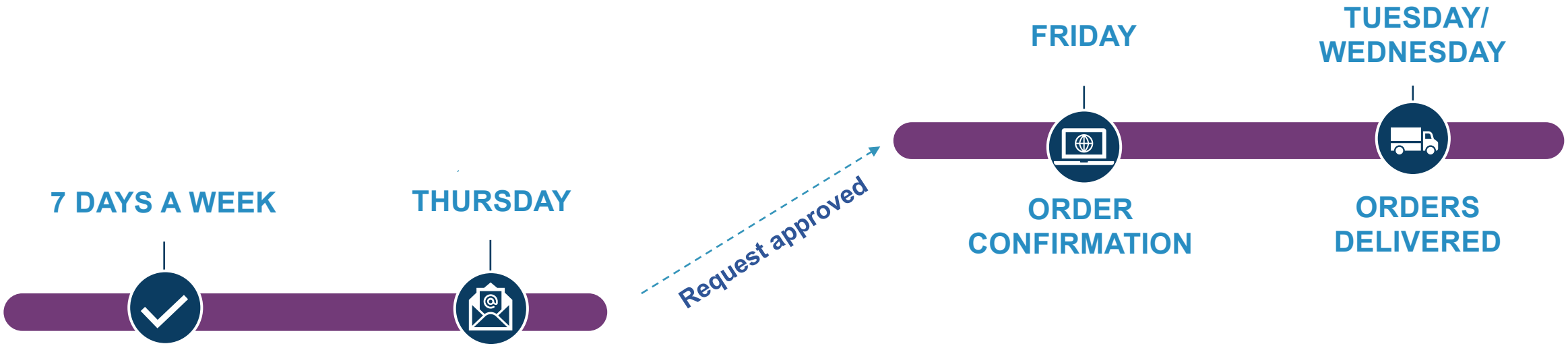
- Cartons and vials of Pfizer vaccine with an expiration date of August 2021 - February 2022 may remain in use beyond the printed date as long as approved storage conditions between -90ºC to -60ºC (-130ºF to -76ºF) have been maintained.
- Updated expiration dates are shown on slide 6.

Immediate Action for Location Managers:

Update the expiration dates for your on-hand Pfizer Covid-19 doses currently in ultra-cold freezing storage in CVMS. Please reference the COVID-19 Vaccine Expiration Date Job Aid for steps on how to change expiration dates in CVMS.

NC DHHS will not be able to update expiration dates on the backend. Continue to follow the beyond-use date guidance for doses being stored at frozen (-25°C to -15°C) or refrigerated (2°C to 8°C) temperatures.

WEEKLY ALLOCATION REQUEST PROCESS



Requests must be received by **Thursday at 10 am** to be considered for shipment the following week

NCDHHS will review all requests to ensure requests are in line with guidelines below

In most cases, denied requests will be due to insufficient administration history and/or forecasted booster dose demand at your site. Please only request direct allocation if you can administer the MOQ within 3 months of receipt.

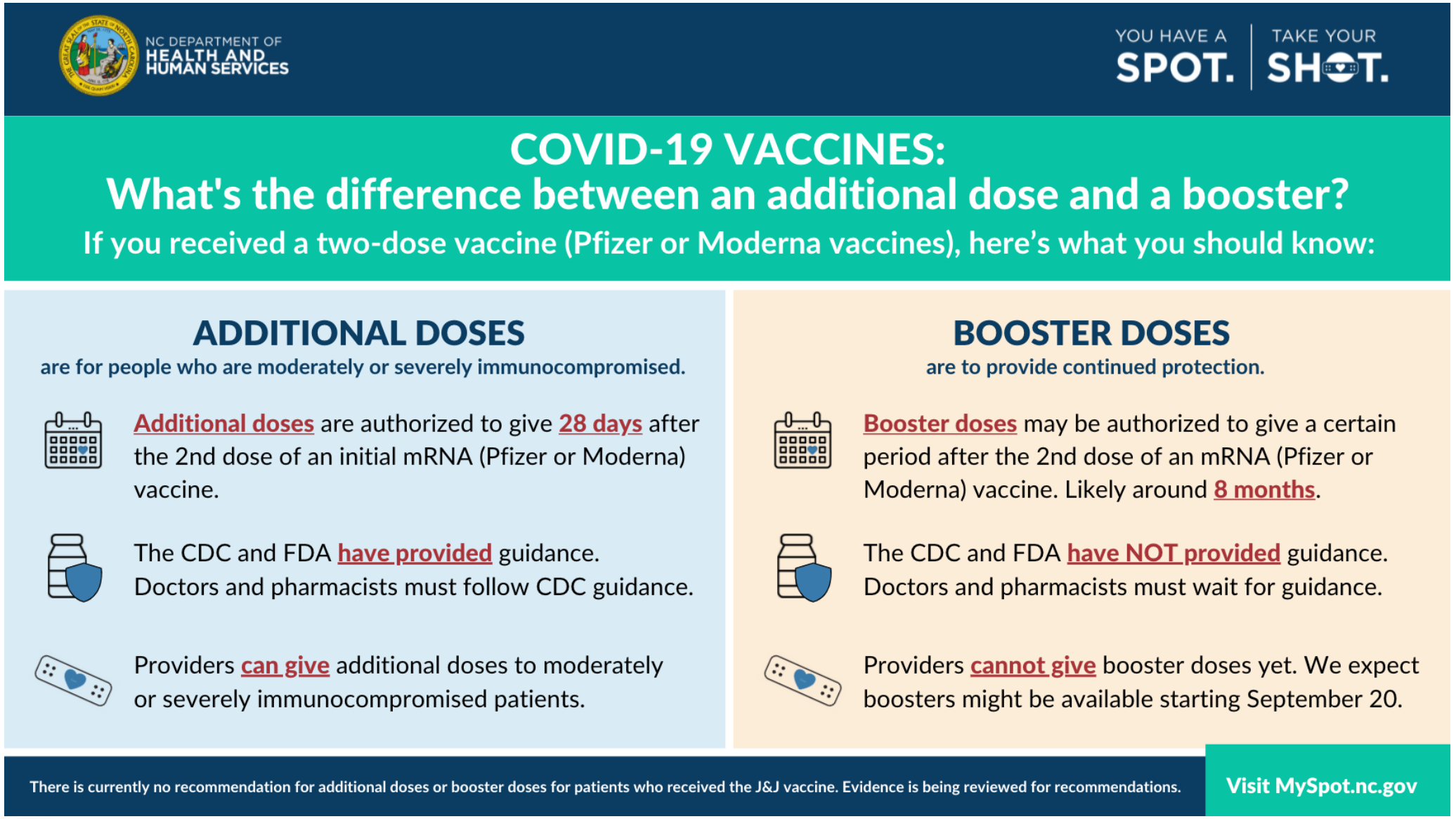
If you believe your vaccine request was denied in error, please review the ordering guidelines below and resubmit with sufficient justification for how you will administer all doses within 3 months of receipt.

VACCINE ORDERING GUIDELINES

	Pfizer	Moderna	Janssen
Minimum Order Quantity (MOQ)	**1170**	**140**	**100**
Maximum Order Request	If requesting > MOQ: Estimated administrations for **next 4 weeks** If requesting 1 MOQ: estimated administrations must be greater than or equal to the MOQ **for the next 3 months** (i.e. site must be able to exhaust all supply within 3 months)		
Direct Ship Available	✓	**Existing state Moderna supply exceeds forecasted demand.** *Will revisit opening ordering in mid September*	✗ *Expected to become available early September*
Recommended Request Method	**Allocation Request** *Providers who can store and admin MOQ* **Vaccine Hub** *Smaller Providers who cannot exhaust MOQ*	**Vaccine Hub** *All Providers* *NC DHHS is committed to ensuring that all hub sites have sufficient Moderna supply. If your hub does not have supply, please place an allocation request*	**Allocation Request** *Although ordering is closed for Janssen, we are collecting requests and hope to be able to fulfill when ordering reopens*

Additional Dose and Booster planning

BOOSTER COMMUNICATIONS: COMMUNICATING ADDITIONAL VS. BOOSTER



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covid19.ncdhhs.gov/covid-19-vaccine-additional-doses-and-boosters

ADDITIONAL DOSE: MODERATE TO SEVERE IMMUNOCOMPROMISE

These conditions and treatments include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR) T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV infection)
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

- Factors to consider in assessing the general level of immune competence in a patient include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.

- Patients can self-attest

- https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

ADDITIONAL DOSES/BOOSTER PLANNING

Additional Dose

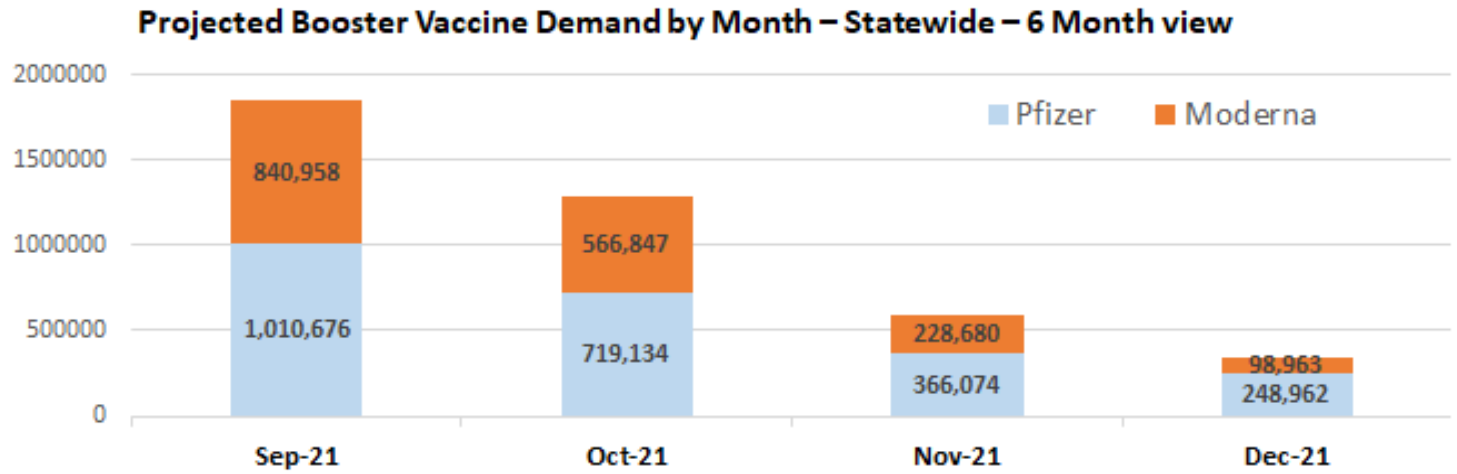
- The additional mRNA COVID-19 vaccine dose should be the same vaccine product as the initial 2-dose mRNA COVID-19 primary vaccine series (Pfizer-BioNTech or Moderna).
- If the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered.
- A person should not receive more than three mRNA COVID-19 vaccine doses.
- Same administration rate as first 2 doses

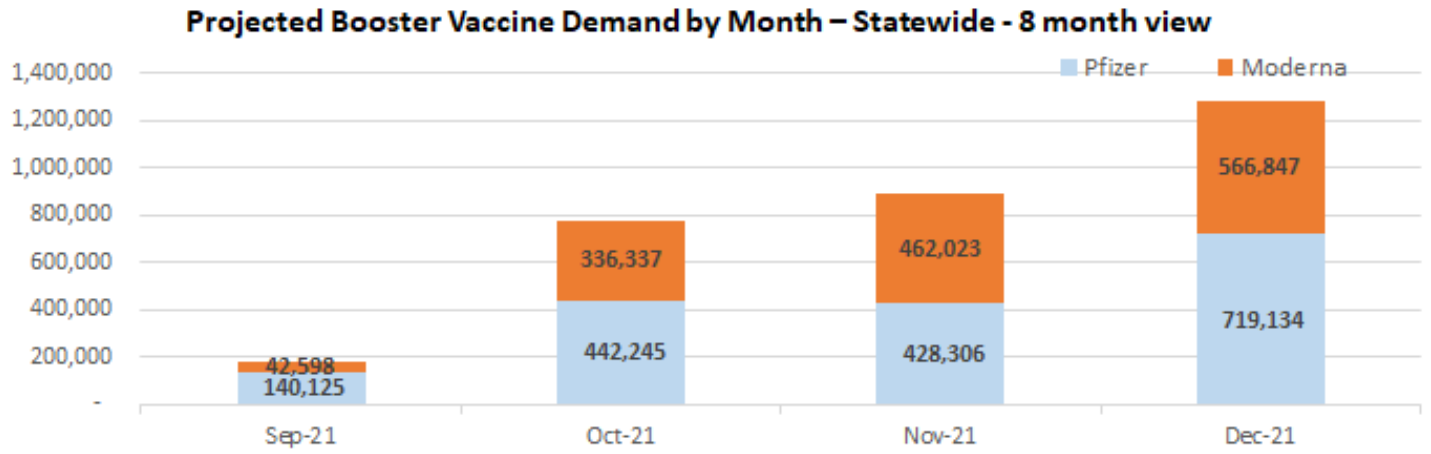
Booster doses

- Federal DHHS put out notice as a **Planning Assumption** – Booster doses may start around Sept 20th, 8 months after initial series. NC DHHS Planning now
- Awaiting **authorization, recommendation, guidance from FDA, CDC** on need for and timing – e.g., 6 or 8 months
- Many more providers than first time - more than 3,200 enrolled providers - and good supply
- May have some mass vax, but likely more points of entry.
- Staggered doses based on date of completing of first dose

ADDITIONAL DOSES/BOOSTER PLANNING

Booster doses





Key Assumptions:

- Booster shot time is calculated from vaccination date of the 2nd dose received
- This is based off historical administrations and does not factor in that vaccine is available at more places now.
- Assuming that the declining vaccine demand is offset by the upticks due to vaccine mandates and FDA approval. Thus, the projections for Dose 1 and 2 are assumed to be constant as they were for the month of August.

BOOSTER DOSES IN LONG TERM CARE

Ensuring Access to Booster Doses in LTC

With booster doses on the horizon, North Carolina long-term care residents and staff will be among some of the first individuals eligible based on the 6-8-month timeline. We are planning to activate **all willing and able providers** interesting in supporting LTC booster doses this fall.

1. Encourage long term care facilities to make plans now for booster administrations

2. Launch and sustain communications around booster doses as additional information becomes available

3. Identify NC vaccine providers willing and able to provide LTC booster vaccines

4. Monitor facility access and provider capacity for boosters in LTC settings

The Ask for Vaccine Providers: Complete our Survey if willing to provide vaccines in LTC, including your capacity and coverage areas

TREATMENT

Ivermectin Official Health Advisory
Monoclonal Antibodies

Ivermectin Official Health Advisory

This is an official CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
August 26, 2021, 11:40 AM ET

Rapid Increase in Ivermectin Prescriptions and Reports of Severe Illness Associated with Use of Products Containing Ivermectin to Prevent or Treat COVID-19

Summary

• Ivermectin is a U.S. Food and Drug Administration (FDA)-approved prescription medication used to treat certain infections caused by internal and external parasites. When used as prescribed for approved indications, it is generally safe and well tolerated.

• During the COVID-19 pandemic, ivermectin dispensing by retail pharmacies has increased, as has use of veterinary formulations available over the counter but not intended for human use. FDA has cautioned about the potential risks of use for prevention or treatment of COVID-19.

• Ivermectin is not authorized or approved by FDA for prevention or treatment of COVID-19. The National Institutes of Health's (NIH) COVID-19 Treatment Guidelines Panel has also determined that there are currently insufficient data to recommend ivermectin for treatment of COVID-19. ClinicalTrials.gov has listings of ongoing clinical trials that might provide more information about these hypothesized uses in the future.

• Adverse effects associated with ivermectin misuse and overdose are increasing, as shown by a rise in calls to poison control centers reporting overdoses and more people experiencing adverse effects.

Monoclonal Antibodies

MONOCLONAL ANTIBODIES

What we'll cover:

- Overview
- Who can get it and When?
  - EUA Age Range
- What is REGEN-COV?
- Subcutaneous Injection vs. IV Infusion
- How to order

MONOCLONAL ANTIBODIES: OVERVIEW

What are mAbs?

- Monoclonal antibodies, or mAbs, are antibodies made in a laboratory to fight a particular infection
  - REGEN-COV (casirivimab and imdevimab)
  - Sotrovimab
  - Bamlanivimab and etesevimab
    - The EUA for bamlanivimab administered alone was revoked in April 2021 due to its ineffectiveness against certain circulating variants of SARS-CoV-2, but in Aug 2021 reinstated only in states, territories, and U.S. jurisdictions in which recent data shows the combined frequency of variants resistant to bamlanivimab and etesevimab administered together is less than or equal to 5% - NC is NOT included in this.
- Given to patients directly with an infusion or a subcutaneous injection
- If taken early, they can reduce the risk of severe disease, hospitalization, and death
- Individuals are encouraged to talk to their healthcare provider to see if monoclonal antibody treatment is right for them

For more information:
http://covid19.ncdhhs.gov/about-covid-19/treatment

To find a testing center:
http://covid.infusioncenter.org/

Combat COVID Monoclonal Antibodies Call Center at
1-877-332-6585

WHO CAN GET IT, AND WHEN?

- The Food and Drug Administration (FDA) has issued **Emergency Use Authorization (EUA)** for the use of monoclonal antibody therapies for adult and pediatric patients **(12 years of age and older weighing at least 40 kg)** who:
  - have tested positive for COVID-19
  - have mild to moderate symptoms for 10 days or less, **and**
  - are at high risk of getting more serious symptoms

- Limitations of Authorized Use for Treatment:
  - who are hospitalized due to COVID-19, **OR**
  - who require oxygen therapy due to COVID-19, **OR**
  - who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity. Monoclonal antibodies, such as REGEN-COV, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation

WHO CAN GET IT, AND WHEN?

- The following medical conditions or other factors may place adults and pediatric patients (age 12-17 years and weighing at least 40 kg) at higher risk for progression to severe COVID-19:
  - Older age (for example age ≥65 years of age)
  - Obesity or being overweight (for example, adults with BMI >25 kg/m2, or if age 12-17, have BMI ≥85th percentile for their age and gender based on CDC growth charts
  - Pregnancy
  - Chronic kidney disease
  - Diabetes
  - Immunosuppressive disease or immunosuppressive treatment
  - Cardiovascular disease (including congenital heart disease) or hypertension
  - Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderateto-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
  - Sickle cell disease
  - Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
  - Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)

- **Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19, and authorization of REGEN-COV under the EUA is not limited to the medical conditions or factors listed above**

REGEN-COV: POST-EXPOSURE PROPHYLAXIS

- For use as post-exposure prophylaxis of COVID-19 in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death, and are:
  - not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (individuals with immunocompromising conditions and/or taking immunosuppressive medications) **and**
  - have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Centers for Disease Control and Prevention (CDC) **or**
  - who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing home or prisons)

- Limitations of Authorized Use for Post-Exposure Prophylaxis:
  - REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID19

SUBCUTANEOUS INJECTION VS. IV INFUSION

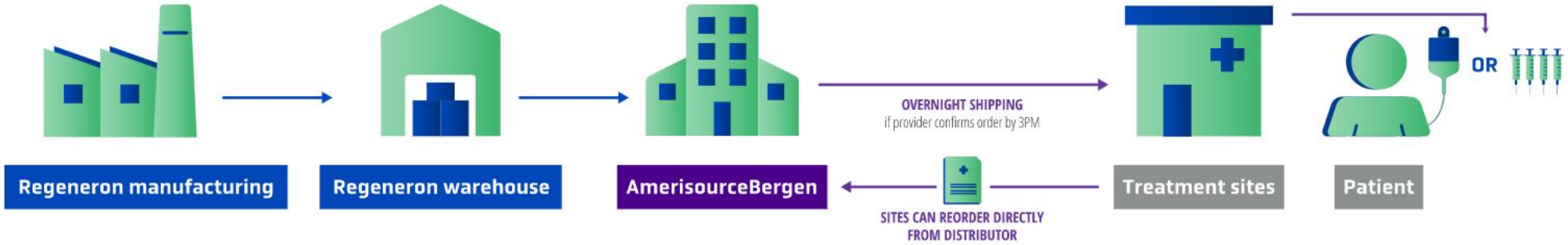
- The authorized dose for REGEN-COV for both treatment and as post-exposure prophylaxis is 600 mg of casirivimab and 600 mg of imdevimab administered together
- For treatment, IV infusion is recommended
- Subcutaneous injection (shots administered underneath the skin) is an alternative route of administration when IV infusion is not feasible and would lead to delay in treatment
- For post-exposure prophylaxis, either intravenous infusion or subcutaneous injection is appropriate
- Providers should clinically monitor patients for at least one hour following the infusion/ injection for reactions

Mixing and Dosing instructions: https://www.regencov.com/hcp/dosing/dosing-administration

Visit the Health Care Provider Fact Sheet for further provider guidance and information

HOW TO ORDER

- Healthcare facilities or providers may request quantities of REGEN-COV or bamlanivimab and etesevimab (BAM/ETE)* are via direct ordering through AmeriSource Bergen Company (ABC)
- ABC will distribute for the U.S. Government
- REGEN-COV and BAM/ETE are free of charge to requesting treatment sites, as the United States government is paying for the product
- Sotrovimab is not controlled by the federal government and is available at $2100 per dose



*Not currently authorized for use in NC due to variant circulation.

For more information, please visit:
https://www.regencov.com/hcp/access

OTHER HELPFUL LINKS ON BILLING, CODING, REIMBURSEMENT

- Summary Monoclonal Antibody Infographic
- Reimbursement, including the proper billing codes - Centers for Medicare & Medicaid Services Monoclonal Antibody Website.
- Current reimbursement rates can be found here.
- Information about COVID-19 Claims reimbursement to Health Care Providers for the uninsured Health Resources and Services Administration (HRSA) Website

MONOCLONAL ANTIBODIES: CURRENT STATE SNAPSHOT (DATA AS OF 8/24/21)

Administration

3,018 (62% ↑)
Courses Administered
(8/18-8/24)

163 (12 ↑)
Total Providers with mAbs
(8/18-8/24)

180
Total Hospitalizations prevented with mAbs
(8/18-8/24)
*Based on NNT of 16.7 from REGEN-COV clinical trial data

22,734
Total Courses Administered

Demographics

High level mAb Demographic data was collected from Medicaid covering Claims data from 11/1/2020 through 6/30/2021

46% (387/845)
Black/AA Administration Claims

50% (420/845)
White Administration Claims

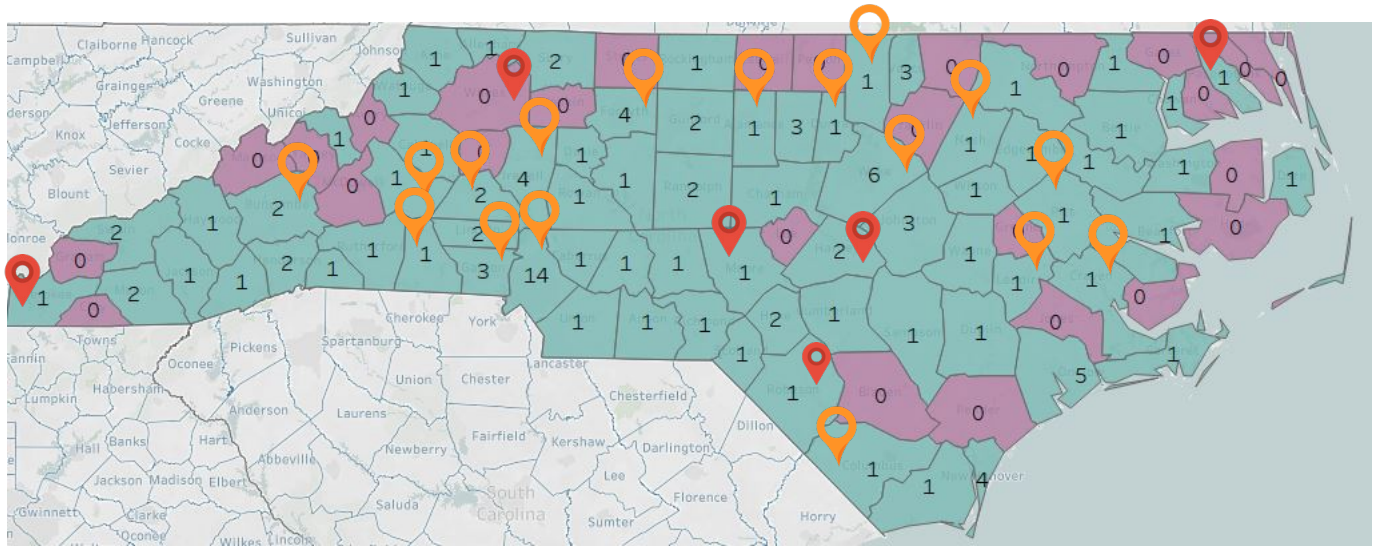
9% (77/845)
Hispanic Administration Claims

87% (737/845)
Non-Hispanic Administration Claims

41% (349/845)
21-44 Age Group

39% (327/845)
45-64 Age Group

Provider Coverage

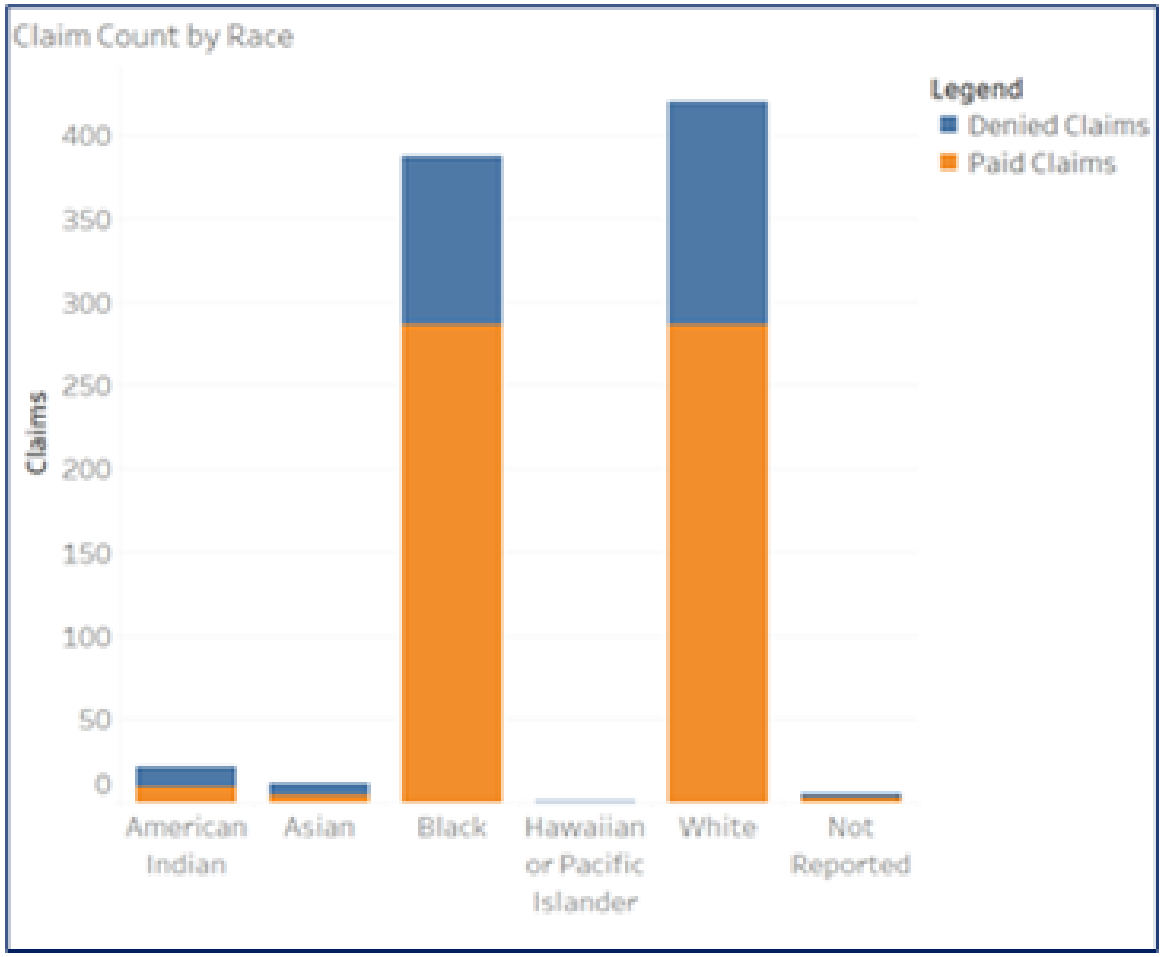


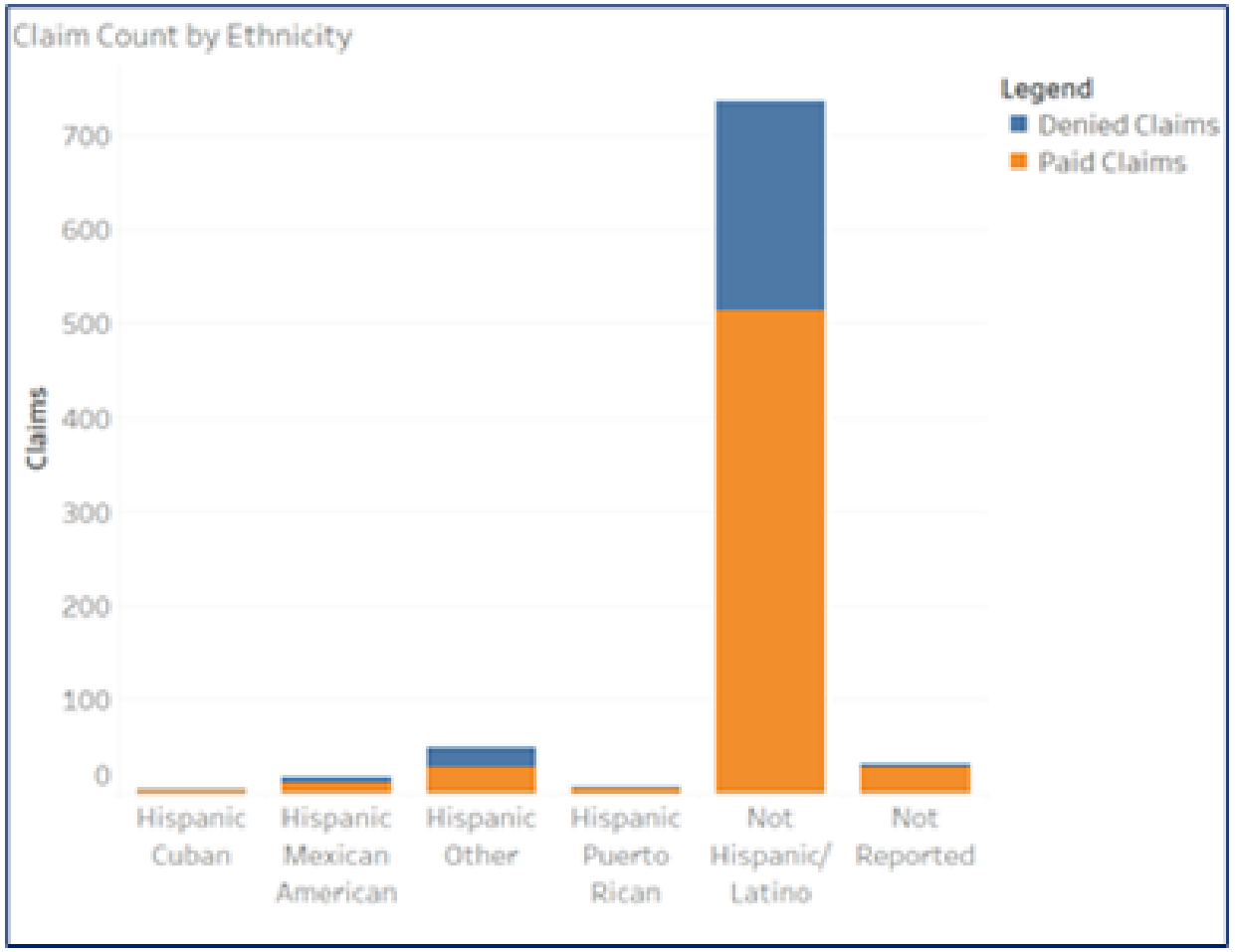
- **25 (↓4)** Counties do not currently have mAb Coverage
- In Counties with no 'Active' providers, the average first dose, 18+ vaccination rate is **46%**
- Of the 20 Prevention/Response Counties, Bladen, Perquimans, and Stokes county have no 'Active' providers

legend

# = Number of Open Providers in County
Purple = Counties w/ No Active Providers
Teal = Counties w/ Active Providers
= **6** counties where Federal Mobile Sites are being deployed (Cherokee, Wilkes, Harnett, Moore, Robeson, Pasquotank). These sites were chosen based on counties with low vaccination rates (<40%), high case rates, and strain on local hospitals
= **17** counties with Closed Providers (LTCs, DSOHF, Jails)

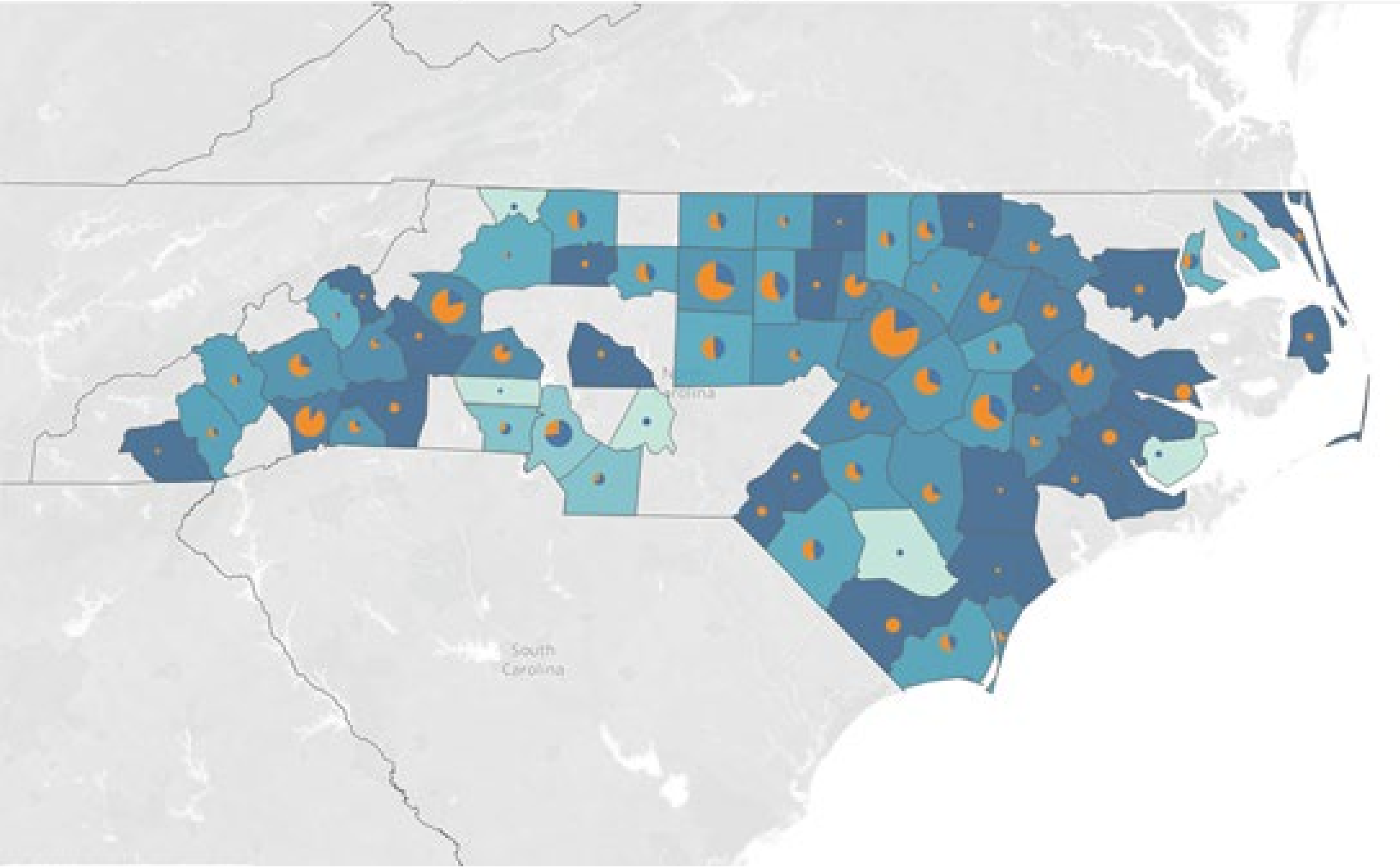
Consider targeted outreach to high risk, unvaccinated members and members from historically marginalized populations for awareness of MAB resources in their community and benefit in early diagnosis or as post exposure prophylaxis.





NC Medicaid MAB claims analysis 1/1/21-6/30/21 by race and ethnicity

Claim Approval Rate and Count by Residential County



Total Claims
1
20
40
60
80
100

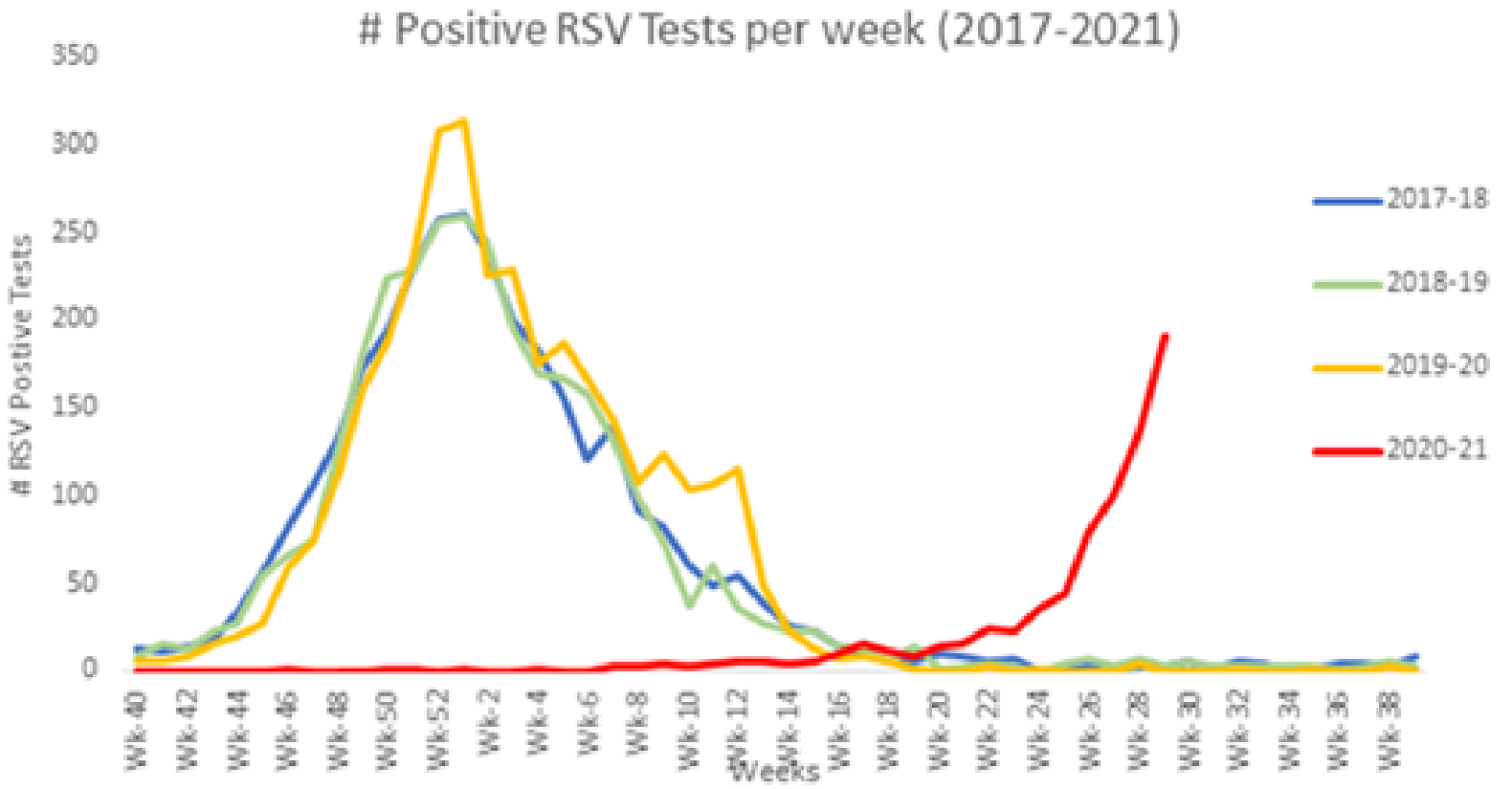
Legend
Denied Claims
Paid Claims

Approval %
0%
100%

RSV EARLY SEASON – REMOVE BARRIERS TO PALIVIZUMAB

North Carolina RSV Activity

DPH Epidemiology Graph



After consultation with NC DPH Epidemiology section, the Pediatric Infectious Disease specialists from all major hospitals, and consultation the Medicaid Managed Care CMOs, NC Medicaid declared on early season on 8/15/21 and will allow up to 8 doses as appropriate based on new Redbook Guidelines; NC Medicaid will consider this a "second season" for 2021.

USING MEDICAID LEVERS TO RESPOND TO SURGE

WHAT	WHEN	DETAILS	AFFECTS	IMPACT	COST	HOLDER
Hospital at Home Reimbursement for CMS Waived Hospitals	Sept 1-Dec 30	Condition Code DR Only CMS Waived hospitals *encourage all payers to follow	Hospitals	Opening Beds, Moderate	Neutral	Sandy Reggie
Medicaid/PHP Waive Prior Authorization for Post Acute Care	Sept 1-Sept 30	Bulletin *encourage all payers to follow	Hospitals LTAC SNF Home Health/Hospice	Opening Beds, Low	Neutral	Sandy Beverly
RSV Early Season Provision of Synagis *https://medicaid.ncdhhs.gov/blog/2021/08/11/procedures-prior-authorization-palivizumab-synagisr-respiratory-syncytial-virus-season-2021-2022*	Aug 15-Mar 30	Initiate Coverage Allow up to 8 doses *encourage all payers to follow	Ambulatory Providers	Preventing Admissions, Moderate	<1M State	Angela
Monoclonal Antibody Provision *https://medicaid.ncdhhs.gov/blog/2021/08/31/special-bulletin-covid-19-177-casirivimab-and-imdevimab-approved-emergency-use*	NOW	Allow coverage for FQHC/RHC	Ambulatory Providers	Preventing admissions, Moderate-High,	TBD Potentially State or CARES Fund for FQHC/RHC Coverage	Beth Reggie
Medicaid/PHP Out of Network Extensions *https://medicaid.ncdhhs.gov/blog/2021/08/19/extension-out-network-provisions*	July 1-Nov 30	All providers considered in network	Hospitals Ambulatory Providers	Reducing Administrative Burden, High Opening Beds, Low	Neutral	Cassandra
Medicaid/PHP In Network PA Extension *https://medicaid.ncdhhs.gov/blog/2021/08/27/network-provisions-extended-through-september*	Sept 1-Sept 30	Allows for delayed PA	Hospitals Ambulatory Providers	Reducing Administrative Burden, Moderate Opening Beds, Low	3M State	Cassandra
Swing Bed Provisions	Mar 2020-present	See 1135, K, and Disaster Waivers	Hospitals	Opening Beds, Moderate	Neutral	Sandy Reggie
Skilled Nursing Surge Facilities	September	Contracting with 4 facilities to create bed capacity; expanding.	Hospitals	Opening Beds, Moderate		Sabrena Reggie
COVID Vaccine Incentives	September	PHPs devote resources to incentivize members	All Providers	Decrease COVID Cases Overall	2.5M State	Julia Sarah
Public Health Emergency Provisions Remain, Including Payment Increases	Mar 2020-present	See 1135, K, and Disaster Waivers	All Providers	Broad Impact	TNTC	ALL

Testing

TESTING Q AND A

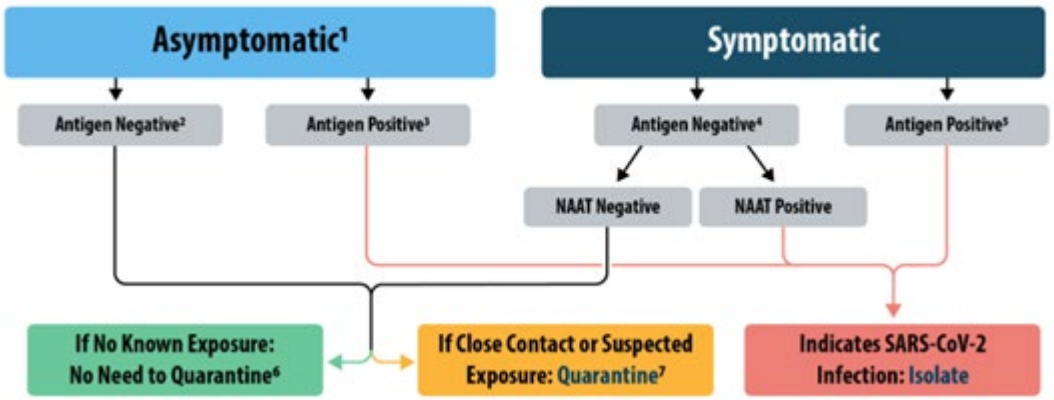
covid19.ncdhhs.gov/about-covid-19/testing/find-my-testing-place

- **I have heard that we are running low on testing reagents again. Is this true and what can the state do to prevent a major issue and delay again?**
- There are minor shortages reported for one manufacturer, Cepheid, but that is due to their shift from producing tests only for COVID to multiplexing for multiple respiratory pathogens. We have not heard of any other shortages in testing reagents other than antigen tests.

- **Any changes in reliability from different testing methods, particularly with Delta variant?**
- No. The FDA is working with manufacturers to routinely evaluate diagnostic test performance. All methods with current EUAs are effective at identifying all currently circulating variants

- **Is antigen testing okay, since we are in such a high state of community transmission? Is the reliability of Antigen testing better so that if negative with no symptoms, it is okay not to follow with a PCR test?**
- PCR is the most sensitive method, but they are both valid diagnostic tests and sites just need to follow the antigen flowchart (interpretation depends on symptoms and contacts)

Figure 2. Antigen Test Algorithm for Community Settings



TESTING Q AND A

covid19.ncdhhs.gov/about-covid-19/testing/find-my-testing-place

• **Can providers rely on home tests for back to school notices?** No. We are working on guidance for LHDs to address this and how to manage positive cases that are reported to them based on tests done without CLIA oversight.

• **Is there concern about availability of PPE? – especially if more testing and treatment going to occur in primary care**

• No concerns on PPE, we are well stocked. Providers can go to: https://covid19.ncdhhs.gov/information/health-care/requesting-ppe to request.

Do you have any

questions?

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

Appendix

VACCINE SAFETY IN ADOLESCENTS

- Among 8.9M US adolescents 12-17 vaccinated through July 16, 2021:
  - **VAERS** 9,246 reports received: 58.1% in ages 12-15 years; 41.9% in ages 16-17 years
    - **90.7% nonserious adverse events.** Common conditions were **dizziness** (20.1%), **syncope** (13.3%, 61% in females, median age 15, 16% transported to ED for evaluation), **headache** (11.1%)
    - **9.3% serious adverse events**. Common conditions were chest pain (56.4%), increased troponin level (41.7%), myocarditis (40.3%), increased CRP (30.6%) → all consistent with **myocarditis diagnosis**
  - **V-safe** 129,000 adolescents enrolled: 63.4% local reactions, 48.9% systemic reactions (more after dose 2)
    - Most common: injection site pain, fatigue, headache, and myalgia
    - In week after dose 2: ~1/3 reported fever, ~1/4 unable to perform normal daily activities

www.cdc.gov/mmwr/volumes/70/wr/mm7031e1.htm?s_cid=mm7031e1_w