

A close-up photograph of a healthcare professional, likely a doctor or nurse, wearing a white lab coat and blue nitrile gloves. The person is holding a clear plastic syringe with a needle attached. A stethoscope is visible around the neck of the person in the lab coat. The background is a soft, out-of-focus light color. Two vertical blue bars are positioned on either side of the text.

All LHD Call

August 9th, 2022

Opening Remarks & Leadership Update

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Question & Answer Session	Open for Questions – Please use the Zoom Q&A function

Epi Picture

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SLPH

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QUESTIONS?
Please use the Zoom Q&A function

Treatment

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Monkeypox 2022: MCM Update

COVID-19 Therapeutics

COVID-19 THERAPEUTICS UPDATE

Bebtelovimab Commercialization

- Beginning 8/15 – available for purchase through AmerisourceBergen (ABC)
- WAC \$2,100 per dose
- CMS guidance on reimbursement rates coming soon
- State allocation of free product expected to continue through week of August 22nd.
 - Full allocation on 8/15
 - Reduced allocation on 8/22
- Ordering limits for commercial product expected, exact details still TBD
- Existing ABC customers have instant access
 - New customers would be required to set up an ABC account to order bebtelovimab commercially.

Paxlovid, Molnupiravir & Evusheld

- Remain available through existing state allocation process
- No supply issues

General Reminders:

- Paxlovid and Veklury (remdesivir) remain first line choices as per NIH guidelines
- Paxlovid, Bebtelovimab and Evusheld authorized for ages 12+
- Veklury (remdesivir) approved/authorized for ages 28 days and older weighing at least 3kg
- Molnupiravir is authorized for ages 18+

Monkeypox Therapeutics

HOW TO OBTAIN ACCESS TO MONKEYPOX TREATMENT

- Providers wishing to treat monkeypox patients can request therapeutics using: [NC DHHS Monkeypox MCM Request Form](#)

CDC Recently Revised TPOXX EA-IND Protocol

- Streamlined to make treatment easier, reduce patient visits, and required forms
- All visits can be conducted via **telemedicine**
- All **laboratory testing is optional**
- Required adverse event reporting on **serious adverse events only**
- **No pre-registration is required** to begin providing tecovirimat treatment
- Forms required for EA-IND can all be returned to CDC after treatment begins

Required As part of EA-IND Process:

- Obtain informed consent **prior** to treatment
- Conduct a baseline assessment and complete patient intake form
- Document progress once during and once after treatment on the Clinical Outcome Form
- Report life-threatening or serious adverse events with tecovirimat by completing a PDF MedWatch Form and returning to CDC
- Complete FDA Form 1572: **One signed per facility**

For more information: <https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html>



Monkey Pox Vaccine Update

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NC VACCINE RESPONSE – VAX ADMIN DATA

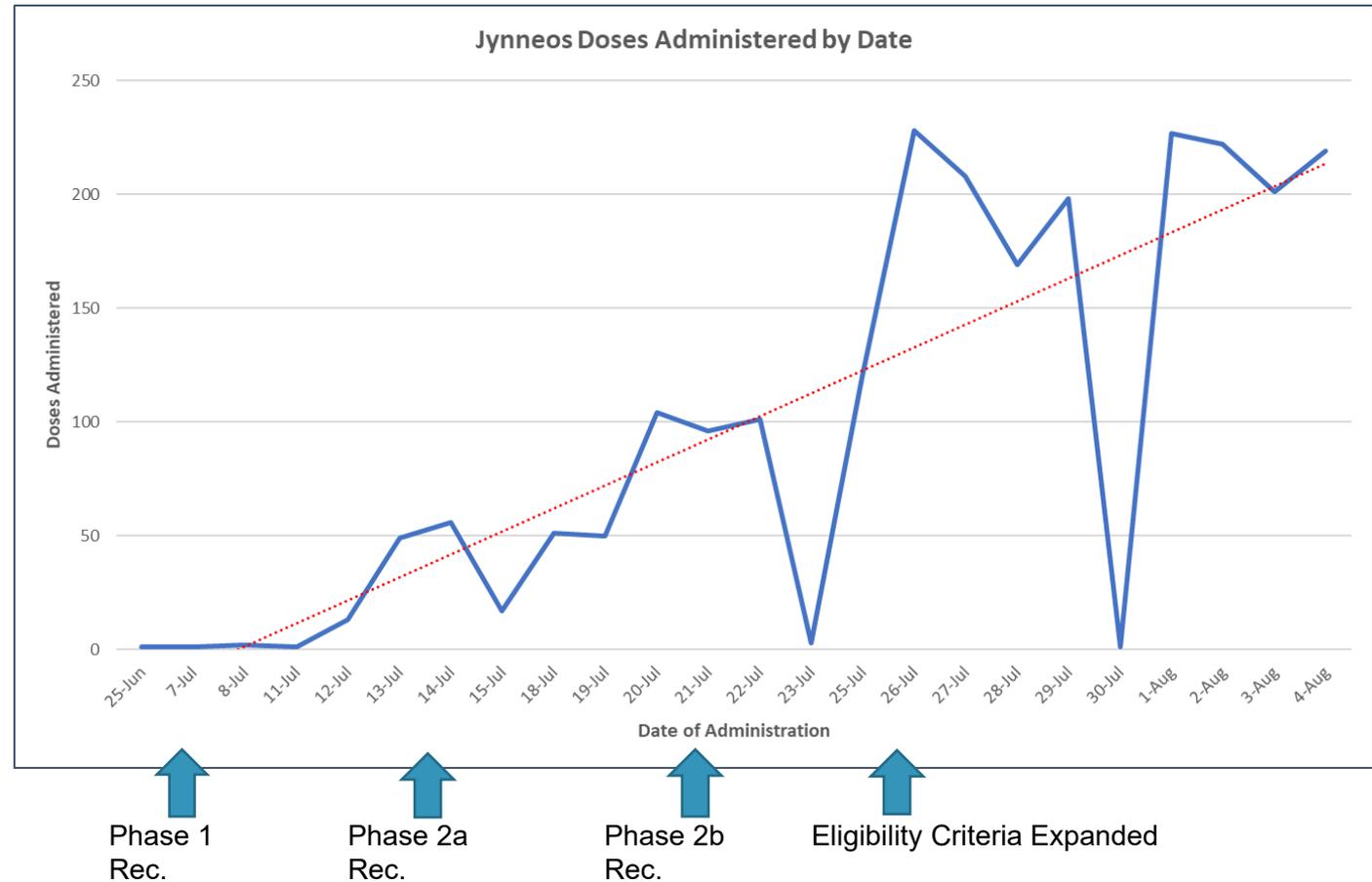
Administration Summary

Total New Administrations (between Fri. 8/5 3pm and Monday 8/8 3pm)	529
Total Administrations:	3055
Total Allocation:	10,148
Current Utilization	30.1%
Total Providers Vaccinating:	32
Counties with Administrations:	20

Topline Updates

- **Vaccination Pace accelerating**
- **90% utilization by Sept 11 at current pace**
- Monitoring utilization
- Prioritizing first doses
- Additional 4,152 doses expected next week

Data as of 08/04, 4:00 PM



NC VACCINE RESPONSE – DEMOGRAPHIC DATA

Race	Count of Clients	Percentage:
American Indian or Alaska Native	15	0.5%
Asian	85	2.8%
Black or African-American	719	23.6%
Native Hawaiian or Other Pacific Islander	3	0.1%
Other Race	107	3.5%
Prefer not to answer	80	2.6%
White	2039	66.9%
Total:	3048	

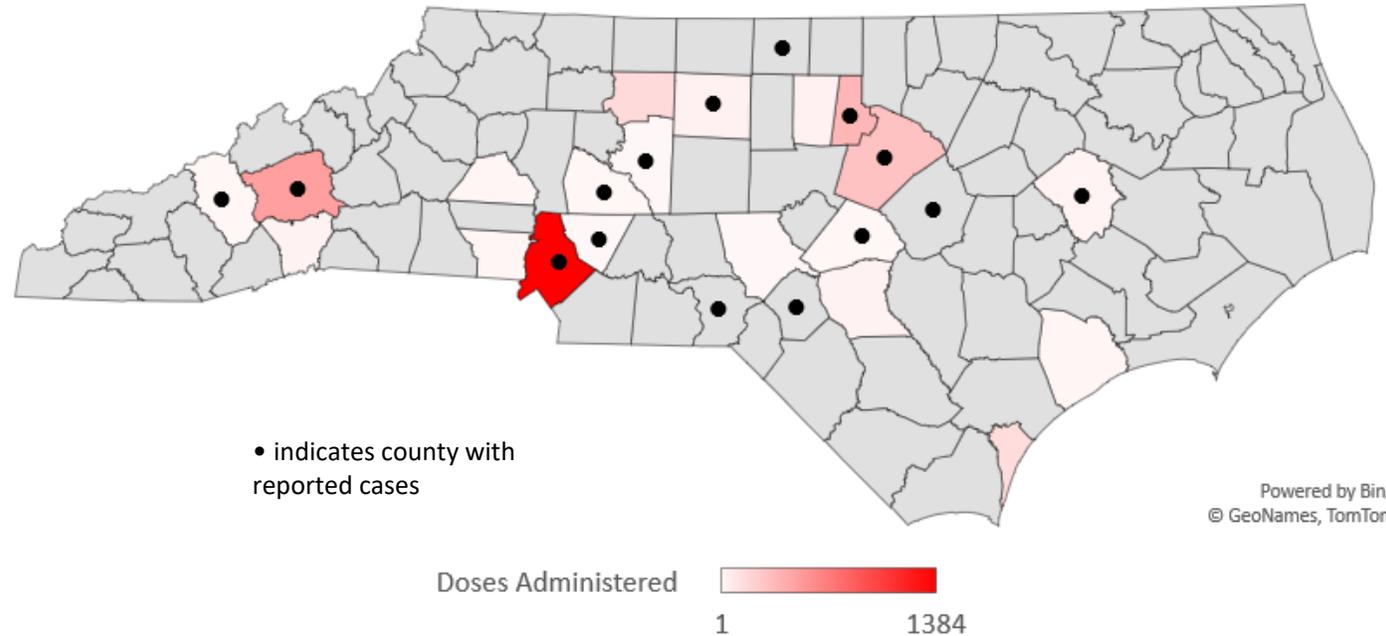
Ethnicity	Count of Clients	Percentage:
Hispanic or Latino	228	7.5%
Not Hispanic or Latino	2721	89.3%
Prefer not to answer	99	3.2%
Total:	3048	

Data based on clients immunized not doses administered
 Data as of 08/08, 3:00 PM

Key Takeaways:

- 74% of cases are in Black men, but they are receiving less than 25% of vaccinations and almost all 100% MSM
- White men account for only 20% of cases but have received 67% of vaccine doses.

Jynneos Doses Administered



Vaccine Eligibility Criteria

- Those who have come in close contact with someone who has been diagnosed with Monkeypox in the last 2 weeks
- Gay or bisexual men or transgender individuals who report any of the following in the last 90 days:
 - Having multiple sex partners or anonymous sex
 - Being diagnosed with a sexually transmitted infection
 - Receiving medications to prevent HIV infection (PrEP)

NCDHHS ACTIONS TO INCREASE ADMINISTRATION

NCDHHS Priorities

- Rapid distribution to impacted populations and geographic areas
- 90% utilization of on hand inventory to unlock remaining doses
- Increased uptake in B/AA MSM
- Outreach and communications
- LHD support

Allocations/Distribution

- Planning for Phase 3, wave 2 allocation of 4,152 doses (30% of total) – delivery likely week of 8/15
- Allocation methodology will be shared when complete
- 5 direct ship locations (regional hubs), vaccine requests to regional hubs for local transfers with State assistance as needed
- Monitoring utilization and transfers to identify opportunities for strategic adjustments (e.g. moving doses to locations with higher demand)

Communication

- Outreach to priority partners and providers (e.g. HIV networks)
- Distribution of approved provider list to LHDs for vaccine transfer and outreach
- Vaccine guidance as the situation evolves (e.g. SO template, Intradermal Jynneos)
- Public facing vaccine data

SUCCESSFUL STRATEGIES IN CURRENT LHD OPERATIONS

Operations

- Applying COVID lesson learned
 - Walk in clinics
 - Vaccinate at trusted partner events
 - Vaccinate in STI, HIV PrEP clinics, and outside Immuniz. Clinic (e.g. conference room)
 - Temporary staffing for vaccine operations

Outreach/Equity

- Collaboration with Equity teams on communications, outreach, partnering with priority health service providers and partners in target areas (HIV, STI, PrEP, LGBTQ)
- Social media and advertising to reach at risk population

Current Challenges

- Limited staff
- Funding sources
- Hospitals and FQHC participation
- Providers referring individuals back to the LHD
- Emergency response fatigue

COVID-19 Vaccine Update

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**THEIR
FUTURE
STARTS
NOW.**

#IVAX2PROTECT



**PROTECT
YOUR
GOLDEN
YEARS**

#IVAX2PROTECT

- Be a champion for ALL vaccines! Use these tools to share a consistent message with patients about the importance of vaccines for their health at all ages.
- Access [the Monthly NIAM resources here!](#)



National

**National
Immunization
Awareness
Month**



WEEK 1

Resources of the Week!

● **Recommended
Immunizations for
Children from Birth
Through 6 Years Old**

● **Child and Adolescent**

This week, we're sharing to

**National
Immunization
Awareness
Month**



WEEK 5

This week, we're focusing on older adults. Here's the top immunization resources to use in immunization conversations!



CDC Recommended

The Adult Vaccine

Vaccination Resources

AUTHORIZED COVID-19 VACCINE PRODUCTS IN THE US

COVID-19 vaccine products currently approved or authorized in the United States

Pfizer-BioNTech							
Age indication	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster doses	
				Dose	Injection volume	Dose	Injection volume
6 months–4 years	Maroon	Maroon	Yes	3 µg	0.2 mL	NA	NA
5–11 years	Orange	Orange	Yes	10 µg	0.2 mL	10 µg	0.2 mL
12 years and older	Purple	Purple	Yes	30 µg	0.3 mL	30 µg	0.3 mL
12 years and older	Gray	Gray	No	30 µg	0.3 mL	30 µg	0.3 mL
Moderna							
Age indication	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster doses	
				Dose	Injection volume	Dose	Injection volume
6 months–5 years	Dark blue	Magenta	No	25 µg	0.25 mL	NA	NA
6-11 years	Dark blue	Purple	No	50 µg	0.5 mL	NA	NA
12–17 years	Red	Light blue	No	100 µg	0.5 mL	NA	NA
18 years and older	Red	Light blue	No	100 µg	0.5 mL	50 µg	0.25 mL
18 years and older	Dark blue	Purple	No	NA	NA	50 µg	0.5 mL
Janssen							
Age indication	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster doses	
				Dose	Injection volume	Dose	Injection volume
18 years and older	Blue	No Color	No	5×10 ¹⁰ viral particles	0.5 mL	5×10 ¹⁰ viral particles	0.5 mL
Novavax							
Age indication	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster doses	
				Dose	Injection volume	Dose	Injection volume
18 years and older	Royal blue	No Color	No	5 µg rS and 50 µg of Matrix-M™ adjuvant	0.5 mL	N/A	N/A

Find out when you can get boosters using the tool [here](#)

Check the CDC ["At-A-Glance" schedule](#)

SPIKEVAX ORDERING

- The FDA-approved Moderna COVID-19 vaccine, Spikevax™, is now available for ordering and administration in individuals 18 years and older.
 - **No change has been made to the vaccine's formula.**
 - [Spikevax™](#) is FDA approved and is now licensed through the BLA process.
 - Spikevax and the FDA-authorized Moderna product have different NDCs and labels.
- Moderna COVID-19 vaccines authorized for use in children and adolescents ages 6 months to 17 years remains unchanged at this time.



NOVAVAX PRODUCT INFORMATION

Vaccine Details

General

- **2 dose primary series, NOT** authorized as a booster, or a 3rd primary series dose for immunocompromised individuals
- 5 mcg SARS-CoV-2rS 50 mcg Matrix-M™ adjuvant, injection volume: 0.5 mL, IM deltoid

Storage and Handling

- Store in standard refrigerators at 36°F to 46°F
- Use within **6 hours** after first puncture

Dosing and administration

- **Non-immunocompromised:** 3 to 8-week interval between doses
- **Immunocompromised:** 3 week interval between doses



Novavax Label²



NOVAVAX DISTRIBUTION SUMMARY

25.5k doses for
12.8k individuals

Strategically placed vaccines across the state but demand is low

State Allocation Summary

116 Total Orders Requested

16,900 Total Doses Ordered

Federal Allocation Summary

27 Total Orders Requested

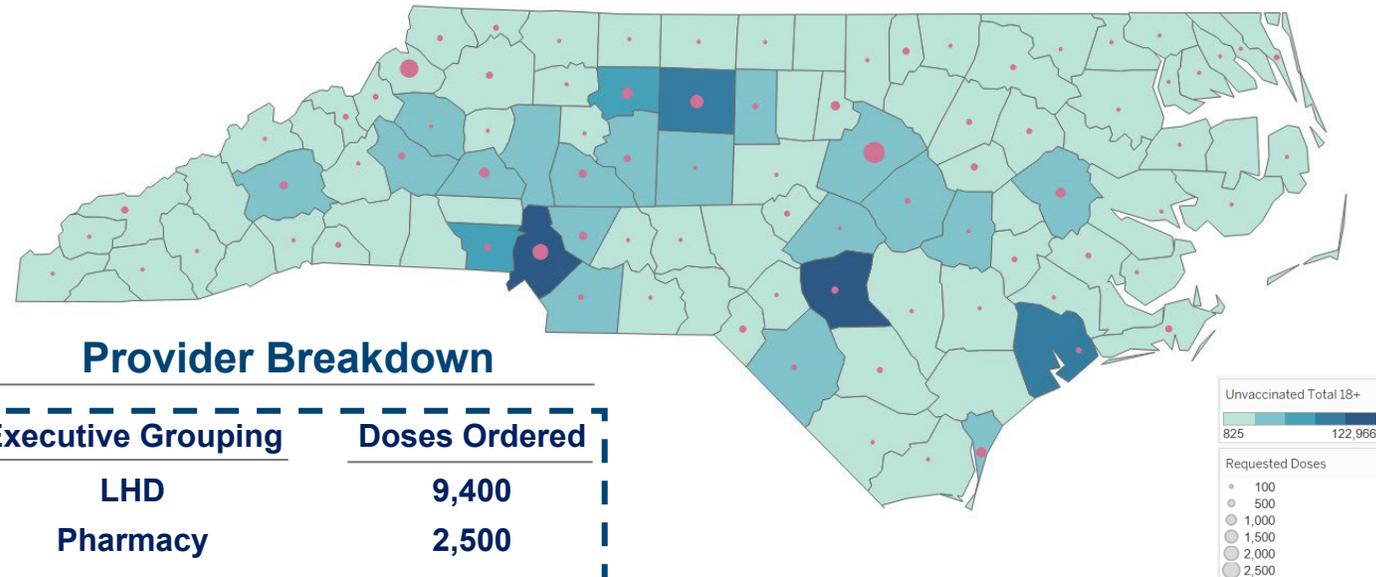
5,000 Total Doses Ordered

Coverage Summary

83 Total Counties Covered

21,900 Total Doses Ordered

Novavax Coverage Map by County



Provider Breakdown

Executive Grouping	Doses Ordered
LHD	9,400
Pharmacy	2,500
Hospital	2,200
PCP	1,200
Other	1,200
FQHC/RHC	400
Federal Allocation*	5,000

55 doses of Novavax administered across 3 counties*



*Includes Pharmacies, FQHC/RHCs, and VA Medical Centers

*Wake, Gaston, and New Hanover

FALL BOOSTER CONSIDERATIONS AND CONSTRAINTS



What we know

- The FDA recommended (6/30) inclusion of an Omicron BA.4/5 component for COVID-19 vaccine booster doses
- Vaccine manufacturers have already reported data from adult clinical trials with bivalent and monovalent formulations.
- HHS has contracted for doses of specific multi-variant fall boosters from both Moderna (66M) and Pfizer (105M)



What we don't know

- Timeline for fall booster availability still TBD, potential for September according to press
- Unclear if other doses will be contracted outside of Moderna and Pfizer
- Eligibility of boosters is unknown at this time (e.g., 18+, 50+, etc)
- Administration schedule (time between other boosters/primary series and fall booster) unclear

MAKE THE SWITCH: TRANSITION FROM CVMS TO NCIR

- We encourage **all providers** to begin the transition from CVMS to NCIR.
- **Switching systems before the start of flu season cuts your workload in half!** You'll only have to document administrations in one system and not two.
- DHHS is here to support you when you transition! You can [submit a ticket](#) or call the NC Vaccines Help Desk at 1-877-873-6247.



[Access the CVMS to NCIR Roadmap Here](#)

CI/CT

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Using CCTC Staff to Support Response to Other Diseases

We are excited to be able to share that you will now be able to use CCTC Staff to support work for other diseases during times when these staff are not needed for their COVID responsibilities.

Based on the requirements of the funding, we can only support these requests if the following criteria are attested to by the LHD:

1. The staffs' primary responsibility remains within the COVID response
2. The COVID response has affected the LHD's ability or reduced your capacity to do the non-COVID work

Examples of non-COVID support that you can request:

-  • Data Entry
-  • Contact Tracing
-  • Call Center Support
-  • Vaccine and Testing (Clinical Staff Only)
-  • Other administrative duties

Please note that most non-clinical CCTC staff are remote. To make the most of this opportunity, we recommend prioritizing duties that can be performed remotely and that can be done by CCTC staff as their time allows.

We are not planning to staff up to meet requests for non-COVID work, nor to newly hire nor backfill on-site positions to meet non-COVID work needs.

You are responsible for training these staff for the non-COVID work.

Using CCTC Staff to Support Other Diseases

Process and Timeline for Requesting Staff:

Today (8/9/22)



CCTC ready to begin discussions. Please reach out to your CCTC Regional or Clinical Supervisor if you are interested in using your current CCTC staff for non-COVID work and they will direct you to the necessary documents for making the request. Note that you will be required to submit a signed PDF attesting that your request meets the two criteria mentioned on the previous slide.

Tomorrow (8/10/22)



Submitted requests and completed attestation forms will begin to be reviewed. Formal meetings with LHDs and CCTC on authorized reallocation of staff can start after review.

Next Week (8/15/22)



CCTC leadership will orient designated staff to expanded scope of work based on the conversations between LHDs and CCTC. CCTC staff cannot start in these expanded roles until the LHD attestation and deployment process is complete. Certain tasks (for example Data Entry in NC EDSS) may need additional time in order to provide training and access.

Reminder of CCTC Supports Available



Outreach to Priority Group 3:

CCTC staff are available to support outreach case patients whose CCTO record indicates that their [automated case notification text](#) was not delivered (priority group #3 in the recommended [state prioritization guidance](#)).

- This is especially relevant if your LHD is not currently utilizing CCTO as that is the only place to see the text delivery status.
- You do not need to be currently working with CCTC to request this service

Interested in using CCTC for outreach to cases without a delivered text? Reach out to your CCTC Regional Director or myself at Laura.Farrell@dhhs.nc.gov.



Letter Writing Queue:

The Letter Writing Queue provides isolation and quarantine letters to case patients and contacts to counties that have opted in

- Actively assists 41 county health departments and 2 school districts with their end of isolation and end of quarantine letter needs.
- Letters are written on NC DHHS letterhead based on a standard template and sent by encrypted email from NCDHHS.nc.gov emails.
- Letters processed/sent within 24-48hrs of request

Interested in using the Letter Queue for your county? Reach out to Nicole Matyas, CCTC Program Manager for the Data Entry Project and Call Center at nmatyas@carolinactc.org or via phone at 484-477-2576.

Considerations for Schools Starting



Changes in CCTC Staff

- Have staff that were working with schools last year been reduced?
- Do you have the capacity to support your schools in the same way you did last year?
- If not, has this been communicated with the school?



Schools Guidance Update

- StrongSchools Toolkit has been removed, however NC's guidance for contact notification has been retained
- Refer to the [CDC's Operational Guidance](#) for K12 Schools for information on how to lower risk of COVID-19 in school settings.
- More information on the changes can be found [here](#) and all other school guidance resources can be found at the [NC DHHS Guidance Webpage](#).



At-Home Testing Program Launch

- With more school testing taking place through at home tests, there will likely be a decrease in the number of tests reported for school aged children
- Some school districts are moving entirely to at home testing; it may be helpful to discuss this topic with your school district(s)

SlowCOVIDNC Being Retired

Utilization of app has been low: The value of the app does not match the investment required to maintain it.

- 11% of NC residents have downloaded the app
- 0.06% of people with covid submitted their positive result in the app (1,879 people)

Plan

- Provide retirement statement in app store ASAP, then proceed with full app wind-down plan
- No press release; reactive statement prepared if needed.
- We will provide information on SlowCOVIDNC web page and other relevant web pages
- Continue to evaluate options for the best tools for the response in future

Timeline

- This week/early next week:
 - Retirement Statement placed in the app (seen by those who download or upgrade app)
 - Relevant websites updated with information on retiring app
 - Pin processes discontinued
- 4-6 Weeks from now:
 - All aspects of app decommissioned
 - App is removed from app stores

Q&A

