

Kentucky COVID-19 Healthcare - Public Health Update #18

Kentucky Department for Public Health
Statewide Webinar for Clinicians and Public Health
Date: September 7, 2021



Kentucky Public Health
Prevent. Promote. Protect.

AGENDA

Dr. Doug Thoroughman
CDC Career Epidemiology Field Officer

Dr. Kathleen Winter
State Epidemiologist
Director, Division of Epidemiology and Health Planning

Dr. Alyson Cavanaugh
CDC Epidemic Intelligence Officer

Dr. Emily Messerli
Immunization Branch Manager

Andrea Flinchum
Manager, HAI/AR Prevention Program

Kenneth Kik
Healthcare Preparedness Program Manager
Preparedness Branch

Welcome and Introductions

Background/Current Situation

Breakthrough Cases Update

Variant Surveillance

Monoclonal Antibody Update

Disease Control Guidance Updates

FDA Approval, 3rd Doses, and Off-label use of Vaccines

RSV Update

COVID-19 Vaccines in Kentucky

Long-term Care COVID-19 Update

Q & A

Situation Update

Doug Thoroughman, PhD, MS



Kentucky Public Health
Prevent. Promote. Protect.



WORLD³

WHO declared pandemic on March 11, 2020

218,946,836

Cases (↑2,643,460 in past 5 days)

4,539,723

Deaths (↑41,272 in past 5 days)

2.1%

Mortality Rate

215 countries

with at least one case

UNITED STATES^{2*}

Risk to Americans is widespread

39,488,866

Cases (↑636,284 in past 5 days)

641,725

Deaths (↑5,710 in past 5 days)

1.6%

Mortality Rate

59 states + territories

with at least one case

KENTUCKY¹

State of Emergency declared March 6, 2020

592,489

Cases (↑19,972 in past 5 days)

7,845

Deaths (↑104 in past 5 days)

1.3%

Mortality Rate

120 counties

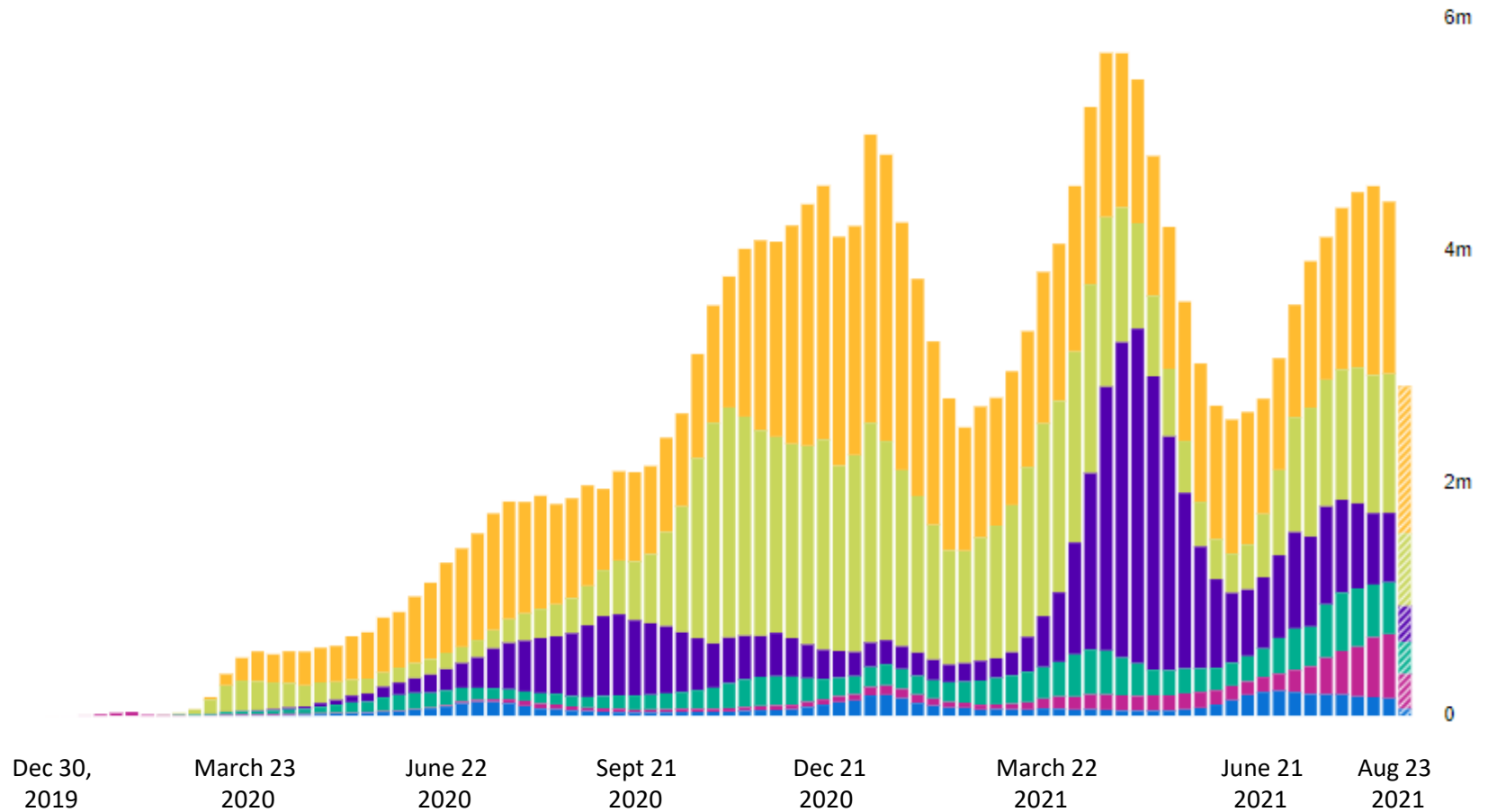
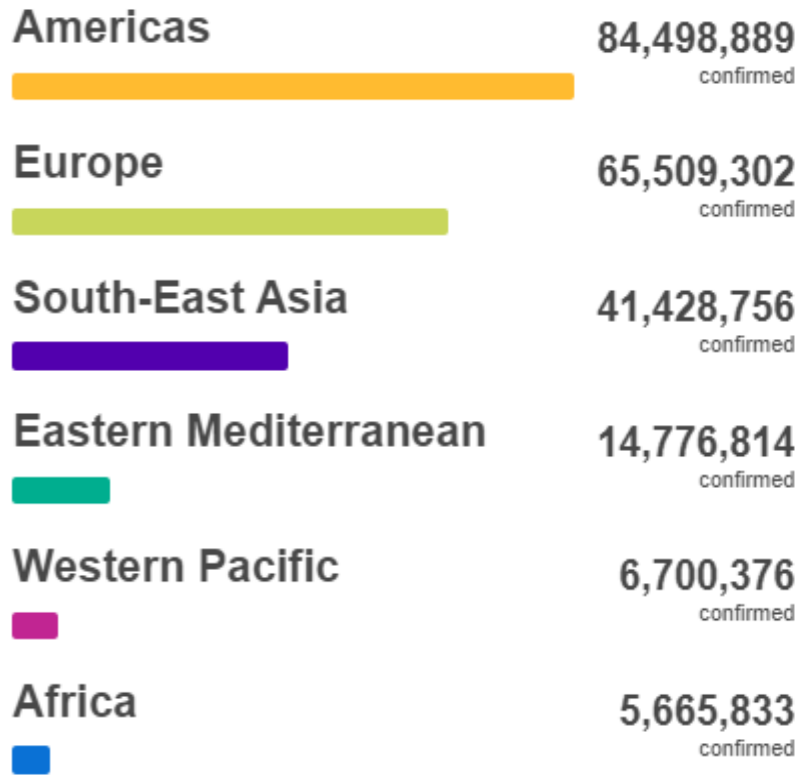
with at least one case

¹Kentucky Department for Public Health

²The Centers for Disease Control and Prevention <https://www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html>

³The World Health Organization <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports/>

COVID-19 Worldwide Case Counts by WHO Regions



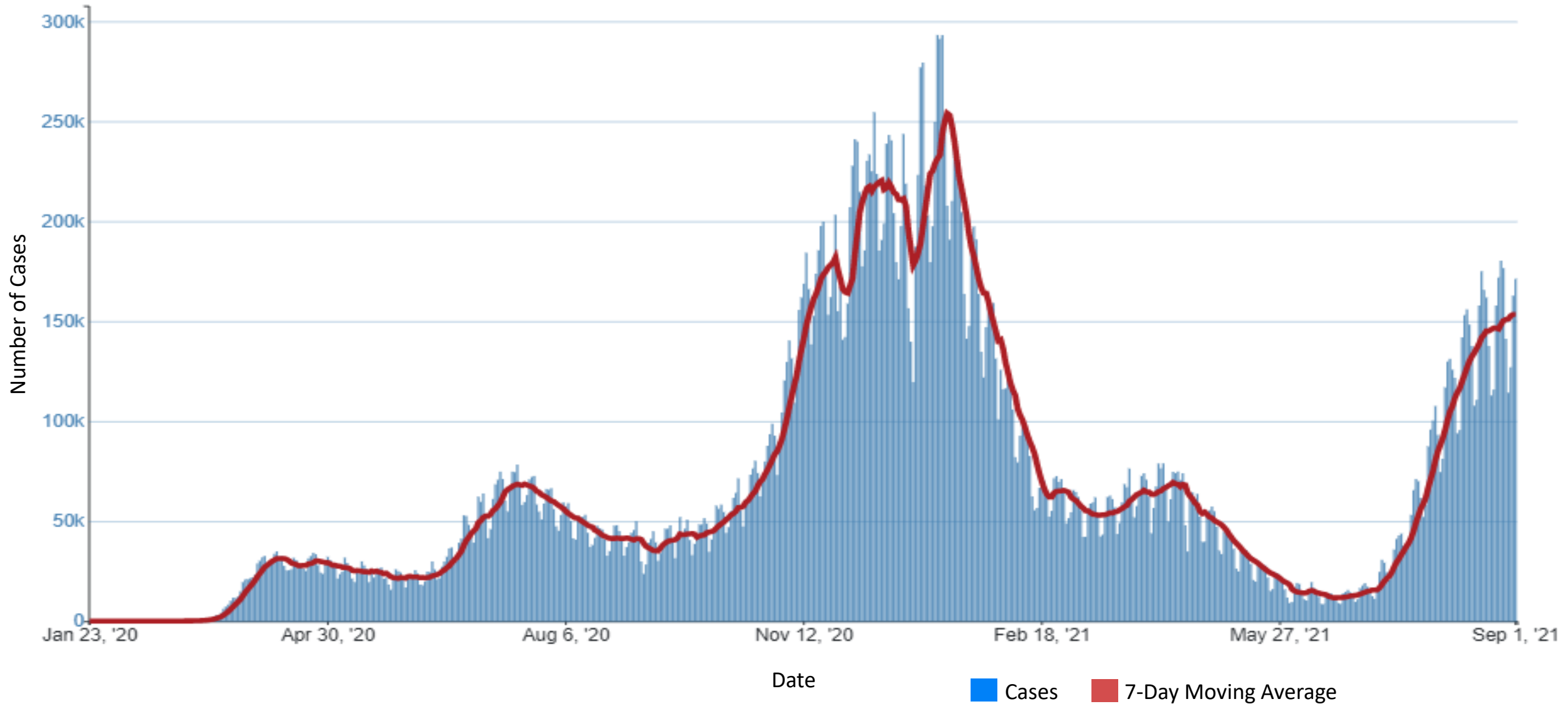
Source: World Health Organization

▨ Data may be incomplete for the current day or week.

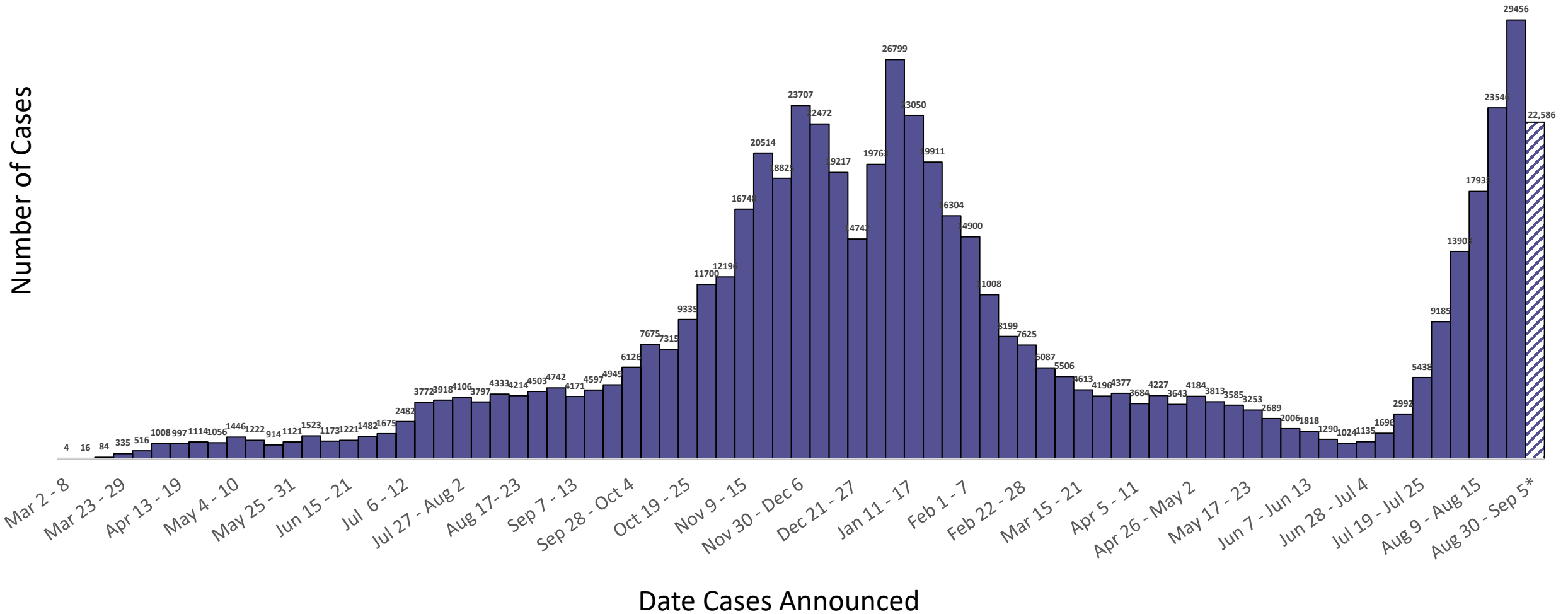
Interpretation: The COVID-19 pandemic began in Wuhan, China, but quickly spread to other countries and then worldwide, surging across continents at different points. First Europe, then the Americas, then SE Asia, reaching a first peak at the end of 2020/start of 2021. After a sharp, post-New Year's decline, rates surged again, particularly in SE Asia, including India, but fell sharply a second time, only to go on a more aggressive rise as the Delta variant spread from India to other countries around the world.

<https://covid19.who.int/>

COVID-19 United States Case Counts, by Date Reported



COVID-19 Kentucky Case Counts by Week (n = 592,489)



7-Day Average Daily Incidence Rate By County – 9/3 vs. 8/3



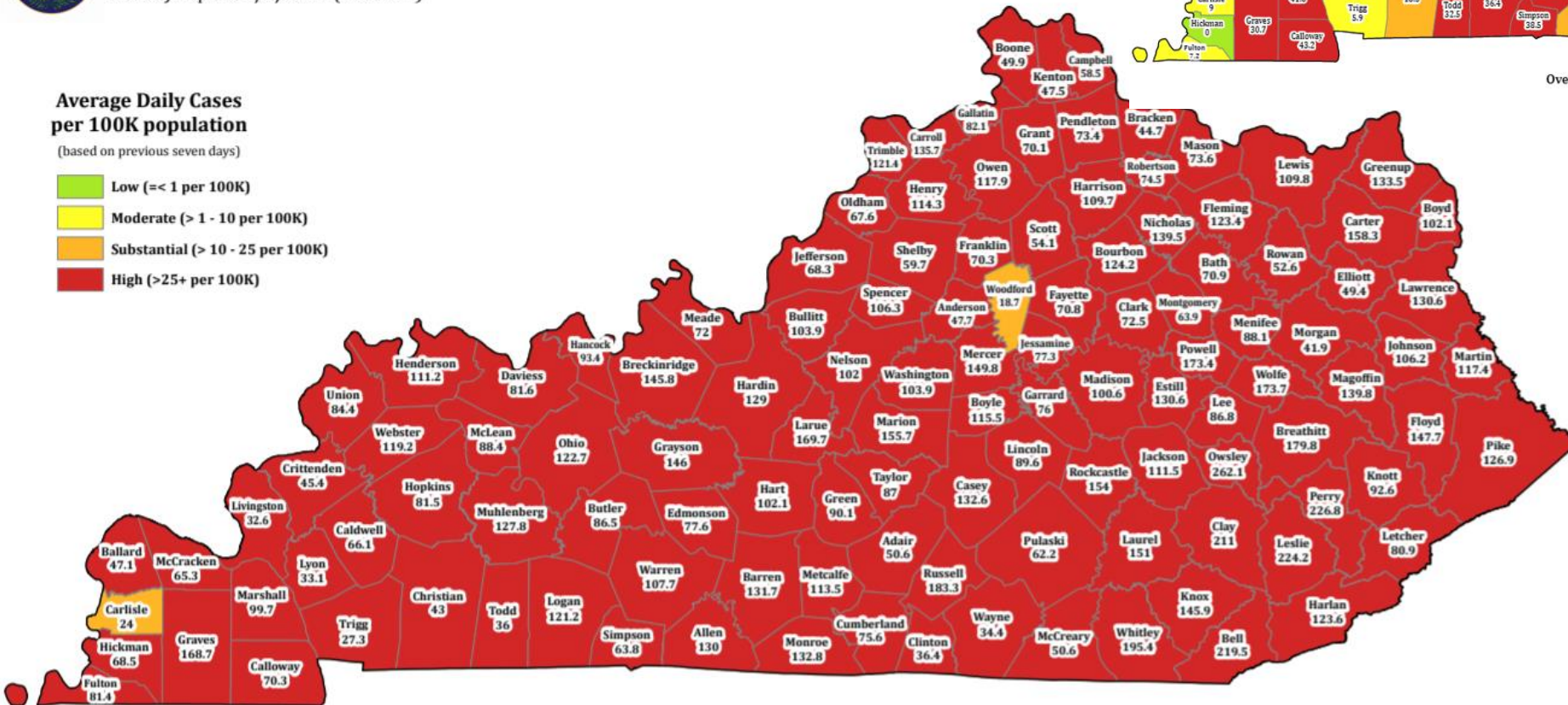
COVID-19 Current Incidence Rate in Kentucky

Date of Report: 9/3/2021 (4:33 PM)

Average Daily Cases per 100K population

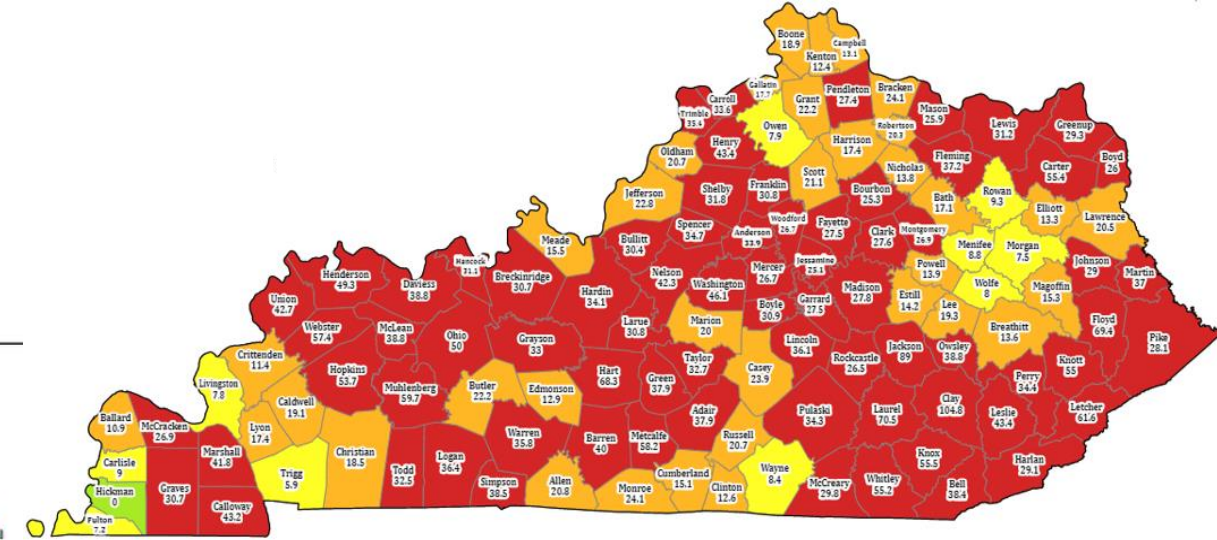
(based on previous seven days)

- Low (≤ 1 per 100K)
- Moderate ($> 1 - 10$ per 100K)
- Substantial ($> 10 - 25$ per 100K)
- High ($> 25+$ per 100K)



Overall Current Incidence Rate
89.89

↑ Up from 87.53/100K 5 days ago



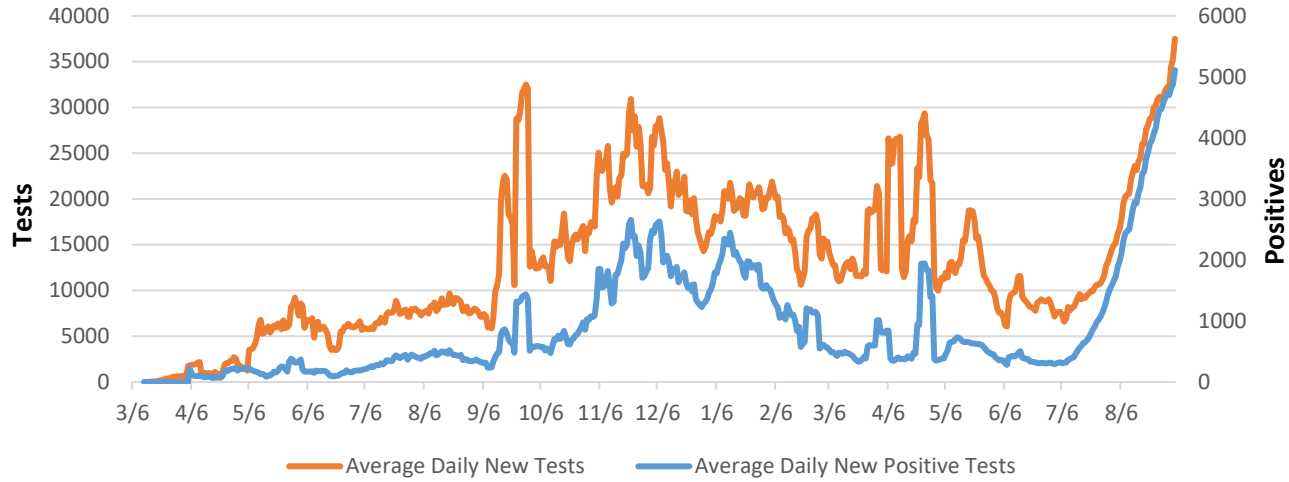
Overall Current Incidence Rate
29.64

Incidence Rates over Time:
(7-day average per 100K Kentuckians)

- Sunday, June 27: 3.13
- Tuesday, July 27: 19.69
- Friday, Aug. 27: 84.49
- Friday, Sept. 3: 89.89

Total Positive Tests vs. Total Tests by Day

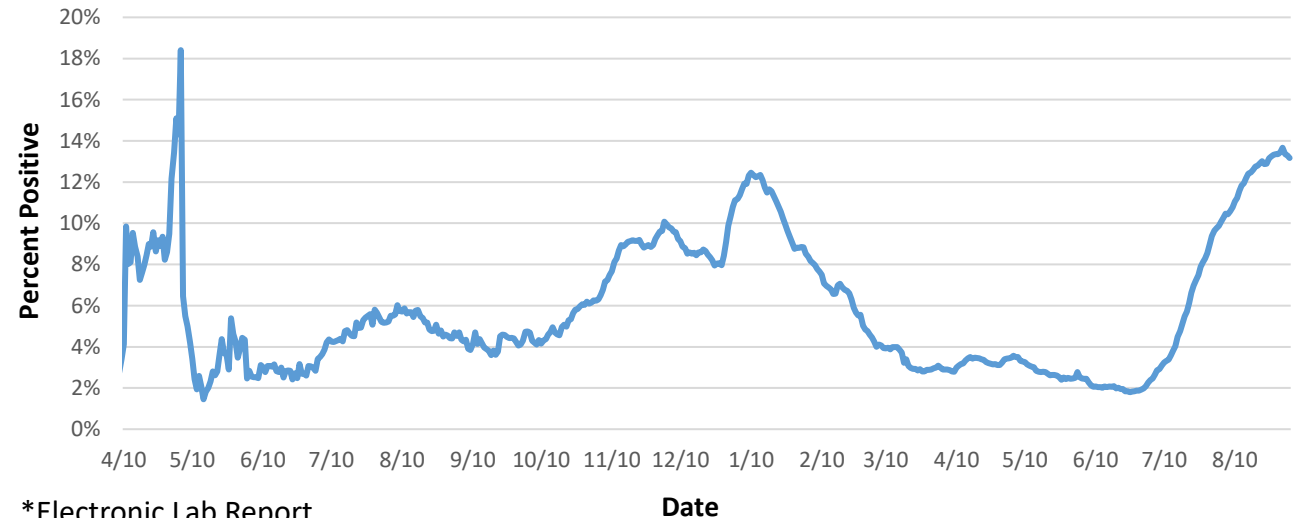
(7-day rolling averages)



On 5/5/21, testing data were updated by combining known testing numbers from the lab result reporting and lab aggregate reporting systems to more accurately reflect the minimum number of tests performed for PCR, antigen and antibody tests

Average Positivity Rate by Date

Total ELR* Positive PCR† Tests/Total ELR* PCR† Tests by Day
(7-day rolling average)



*Electronic Lab Report

†Polymerase Chain Reaction molecular test

Today's Average Positivity Rate

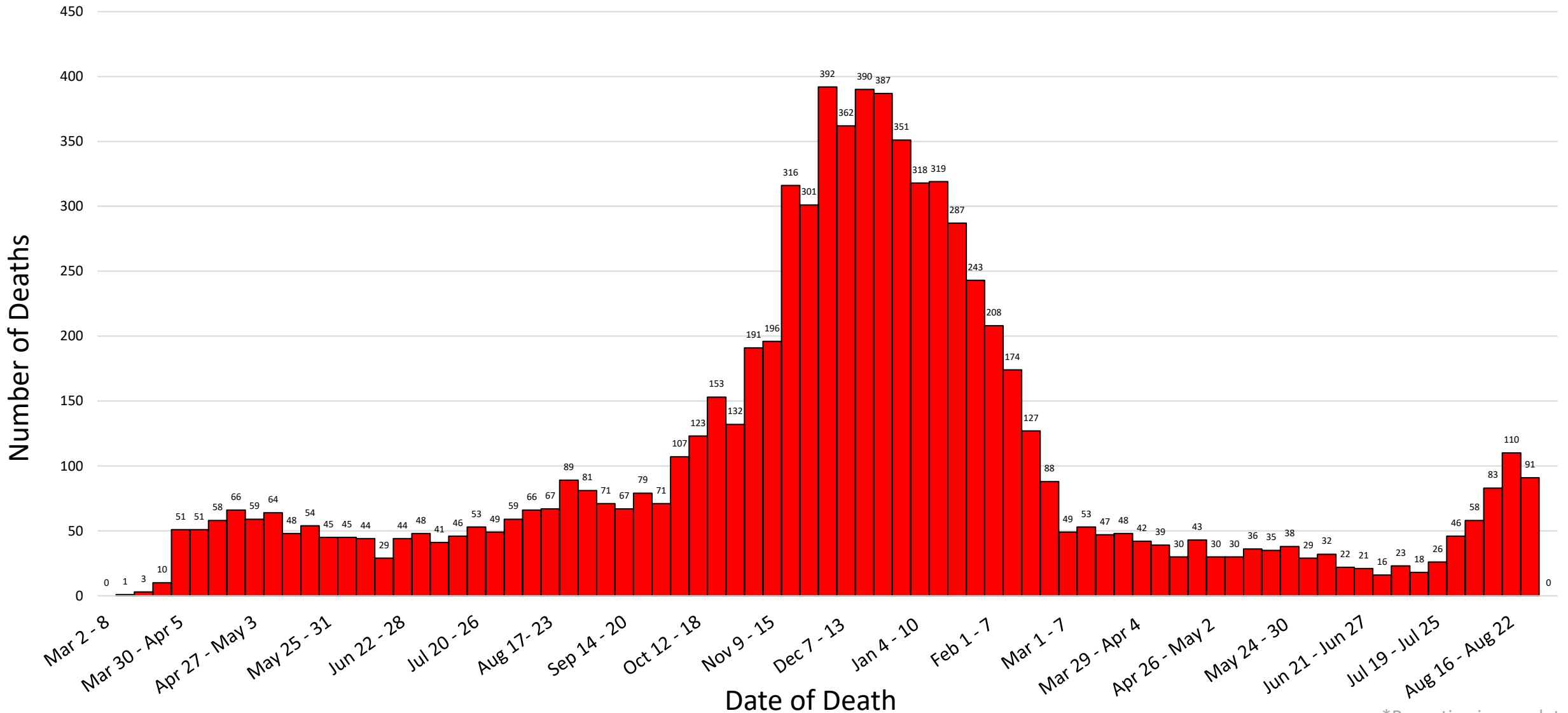
(Average of last 7 days)

13.17%

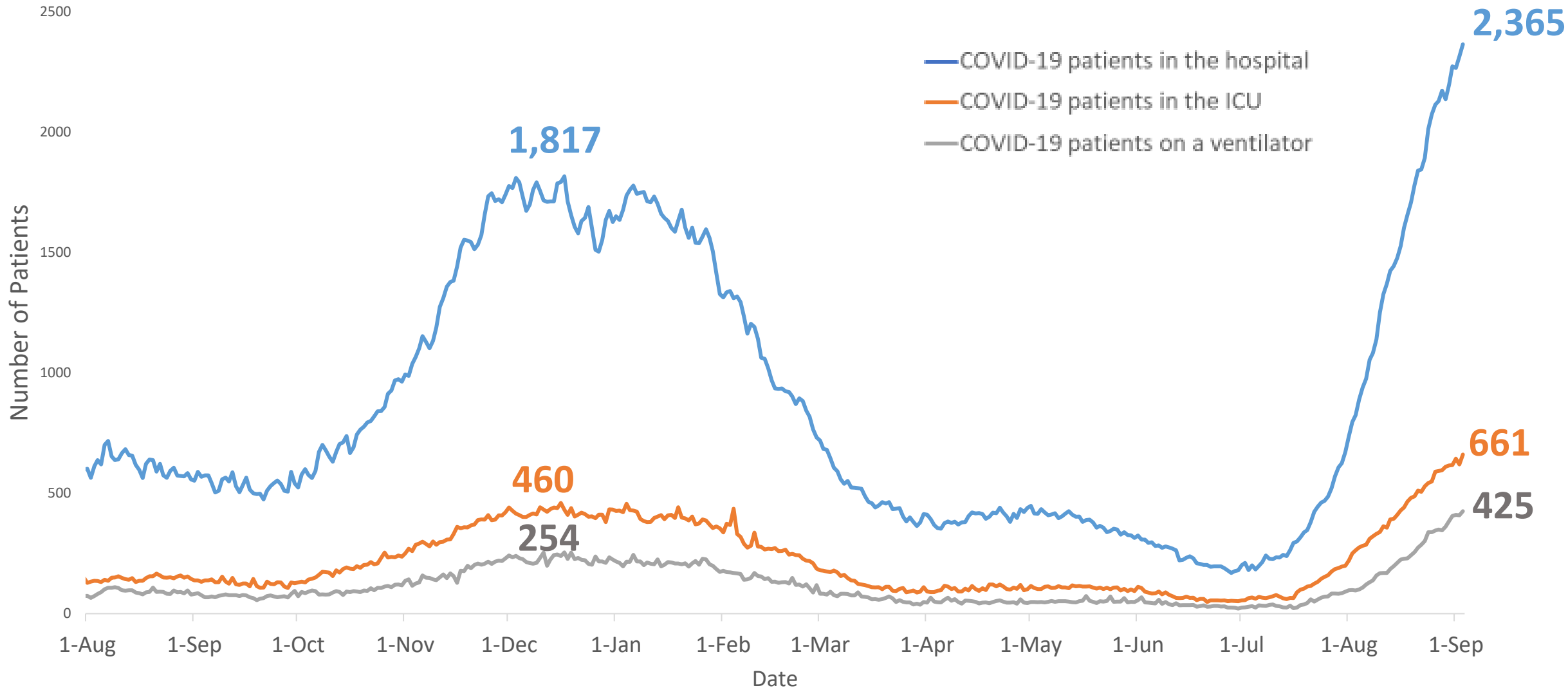


Down from 13.45% 5 days ago

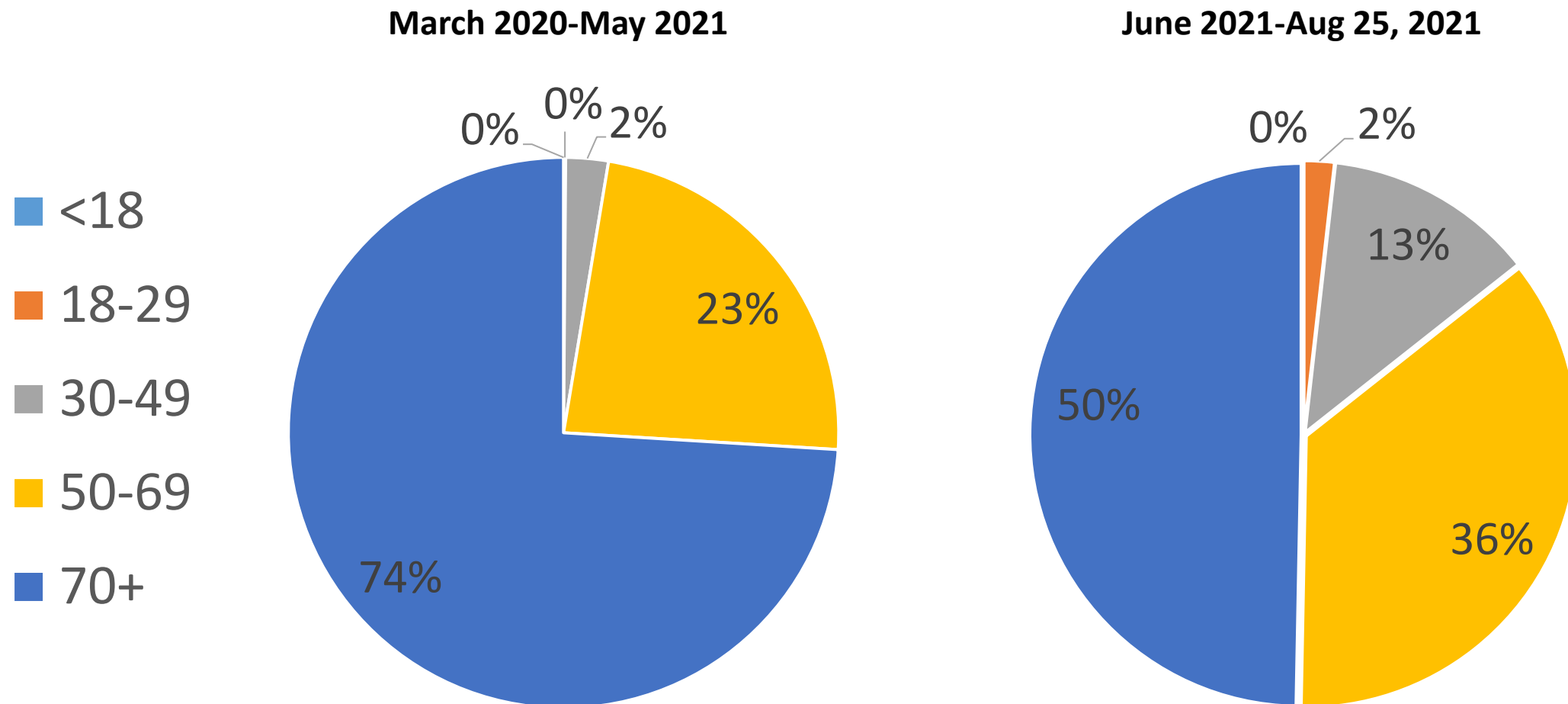
COVID-19 Kentucky Deaths by Week (n = 7,845)



COVID-19 hospitalization, ICU, and ventilator census in Kentucky hospitals - July 11, 2020 – September 3, 2021



Age distribution of COVID-19 deaths – Kentucky



Increased COVID-19 Delta Variant Pediatric Impact

Since Delta arrived:

- Cases are about 30% children 18 and under
- Pediatric admissions are at an all-time high
- Children high proportion of emergency department visits
- Higher number of children admitted to ICU

HOSPITAL CAPACITY BY REGION



REGION 1

Ballard, Caldwell, Calloway, Carlisle, Crittenden, Fulton, Graves, Hickman, Livingston, Lyon, Marshall, McCracken, Trigg

REGION 2

Christian, Daviess, Hancock, Henderson, Hopkins, McLean, Muhlenberg, Ohio, Todd, Union, Webster

REGION 3

Breckinridge, Bullitt, Grayson, Hardin, Henry, Jefferson, LaRue, Marion, Meade, Nelson, Oldham, Shelby, Spencer, Trimble, Washington

REGION 4

Allen, Barren, Butler, Edmonson, Hart, Logan, Metcalfe, Monroe, Simpson, Warren

REGION 5

Anderson, Bourbon, Boyle, Clark, Estill, Fayette, Franklin, Garrard, Harrison, Jessamine, Lincoln, Madison, Mercer, Nicholas, Powell, Scott, Woodford

REGION 6

Boone, Bracken, Campbell, Carroll, Gallatin, Grant, Kenton, Owen, Pendleton

REGION 7

Bath, Boyd, Carter, Elliott, Fleming, Greenup, Lewis, Mason, Menifee, Montgomery, Morgan, Robertson, Rowan

REGION 8

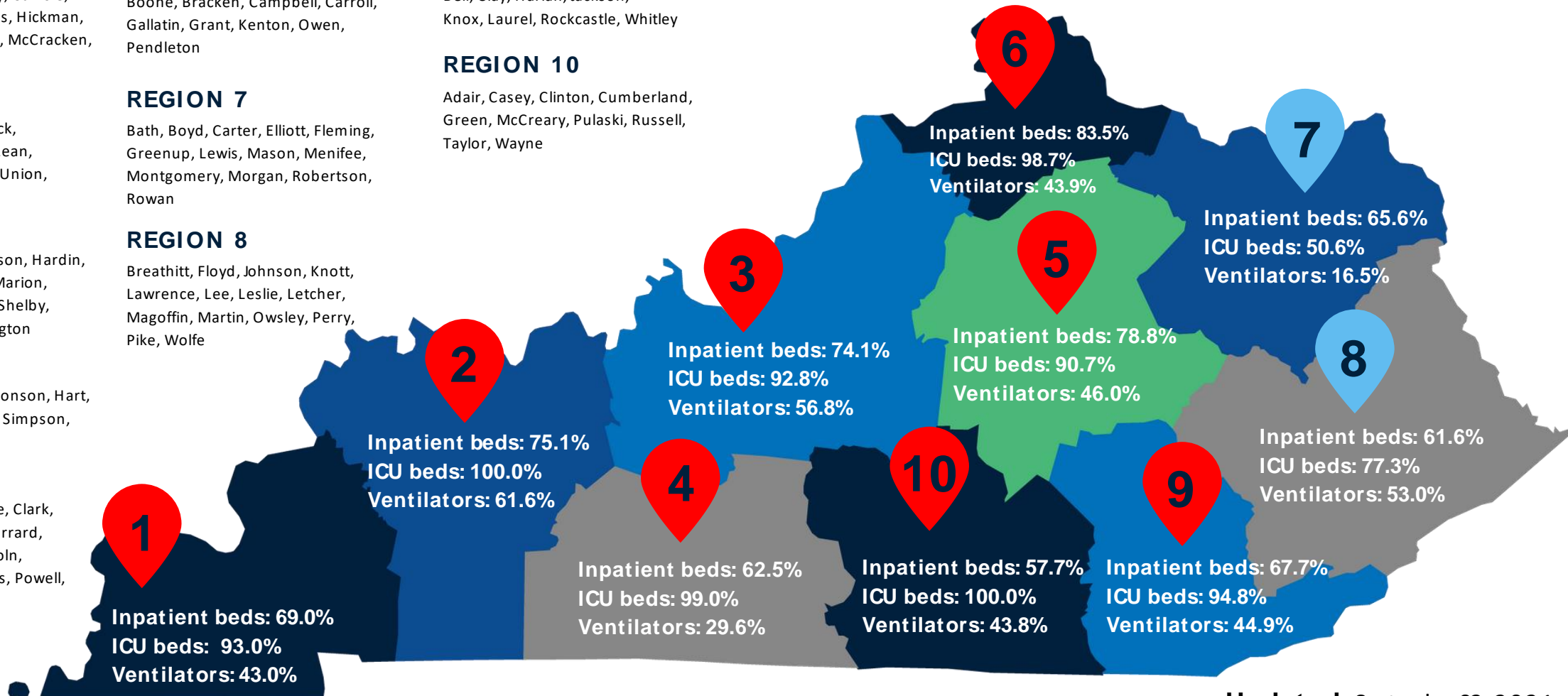
Breathitt, Floyd, Johnson, Knott, Lawrence, Lee, Leslie, Letcher, Magoffin, Martin, Owsley, Perry, Pike, Wolfe

REGION 9

Bell, Clay, Harlan, Jackson, Knox, Laurel, Rockcastle, Whitley

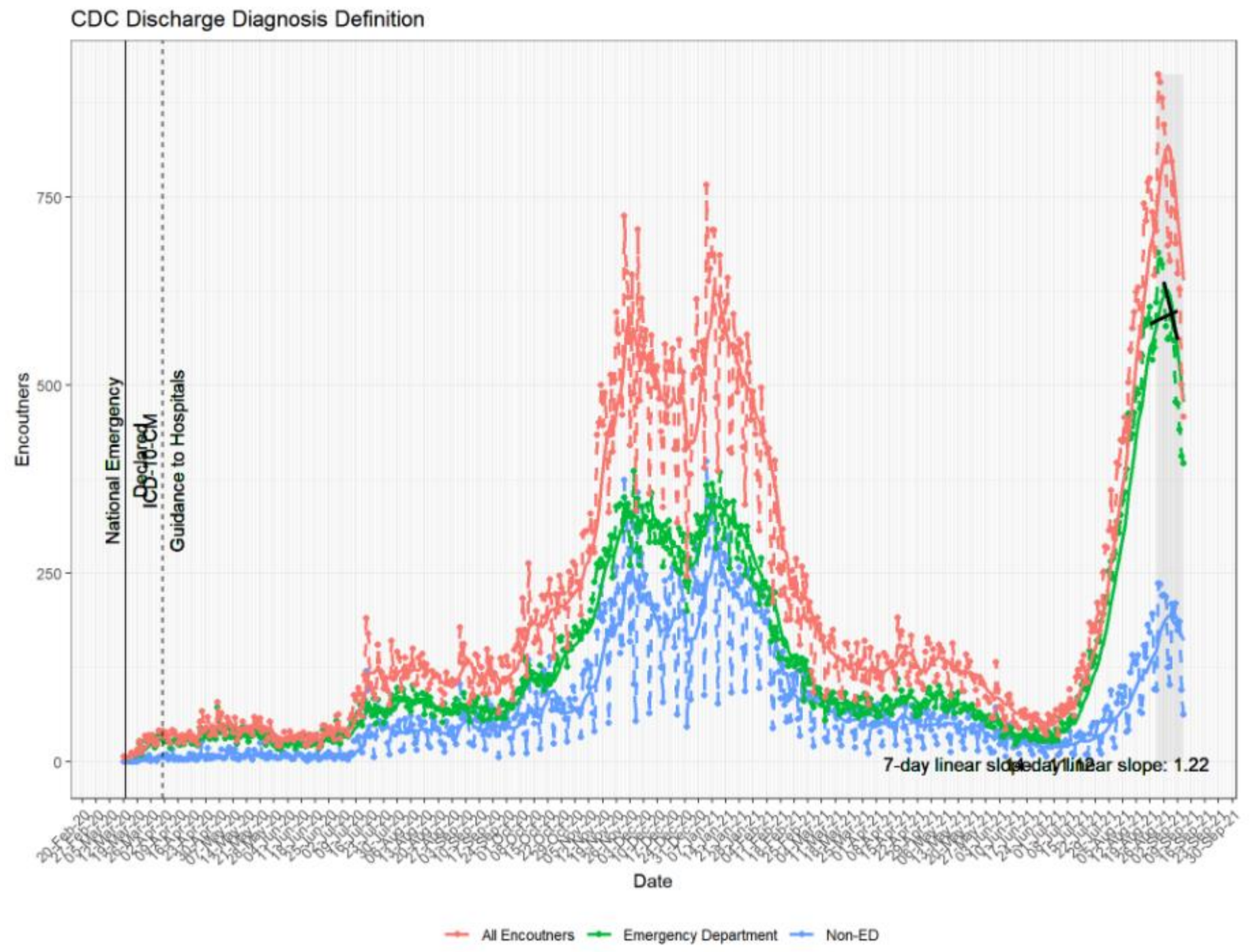
REGION 10

Adair, Casey, Clinton, Cumberland, Green, McCreary, Pulaski, Russell, Taylor, Wayne

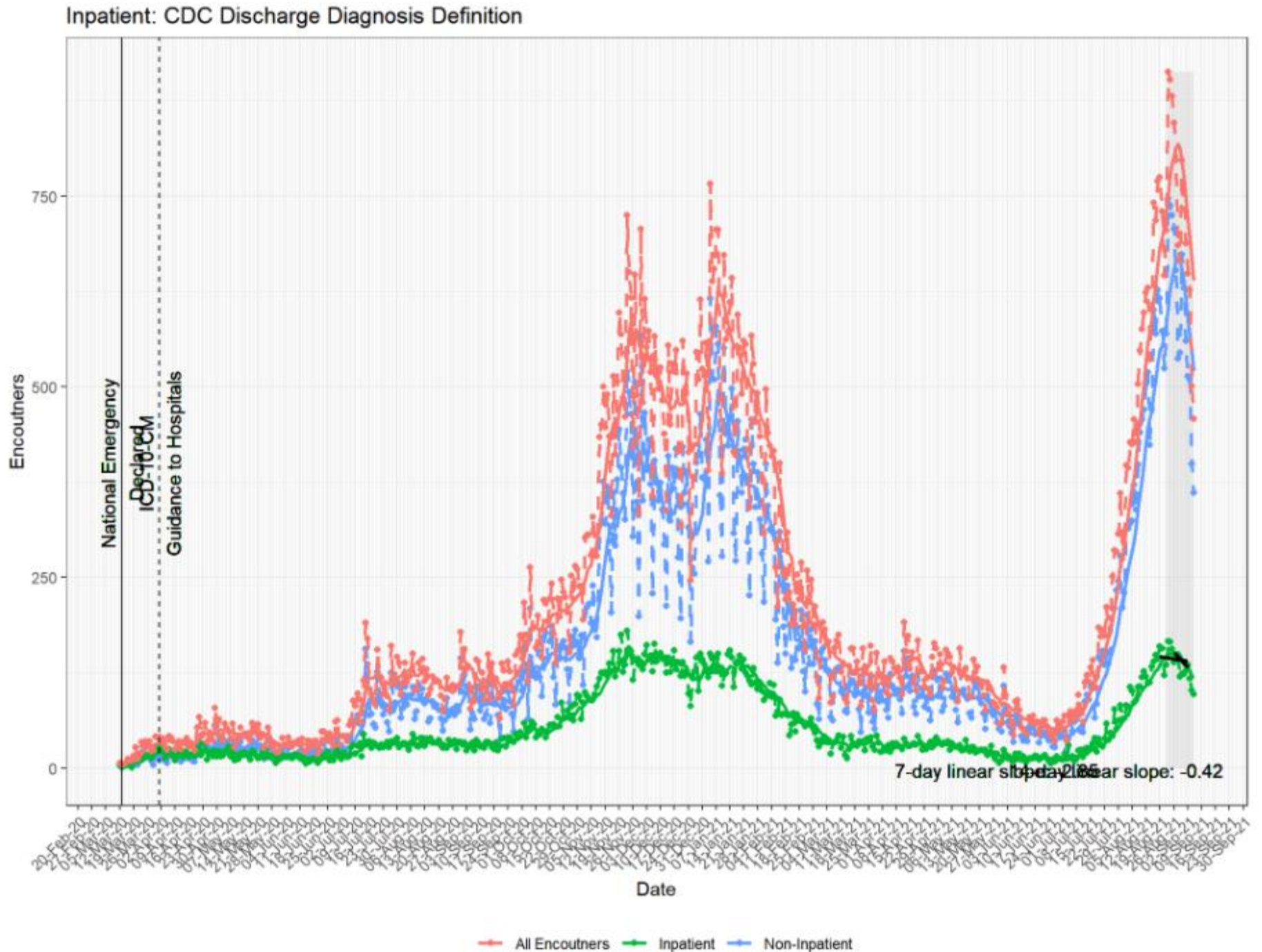


Updated: September 03, 2021

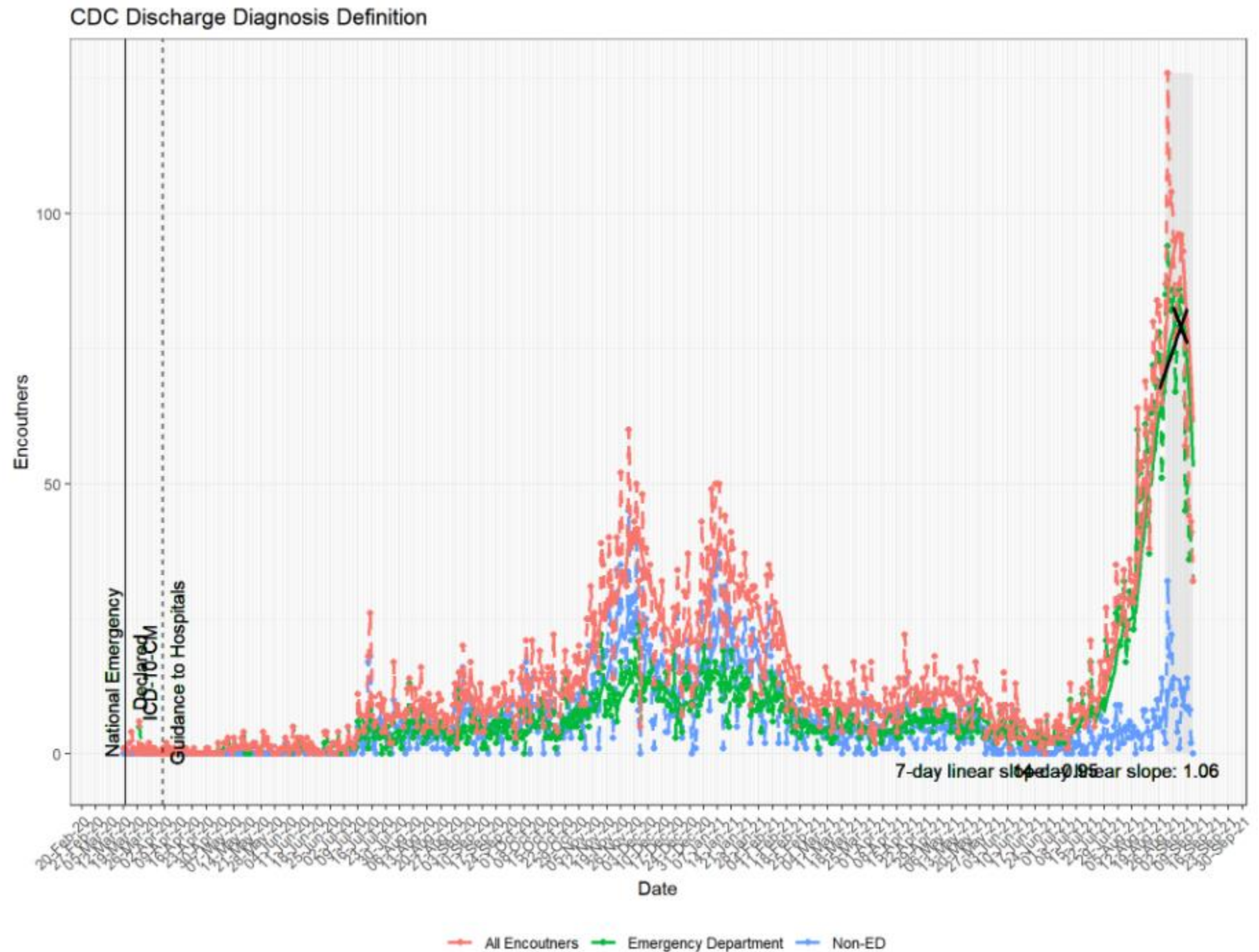
ED Based Visits: COVID-19



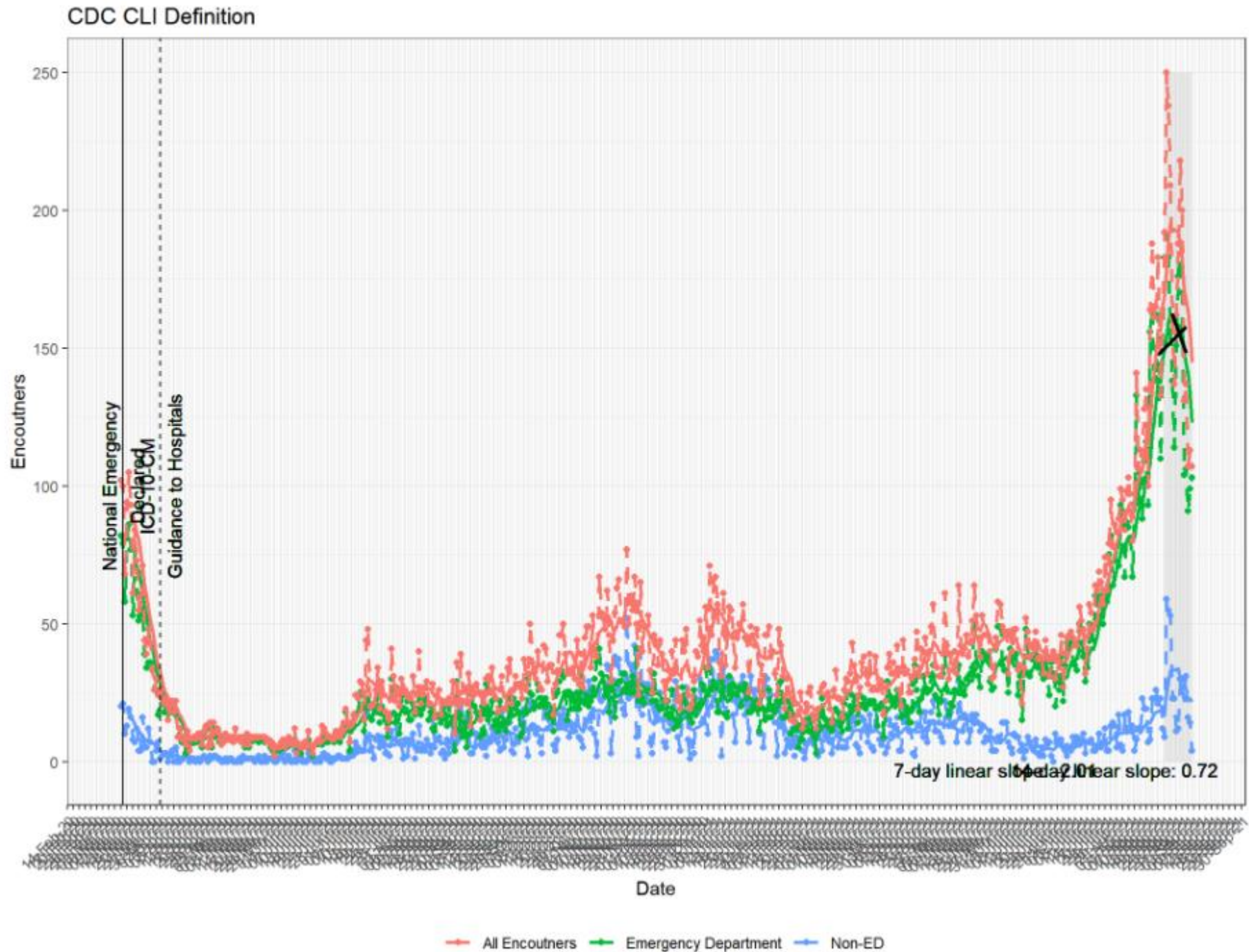
Inpatient Encounters: COVID-19



ED Based Visits - 18 and Under: COVID-19



ED Based Visits - 18 and Under: COVID-Like Illness



COVID-19 Vaccinations in Kentucky

4,585,627

Total Doses
Administered in Kentucky

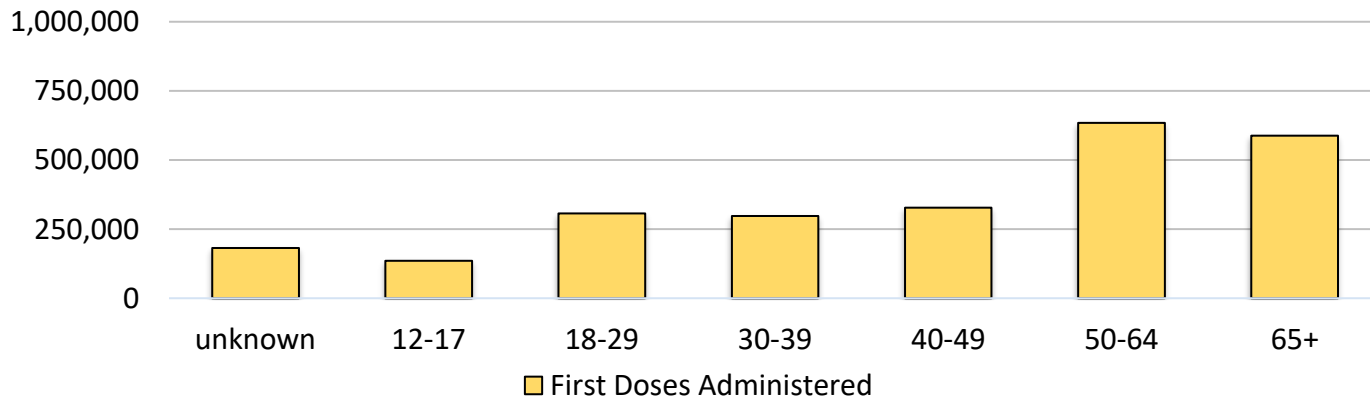
2,550,448

Total Unique Persons
Vaccinated in Kentucky

**589,233 Unique 65+ Persons
(85.0%)
Vaccinated in KY**

**1,228,615 Unique 50+ Persons
(77.4%)
Vaccinated in KY**

COVID-19 Vaccine Recipients' Age



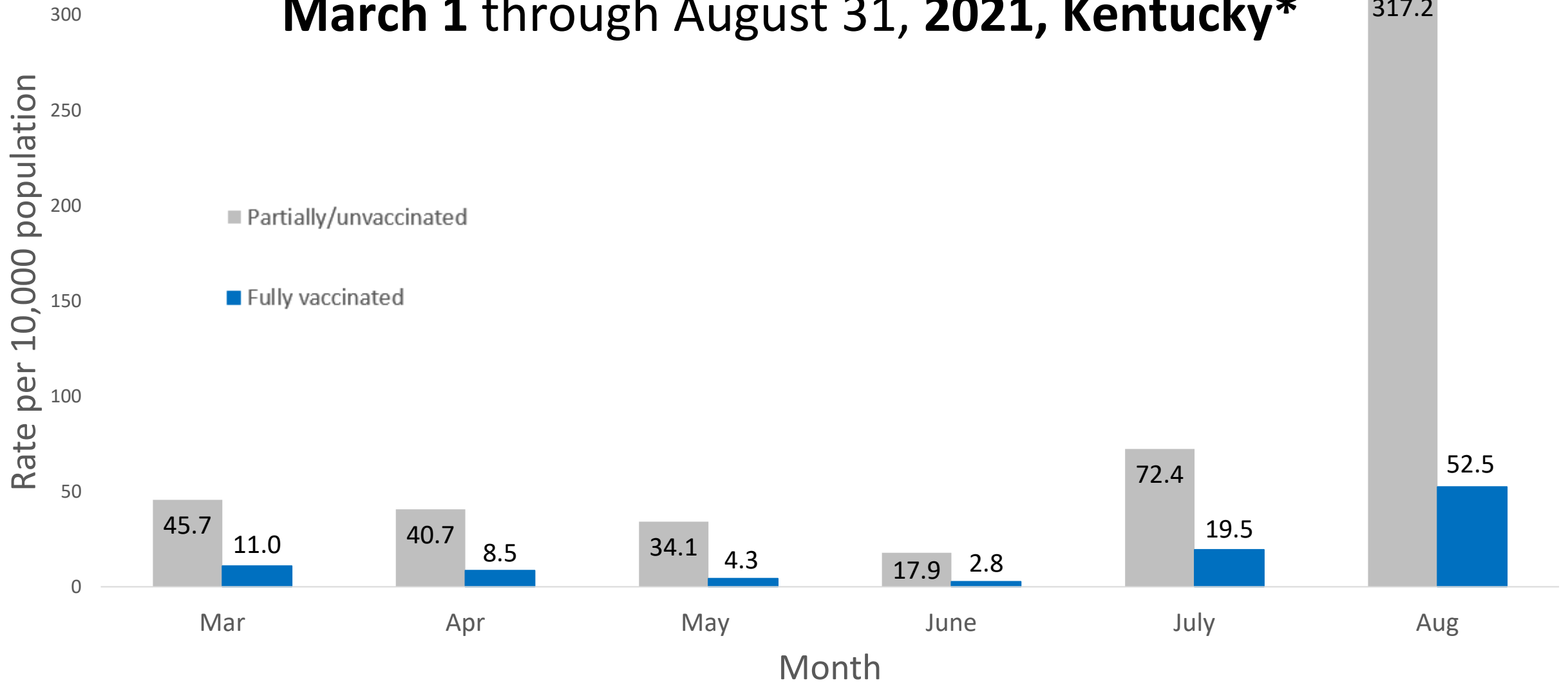
Breakthrough Infections

Alyson Cavanaugh, DPT, MPH, PhD



Kentucky Public Health
Prevent. Promote. Protect.

Rate of COVID-19 cases by Vaccination Status— March 1 through August 31, 2021, Kentucky*



*Data updated through 8/31/2021; data are provisional and subject to change; fully vaccinated includes individuals who have received the second dose of an mRNA vaccine or the Janssen vaccine ≥ 2 weeks prior to the illness; unvaccinated individuals have no evidence of vaccination in KYIR or are partially vaccinated

Vaccination Status of COVID-19 Cases, Hospitalizations, and Deaths March 1 – August 31, 2021*

Vaccination status of COVID-19 cases, hospitalizations, and deaths - March 1 - August 31*

	Fully Vaccinated		Partial/unvaccinated		Total
	N	%	N	%	
Cases	15,768	9.6%	148,991	90.4%	164,759
Hospitalizations**	436	8.7%	4,604	91.3%	5,040
Deaths	131	14.6%	766	85.4%	897

*Data are provisional and subject to change; fully vaccinated includes individuals who have received the second dose of an mRNA vaccine or the Janssen vaccine ≥ 2 weeks prior to the illness; unvaccinated individuals have no evidence of vaccination in KYIR or are partially vaccinated

**Hospitalization data may be underreported

Frequently Asked Questions

- I am vaccinated but tested positive for COVID. Do I need to isolate.
 - Yes. Isolation is required regardless of vaccination status.
- I am vaccinated but starting experiencing symptoms of COVID-19. Should I be tested?
 - Yes. Testing for symptomatic individuals is recommended regardless of vaccination status

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html>

Frequently Asked Questions

- I am vaccinated but I have been in contact with someone who has COVID-19. Do I need to quarantine?
 - You do not need to quarantine if you are fully vaccinated
 - You should get tested 3-5 days after your exposure, even if you don't have symptoms.
 - You should wear a mask indoors in public places for 14 days following exposure or until your 3-5 day test result comes back negative.
 - If symptoms develop during the 14 days after exposure, you should isolate.
 - If any test result is positive you should isolate for 10 days.
 - <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html>

Clinical and Public Health Implications

- Breakthrough infection risk increases when community transmission is high
 - Vaccination is key to lowering community transmission!
- Immunocompromised adults may not build an adequate immune response after vaccination. They should be counselled on additional steps for protection.
 - Third dose if mRNA vaccine previously received.
 - Continued use of mask, physical distancing, and avoiding crowded indoor settings.

Contact info

Additional questions, please contact:

CHFSDPHbreakthrough@ky.gov

Variant Surveillance

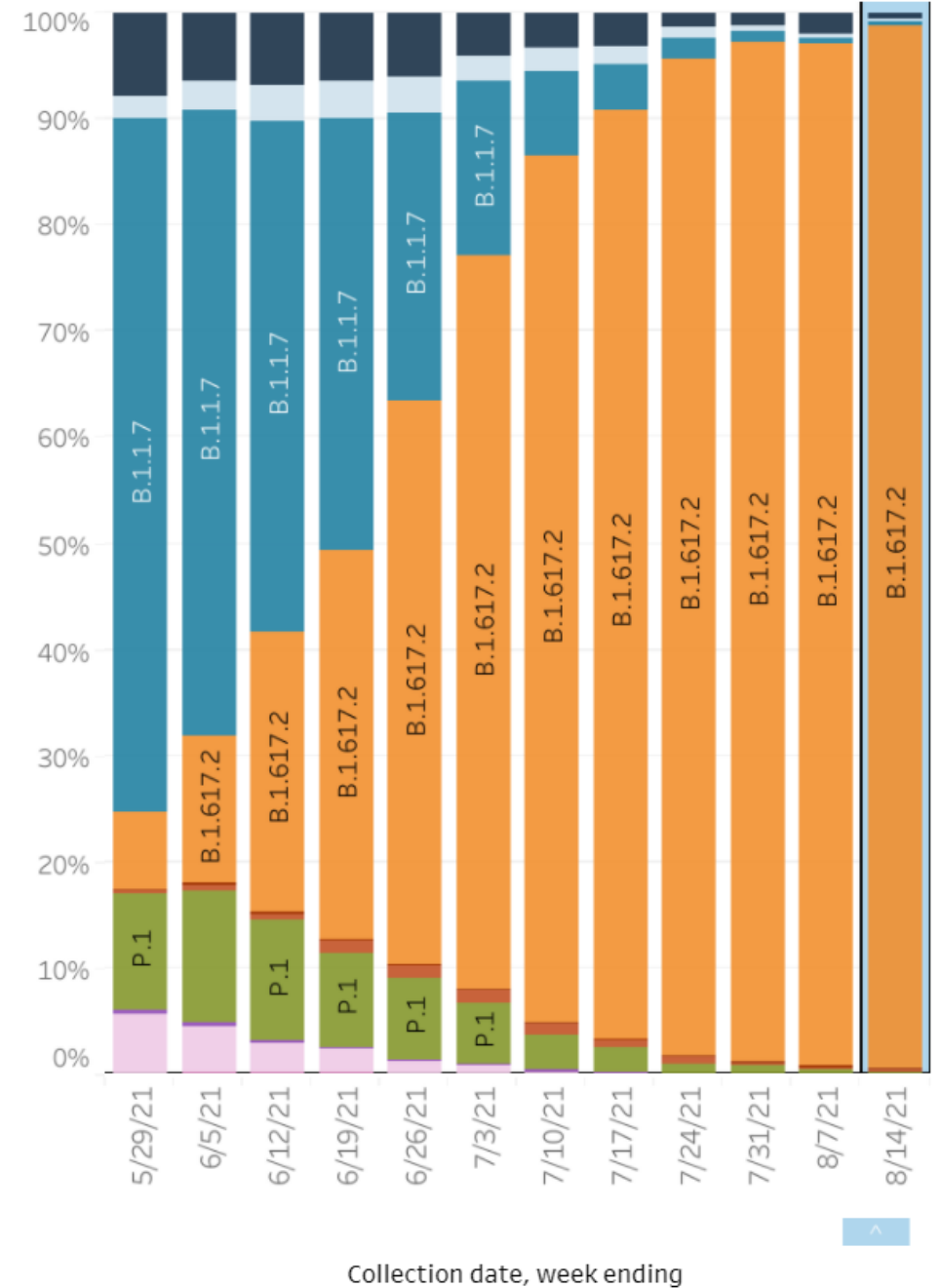
Alyson Cavanaugh, DPT, MPH, PhD



Kentucky Public Health
Prevent. Promote. Protect.

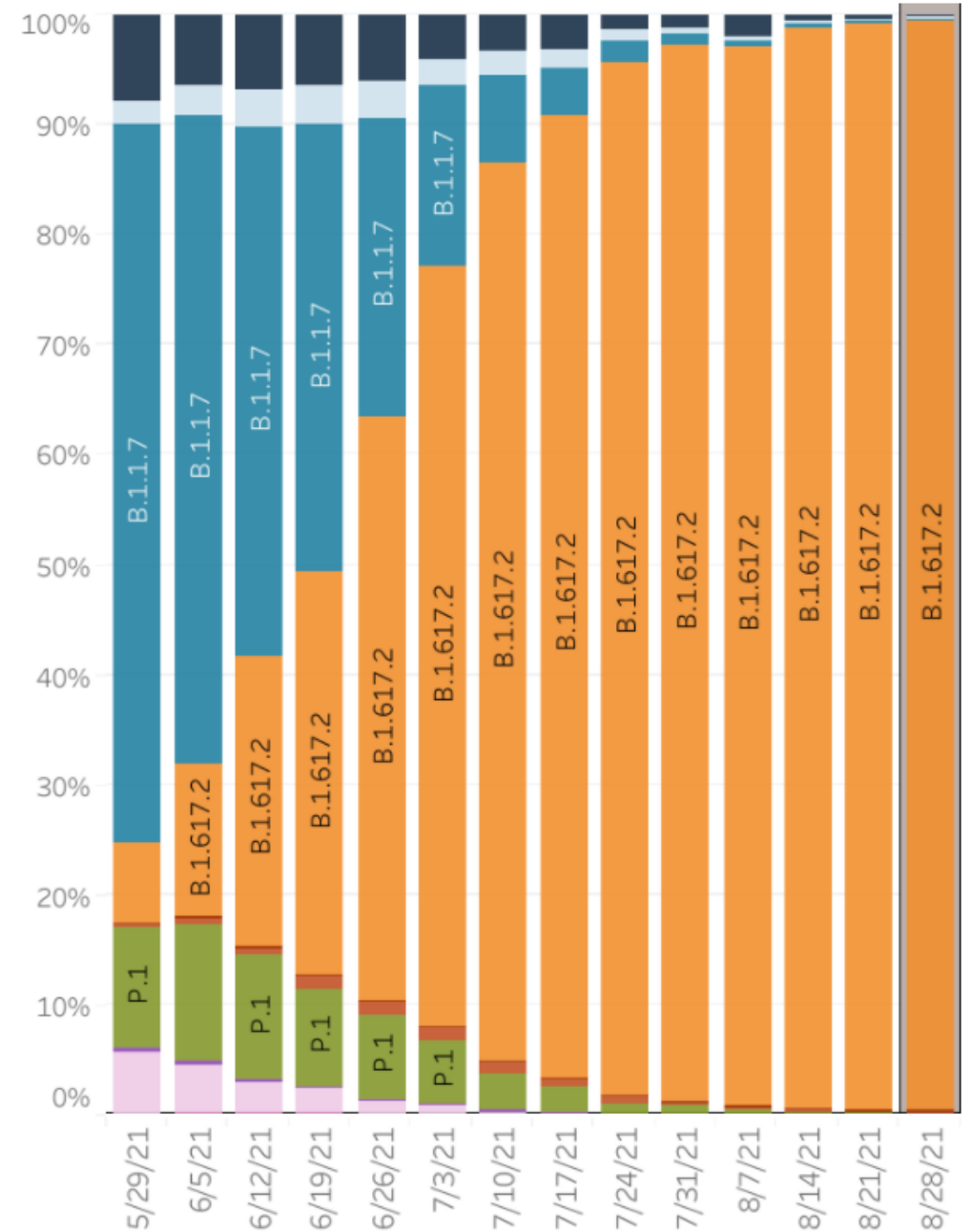
Estimated Proportions of SARS-CoV-2 Lineages in the U.S.

CDC COVID Data Tracker
<https://covid.cdc.gov/covid-data-tracker/#variant-proportions>



Estimated Proportions of SARS-CoV-2 Lineages in the U.S. (Nowcast On)

CDC COVID Data Tracker
<https://covid.cdc.gov/covid-data-tracker/#variant-proportions>

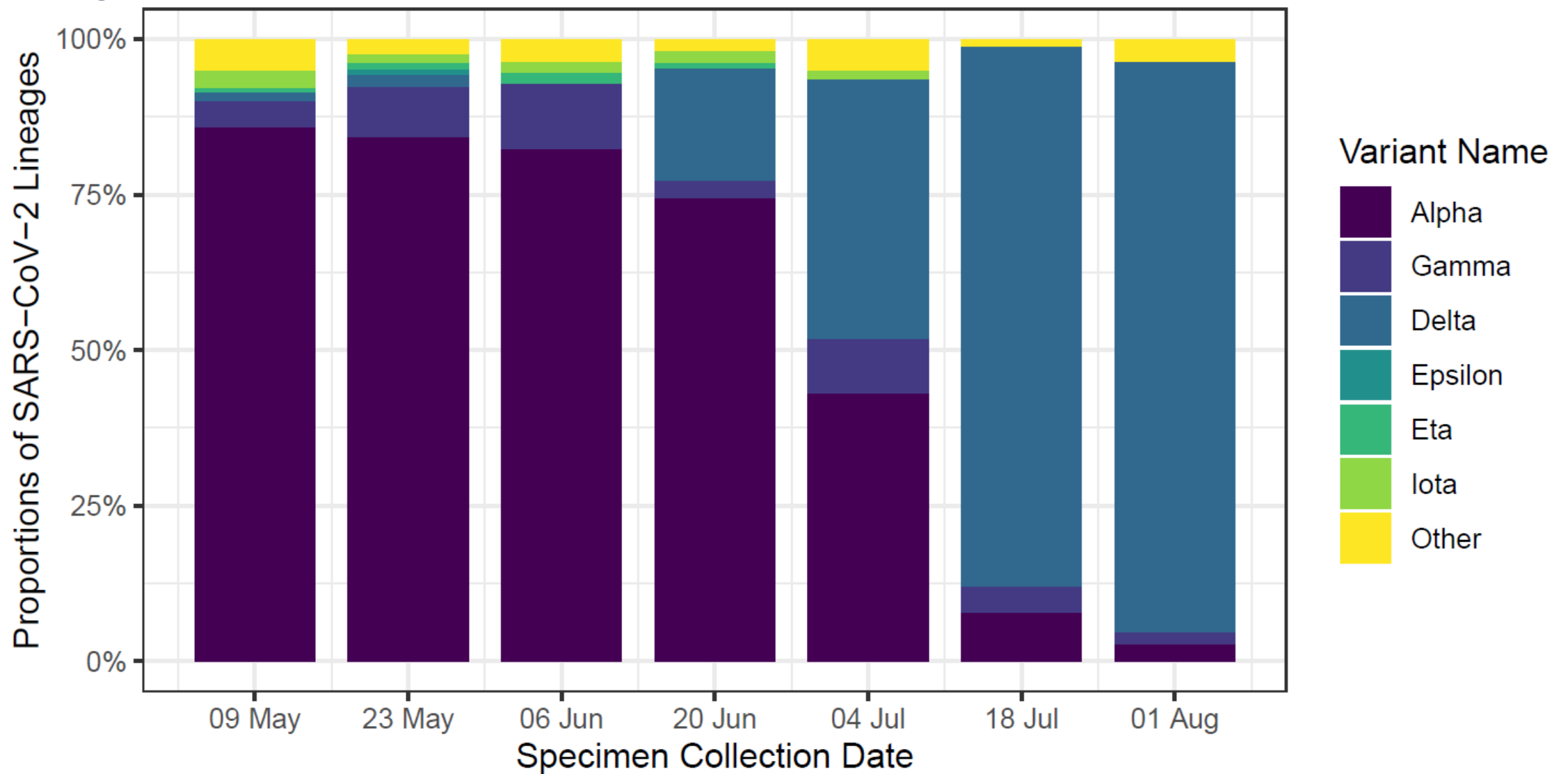


CDC COVID Data Tracker

<https://covid.cdc.gov/covid-data-tracker/#variant-proportions>

State	B.1.1.7	B.1.351	B.1.617.2	P.1	AY.1	AY.2	Other	Total available sequences
Alabama	1.6%		95.0%	0.5%	0.1%	0.1%	2.7%	2,542
Arizona	0.8%		93.8%	1.1%	0.1%	0.3%	3.9%	1,425
Arkansas	0.6%		96.6%	0.2%		0.3%	2.4%	679
California	0.7%	0.0%	94.9%	0.6%	0.6%	0.9%	2.3%	33,472
Colorado	1.2%	0.1%	96.1%	0.2%	0.1%	0.4%	2.0%	2,874
Connecticut	1.2%		95.9%	0.7%		0.2%	2.0%	588
District of Columbia	0.3%		98.9%				0.8%	378
Florida	1.3%	0.0%	92.5%	1.1%	0.0%	0.2%	4.9%	18,661
Georgia	0.9%		95.6%	0.5%	0.0%	0.3%	2.8%	5,584
Illinois	0.8%		95.3%	0.3%	0.1%	0.8%	2.7%	2,156
Indiana	0.7%		96.6%	0.7%		0.3%	1.8%	774
Kansas	0.2%		97.8%				1.9%	464
Kentucky	1.6%		94.0%	0.8%	0.1%	0.2%	3.4%	894
Louisiana	2.1%		92.8%	0.2%		0.1%	4.9%	1,378
Maryland	0.8%		95.9%	0.8%	0.1%	0.2%	2.1%	1,679
Massachusetts	0.1%		96.7%	0.8%	0.2%	0.0%	2.2%	6,492
Michigan	0.4%		96.4%	0.6%		0.4%	2.2%	502
Minnesota	0.2%		97.3%	0.4%		0.2%	1.9%	2,590
Mississippi	0.7%		95.1%	0.3%			3.9%	698
Missouri	0.6%		96.3%	0.3%			2.8%	1,216
Nevada	0.7%		94.2%	0.1%	0.1%	2.2%	2.6%	1,397
New Jersey	0.7%		96.3%	0.3%	0.2%	0.1%	2.4%	3,601
New Mexico	0.9%		94.4%	0.6%			4.1%	467
New York	0.4%		96.8%	0.5%	0.4%	0.1%	1.8%	2,819
North Carolina	0.7%		97.3%	0.3%	0.0%	0.0%	1.6%	7,292
Ohio	1.5%		94.3%	0.7%		0.2%	3.3%	943
Oklahoma			94.3%				5.7%	406

Proportion of SARS-CoV-2 Variants in KY over Time



Monoclonal Antibody Updates


Kenneth Kik, EMT-P, FP



Kentucky Public Health
Prevent. Promote. Protect.

Monoclonal Antibody Guidance

➤ KYCOVID19.KY.GOV: <https://chfs.ky.gov/agencies/dph/covid19/KYMonoclonalAntibodyGuidance.pdf>



The image shows the cover of a guidance document. At the top left is the logo for the Kentucky Cabinet for Health and Family Services, featuring a sun and a map of Kentucky. In the center is the 'TEAM KENTUCKY' logo with a map of the state. At the top right is the Kentucky Public Health logo, which includes a shield with a cross and the tagline 'Prevent. Promote. Protect.' Below these logos is the title 'Monoclonal Antibody (mAb) Therapeutics Program Information for Clinicians and Healthcare Entities'. The main text describes how monoclonal antibodies (mAbs) neutralize the COVID-19 virus and are used to prevent disease progression. It notes that since November 9th, 2020, Kentucky hospitals and clinicians have administered mAbs to high-risk patients, and that KDPH encourages coordination between healthcare entities to increase access to these treatments. A section titled 'Current guidance' states that recent updates allow for subcutaneous injection and post-exposure prophylaxis, and refers to the HHS Federal Response to COVID-19: Monoclonal Antibody Playbook (updated July 30, 2021) and manufacturer guidance. A bulleted list includes 'Regen-COV' with two URLs: <https://www.regencov.com/> and <https://www.covid19.lilly.com/assets/pdf/bam-ete/lilly-antibodies-playbook.pdf>. The second item is 'Bamlanivimab / Etesevimab:'. In the bottom right corner, there is a small image of a coronavirus particle with several Y-shaped antibodies attached to its surface.

KENTUCKY CABINET FOR HEALTH AND FAMILY SERVICES

TEAM KENTUCKY

Kentucky Public Health
Prevent. Promote. Protect.

Monoclonal Antibody (mAb) Therapeutics Program Information for Clinicians and Healthcare Entities

Monoclonal antibodies (mAbs) directly neutralize the COVID-19 virus, are intended to prevent progression of the disease, and are most effective when given early in infection. Since Nov 9th, 2020, Kentucky hospitals and clinicians have administered mAbs for the treatment of recently diagnosed, mild to moderate COVID-19 illness in high-risk patients who are not hospitalized. mAb administration has been expanded and successfully implemented in a variety of outpatient settings. KDPH encourages hospitals, clinics and other healthcare entities to coordinate to increase access to mAbs with the goal of reducing hospitalizations.

Current guidance

Recent updates allow for administration of mAbs via subcutaneous injection and for post-exposure prophylaxis. For current information and clinical guidance, please refer to the [HHS Federal Response to COVID-19: Monoclonal Antibody Playbook – updated July, 30, 2021](#) and manufacturers guidance.

- **Regen-COV:**
<https://www.regencov.com/>
<https://www.covid19.lilly.com/assets/pdf/bam-ete/lilly-antibodies-playbook.pdf>
- **Bamlanivimab / Etesevimab:**



Disease Control Guidance Updates

Kathleen Winter, PhD, MPH



Kentucky Public Health
Prevent. Promote. Protect.



KENTUCKY CABINET FOR HEALTH AND FAMILY SERVICES



Kentucky Public Health Prevent. Promote. Protect.

22 Shares



Home COVID Testing Vaccine Travel Advisory KDPH Guidance KDPH Data

Select Language dropdown menu, Powered by Google Translate

Learn about the safe, effective COVID-19 vaccines and find where to get vaccinated at vaccine.ky.gov.

KDPH COVID-19 Data

COVID-19 Data is reported Monday through Friday at 4:45 pm

Important! This page is in development. We are updating this page regularly.

COVID-19 SURVEILLANCE DATA

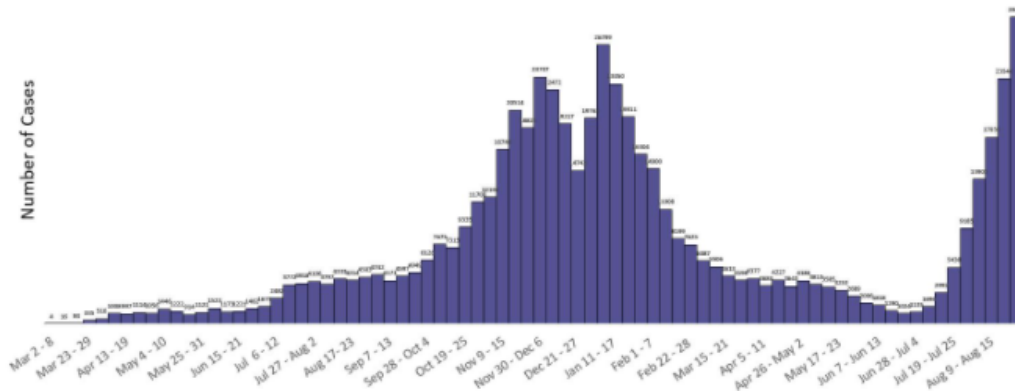
- Daily Numbers
- Incidence Rate Map
- Cases by County
- Weekly Surveillance Data**

VACCINE DATA

- County Map
- County Percentages
- First Dose by Age
- One Dose - Summary

Weekly Surveillance Data

Kentucky COVID-19 New Cases by Week (n = 569,903)



Have you been exposed to or tested positive for COVID-19?

If you have tested **POSITIVE FOR COVID-19** and have **SYMPTOMS**:

Isolate for

10

DAYS from the date symptoms began.

If you have tested **POSITIVE FOR COVID-19** and have **NO SYMPTOMS**:

Isolate for

10

DAYS from the date you had your test done.

If you are unvaccinated and have been in **CLOSE CONTACT** with someone diagnosed with COVID-19:

Quarantine* for

10

DAYS from your last exposure.

*Quarantine may be shortened to 7 days if you have no symptoms and test negative for COVID-19 on day 5 or later. If you have been in close contact with someone diagnosed with COVID-19 and are fully vaccinated, you do not need to quarantine but are recommended to get tested 3-5 days after exposure.

Quarantine Guidance

- Unvaccinated/partially-vaccinated persons
 - Quarantine for:
 - 10 days or
 - 7 days if asymptomatic and test negative (PCR or antigen) day 5 or later
 - Should be tested if symptoms occur
 - Exceptions: healthcare personnel and first responders

If you were exposed to COVID-19 and are NOT FULLY VACCINATED

Self-quarantine to protect yourself and others:

- Stay home. Do not go to work, school, or other public places. Self-quarantine for:
 - 10 full days if you have NO symptoms; or
 - 7 days if you NO symptoms and test negative on or after day 5 of quarantine. Learn more about the [CDC Quarantine Guidance](#).
- Stay away from people you live with, if possible. Consider wearing a mask at home if you live with persons who are at [high risk](#).
- [Consider vaccination when able](#).

If you develop any of these symptoms, get tested:

- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

Seek emergency medical care if you experience chest pain, blue or gray lips/finger nails, or difficulty staying awake.

If your Local Health Department calls you, tell them:

- Basic information about you
- Where you been (work, school, house of worship, etc.)
- Your medical history and vaccine information
- If you have [COVID-19 symptoms](#) and when they began
- If you need support or help call your healthcare provider

August 18, 2021

Quarantine Guidance

- Fully-vaccinated persons
 - Do not need to quarantine if they are asymptomatic
 - Recommended to get tested 3-5 days after exposure
 - Recommended to wear a mask when around others
 - Should self-isolate and be tested if symptoms occur

If you were exposed to COVID-19 and are FULLY VACCINATED

Take steps to protect yourself and others:

- Get tested 3-5 days after the day you were exposed to COVID-19.
- Wear a mask in indoor public settings for 14 days or until you receive a negative test result.
- If you do not have symptoms of COVID-19, you do not need to quarantine.
- Monitor for symptoms for 14 days following your exposure.
- Consider wearing a mask at home if you live with persons who are at high risk.

Isolate yourself if you develop symptoms:

- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

Seek emergency medical care if you experience chest pain, blue or gray lips/finger nails, or difficulty staying awake.

If your Local Health Department calls you, tell them:

- Basic information about you
- Where you been (work, school, house of worship, etc.)
- Your medical history and vaccine information
- If you have COVID-19 symptoms and when they began
- If you need support or help call your healthcare provider

August 18, 2021

School Guidance

- Universal masking indoors, regardless of vaccination status.
- Screening testing program recommended.
- Students who are masked and ≥ 3 ft from an infectious student do not need to quarantine; the exception does not apply to adults and exposures outside classroom.
- Quarantine lasts 10 full days (can return on day 11); can be shorted to 7 days if test negative (PCR or antigen) on day 5 or later.

<https://chfs.ky.gov/agencies/dph/covid19/K-12Guidance.pdf>



Guidance for K-12 School Operations for In-Person Learning August 10, 2021

Schools are an essential part of community infrastructure and the return to in-person instruction for K-12 students is a priority. The purpose of this document is to provide information on prevention strategies that help protect students, teachers, and staff and slow the spread of COVID-19 in K-12 schools based on updated [CDC guidelines](#) (8/2021). This guidance emphasizes the implementation of layered prevention strategies to protect students, teachers and staff and is intended to help school administrators and local health officials select appropriate, layered prevention strategies in their communities.

Prevention strategies

SARS-CoV-2 transmission in K-12 schools is largely influenced by disease incidence in the community and evidence from the 2020-2021 school year suggests K-12 schools can safely open for in-person instruction when layered prevention strategies are implemented. Decisions around the implementation of layered prevention strategies in the school community should be made collaboratively by local public health officials and school administrators. Factors that should be considered include:

- Level of [community transmission of COVID-19](#) and occurrence of outbreaks in the school or community.
- [COVID-19 vaccination coverage in the community](#) and among students, teachers, and staff.
- Frequency and use of a SARS-CoV-2 testing screening program for students, teachers, and staff who are not fully vaccinated.
- Ages of children served by the schools and associated social and behavioral factors that may affect the risk of transmission and feasibility of different prevention strategies.

Full implementation of all layers of protection is recommended when sustained [incidence of COVID-19 in a community](#) is substantial or high (orange or red). If any of the prevention strategies are removed for a school based on local conditions, they should be removed one at a time and increases in COVID-19 cases should be closely monitored. Schools should communicate their strategies and changes in plans to the

COVID-19 in the Workplace*

If an employee tests positive for COVID-19 or thinks they may have COVID-19, follow this guidance to keep the workplace safe.

WHAT TO DO

Anyone who thinks they may have COVID-19 should stay away from the workplace

All employees or visitors who think they may have COVID-19 should stay away from the workplace even if they have been vaccinated for COVID-19. Symptoms of COVID-19 include fever, chills, new cough, shortness of breath, headache, sore throat, vomiting, diarrhea, and loss of taste or smell. Sick persons are advised to get a COVID-19 test and stay away from the workplace while awaiting test results to prevent unknowingly exposing others.

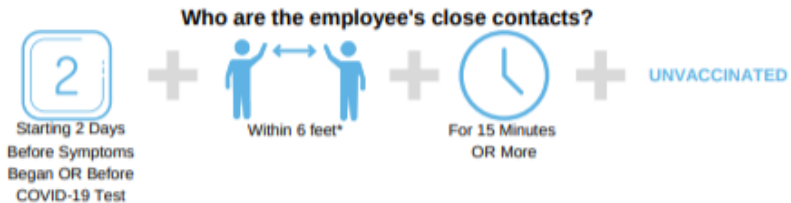
Anyone with a positive COVID-19 test should self-isolate for 10 days even if they are vaccinated

Anyone who has tested positive for COVID-19 should notify their employer and self-isolate (stay away from work and others) for 10 full days starting from either the first day of the start of symptoms, or the day of testing if the person does not have symptoms.

Exposure in the workplace

If an employee tests positive, the workplace should be informed immediately so that close contacts can be identified and those who need to quarantine can be notified. This is critical to slowing the spread of COVID-19. Employers and employees should work together to follow this guidance to keep the workplace safe. In general, Local Health Departments are not providing work release documents for individuals with COVID-19 and their contacts.

WHO SHOULD QUARANTINE



- Unvaccinated contacts should quarantine for **10 full days if they have NO symptoms**; quarantine may be shortened to **7 days** if they have **NO symptoms** and **test negative (PCR or antigen) on or after day 5 of quarantine**.
- Fully vaccinated contacts do not need to quarantine unless they are experiencing symptoms of COVID-19, but are recommended to get a COVID-19 test 3-5 days after their exposure.
- An exposed individual does not need to quarantine if they have had a positive COVID-19 test (with documentation of a positive PCR or antigen test result) within the previous 3 months **and** has recovered **and** remains without COVID-19 symptoms.
- Learn more about the [CDC Quarantine Guidance](#).

*This guidance applies to most workplace settings in the community and does not apply to healthcare settings.

August 20, 2021

FDA Approval, 3rd Doses, and Off-label Use



Kentucky Public Health
Prevent. Promote. Protect.

FDA Approved vs. FDA EUA for COMIRNATY

- On Monday, August 23, 2021, FDA approved “COMIRNATY” (Pfizer COVID-19 Vaccine, mRNA) for use as a two-dose series for individuals 16 years of age and older.
- COMIRNATY can also be used under the EUA for:
 - Individuals 12 through 15 years for a two-dose series
 - A third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

3rd Dose Recommendation

- Recommended for individuals who are considered moderately or severely immunocompromised and who have completed an mRNA vaccine series.
- 3rd dose should be administered 28 days or greater after 2nd dose
- mRNA recipients only; same product should be used
- This is not a booster shot intended for waning immunity. This is a 3rd dose for individuals who may not have had sufficient immune response after the primary 2-dose series.
- Should be postponed if COVID-19 monoclonal antibody therapy has been received in prior 90 days.

Moderately to Severely Immunocompromised:

- Been receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response

LHD name _____
LHD address _____

PEF label
DOCUMENT#: _____
HID/LOC/SITE: _____

3rd Dose COVID-19 VACCINE ADMINISTRATION RECORD

NAME: _____ ID/SOCIAL SECURITY#: _____

ADDRESS: _____

STREET CITY COUNTY STATE ZIP

BIRTHDATE: ____/____/____ PHONE NUMBER: _____
MONTH DAY YEAR

RACE: (Check ONE or MORE) (W) White (B) Black or African American (N) American Indian or Alaska Native*
 (A) Asian (H) Native Hawaiian or Other Pacific Islander ETHNICITY: Hispanic or Latino Yes or No

SEX: (Check ONE) Male Female How many in HOUSEHOLD: ____ Annual INCOME: \$ ____ Income NOT Given

DO YOU HAVE MEDICAID? YES* NO IF YES, MEDICAID NUMBER: _____

DO YOU HAVE MEDICARE? YES NO IF YES, MEDICARE NUMBER: _____

DO YOU HAVE HEALTH INSURANCE? YES NO* IF YES, COMPANY NAME: _____

Policy# _____ Subscriber Name _____ Group# _____

YOU or YOUR CHILD ARE LESS THAN 19yrs old AND HAVE HEALTH INSURANCE COVERAGE:

YES, the insurance does cover vaccines; NO, the insurance does not cover vaccines * ** VFC eligible*

The health department may keep this record in a medical file. They will record what vaccine was given, when the vaccine was given, the name of the company that made the vaccine, the vaccine's special lot number, the vaccine injection site, the signature and title of the person who gave the vaccine, and the address where the vaccine was given.

I have had a chance to ask questions that were answered to my satisfaction. I believe I understand the benefits and risks of COVID-19 vaccine and ask that the vaccine be given to me or to the person named above for whom I am authorized to make this request.

- I attest that I am immunocompromised and am eligible for a third dose of vaccine based on the criteria below
- Receiving active cancer treatment for tumors or cancers of the blood;
 - Received an organ transplant and am taking medicine to suppress my immune system;
 - Received a stem cell transplant within the last 2 years or am taking medicine to suppress the immune system;
 - Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, WiskottAldrich syndrome);
 - Advanced or untreated HIV infection;
 - Active treatment with high-dose corticosteroids or other drugs that suppress my immune response.

Having met the criteria, I am requesting the 3rd dose of (circle one) Pfizer or Moderna and it has been ____ days at least since my last dose of the (circle one) Pfizer or Moderna vaccine.

I request that payment of authorized medical insurance benefits be made to _____ on my behalf or behalf of my child, for services received. I also authorize the local health department to release medical information to Medicare, Other Third Payors (insurance carriers, Medicaid, etc.) and their agents to determine payment for services. I am aware that should Medicare refuse payment for this service, I will be responsible for the cost. If I am covered by a billable private insurance, I am aware that I may be responsible for some additional charges not covered by my plan.

X _____ DATE: _____
Signature of person to receive vaccine or person authorized to make the request (parent or legal guardian/representative)

FOR HEALTH DEPARTMENT USE ONLY

“Off-label” Use

- Use of an FDA-approved product outside of those that have been approved and authorized by FDA (age, indication, risk group, etc)
- Off-label use of FDA approved pharmaceuticals based on clinical judgement is not uncommon.
- For COVID-19 vaccines, off-label use includes:
 - Vaccination of children <12 years of age
 - 2nd dose of Janssen (J&J) vaccine
 - 3rd dose of mRNA vaccines for those who are not moderately immunocompromised

COVID-19 Vaccine Provider Agreement

- Providers are responsible for adhering to all requirements outlined in the agreement and must administer COVID-19 vaccines in accordance with all program requirements and recommendations of CDC, ACIP, and FDA.
- This applies to both EUA and FDA approved COVID-19 vaccines.
- Off-label use is not recommended. It would violate the provider agreement and could expose providers to the following risks:
 - May not be covered under the PREP Act or the PREP Act declaration; therefore, providers may not have immunity from claims.
 - Individuals who receive an off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event.
 - Providers giving off-label doses would be in violation of the CDC Program provider agreement potentially impacting their ability to remain a provider in the CDC program.
 - Administration fees may not be reimbursable by payers.

CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH

Andy Beshear
Governor

275 East Main Street, HS1WGA
Frankfort, KY 40621
502-564-3970
FAX: 502-564-9377
www.chfs.ky.gov/dph

Eric C. Friedlander
Secretary

Steven J. Stack, MD
Commissioner

August 18, 2021

Dear LTC and/or pharmacy provider:

Certain immunocompromising conditions, as well as advanced age and other physical infirmities, can affect an individual's immune response to vaccination. Current Centers for Disease Control (CDC) guidance recommends that individuals who are moderately to severely immunocompromised and who have been fully vaccinated with an mRNA vaccine 28 days or more prior should be offered a 3rd dose of vaccine.

Due to the age, condition, and high COVID-19 mortality rate of nursing home residents across the Commonwealth, I am deeming all residents of licensed nursing homes to be moderately to severely immunocompromised and therefore immediately eligible for a 3rd dose of vaccine under the current FDA EUA for these vaccines to increase their immunity to COVID-19.

All fully vaccinated residents of licensed nursing homes in Kentucky who have completed an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) at least 28 days ago **should be offered a 3rd dose of mRNA vaccine unless contraindicated** or they have received COVID-19 antibody therapy within the past ninety (90) days. This is consistent with CDC guidance based on recommendations from the CDC's Advisory Committee on Immunization Practices.

For additional information, please consult the 3rd dose FAQ attached.

Thank you for your care and support of our LTC residents in Kentucky.



Steven J. Stack, MD
Commissioner

Future Need for Booster Doses for General Public?

- Last week(8/18/2021) the CDC and White House announced an anticipated plan to begin providing booster doses to the general public starting 9/20/2021.
- This is contingent on FDA authorization and ACIP approval. ACIP will be meeting in the coming weeks to review updated vaccine effectiveness data.
- Anticipated schedule would be 8 months after completion of primary series, though schedule would be determined by FDA/ACIP.
- **No booster doses should be given to the general public at this time.**

RSV Update



Kentucky Public Health
Prevent. Promote. Protect.

Emergency Preparedness and Response

Resources for Emergency Health Professionals > Health Alert Network (HAN) > HAN Archive > 2021



Home Health Alert Network (HAN)

HAN Jurisdictions

HAN Message Types

Sign Up for HAN Updates

HAN Archive

2021

HAN00450

HAN00449

HAN00448

HAN00447

HAN00446

HAN00445

HAN00444

HAN00443

HAN00442

HAN00441

HAN00440

Increased Interseasonal Respiratory Syncytial Virus (RSV) Activity in Parts of the Southern United States



Distributed via the CDC Health Alert Network
 June 10, 2021, 1:30 PM ET
 CDCHAN-00443

Summary

The Centers for Disease Control and Prevention (CDC) is issuing this health advisory to notify clinicians and caregivers about increased interseasonal respiratory syncytial virus (RSV) activity across parts of the Southern United States. Due to this increased activity, CDC encourages broader testing for RSV among patients presenting with acute respiratory illness who test negative for SARS-CoV-2, the virus that causes COVID-19. RSV can be associated with severe disease in young children and older adults. This health advisory also serves as a reminder to healthcare personnel, childcare providers, and staff of long-term care facilities to avoid reporting to work while acutely ill – even if they test negative for SARS-CoV-2.

Background

RSV is an RNA virus of the genus *Orthopneumovirus*, family *Pneumoviridae*, primarily spread via respiratory droplets when a person coughs or sneezes, and through direct contact with a contaminated surface. RSV is the most common cause of bronchiolitis and pneumonia in children under one year of age in the United States. Infants, young children, and older adults with chronic medical conditions are at risk of severe disease from RSV infection. Each year in the United States, RSV leads to on average approximately 58,000 hospitalizations¹ with 100-500 deaths among children younger than 5 years old² and 177,000 hospitalizations with 14,000 deaths among adults aged 65 years or older.³

In the United States, RSV infections occur primarily during the fall and winter cold and flu season. In April 2020, RSV activity decreased rapidly, likely due to the adoption of public health measures to reduce the spread of COVID-19.⁴ Compared with previous years, RSV activity remained relatively low from May 2020 to March 2021. However, since late March, CDC has observed an increase in RSV detections reported to the National Respiratory and Enteric Virus Surveillance System (NREVSS)



Search All AAP

Interim Guidance for Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the Current Atypical Interseasonal RSV Spread

Home / Critical Updates on COVID-19 / COVID-19 Interim Guidance / Interim Guidance for Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the Current Atypical Interseasonal RSV Spread



Respiratory syncytial virus (RSV) causes annual epidemics of acute respiratory illnesses in children, ranging from mild upper respiratory tract infections to severe lower respiratory tract disease including bronchiolitis or pneumonia. Severe RSV disease occurs primarily in infants younger than 6 months during their first fall and winter season of life.

RSV activity in the United States usually begins in the fall and extends through spring; peak activity typically occurs in early February, although there can be regional variation.¹ Following the institution of nonpharmacologic interventions (eg, masking, social distancing) for the prevention of COVID-19 in March of 2020, the number of RSV infections in the United States decreased rapidly and dramatically.² Interactions between SARS-CoV-2 and other respiratory viruses may have also altered RSV epidemiology. RSV activity in the United States remained very low through the traditional 2020-2021 fall-winter season but began to increase in the spring of 2021.³ This interseasonal increase in activity is a marked deviation from the typical RSV epidemiology and is believed to be the result of the relaxation of nonpharmacologic interventions that were previously implemented to prevent the spread of SARS-CoV-2. Consequently, RSV activity is on the rise in certain regions of the United States, with corresponding increases in emergency department visits and hospitalizations of infants and children. It is unknown whether the current circulation of RSV in the United States will spread equally to all regions and increase to typically seen fall-winter levels of activity. It is also unclear how long this activity will persist.⁴

Update on COVID-19 Vaccines in Kentucky

Emily Messerli DNP, APRN, FNP-C



Kentucky Public Health
Prevent. Promote. Protect.

Current Data – New site

<https://govstatus.egov.com/ky-covid-data-dashboard>

Messaging on Fraudulent Use of COVID Vaccine Cards

- Falsifying CDC COVID vaccination cards is a federal crime.
- Keep vaccination cards in a secure location.
- Be mindful of how you dispose of COVID-19 materials such as syringes, vials, vial container boxes, vaccination record cards, and shipment or tracking records. Improper disposal of these items could be used by bad actors to commit fraud.
- Educate patients not to share personal information or share completed vaccination cards on social media. This information is used to scam money from vaccine recipients.

Messaging on Fraudulent Use of COVID Vaccine Cards

- Report suspicious activity to:
 - HHS-OIG Hotline: 1-800-HHS-TIPS | tips.hhs.gov
 - FBI Hotline: 1-800-CALL-FBI | ic3.gov
 - CMS/Medicare Hotline: 1-800-MEDICARE

- Additional information can be found at:
HHS Office of Inspector General www.oig.hhs.gov

ACIP Findings-Additional vs Booster Dose

- Additional vs Booster Dose
 - Additional dose after an initial primary vaccine series: administration of an additional vaccine dose when the initial immune response following a primary vaccine series is likely to be insufficient.
 - Booster dose: a dose of vaccine when the initial sufficient immune response to a primary vaccine series is likely to have waned over time. The need for and timing of a COVID-19 booster dose has not been established.

- For more information, visit:
 - <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>
 - <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html>

Storage & Handling Reminders

Pfizer

- Ultra cold storage up to the expiration date
- Freezer storage: -13°F to +5°F (-25°C to -15°C) for up to 2 weeks (14 days)
- Refrigerator storage: 36°F to 46°F (2°C to 8°C) for up to 1 month (31 days)
 - Once punctured all doses must be used within **6 hours**

Moderna

- Freezer storage: -58°F to +5°F (-50°C to -15°C) up to the expiration date
- Refrigerator storage: 36°F to 46°F (2°C to 8°C) for up to 30 days
 - Once punctured they can be stored at temps between 36°F and 77°F
 - All doses must be used within **2 hours**

J&J/Janssen

- Refrigerator storage: 36°F to 46°F (2°C to 8°C) up to the expiration date
 - Once punctured
 - **6 hours if stored at 36°F to 46°F**
 - **2 hours if stored at 47°F to 77°F**

<https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/janssen-storage-handling-summary.pdf>

Thank you

Emily.Messerli@ky.gov

Long Term Care Update

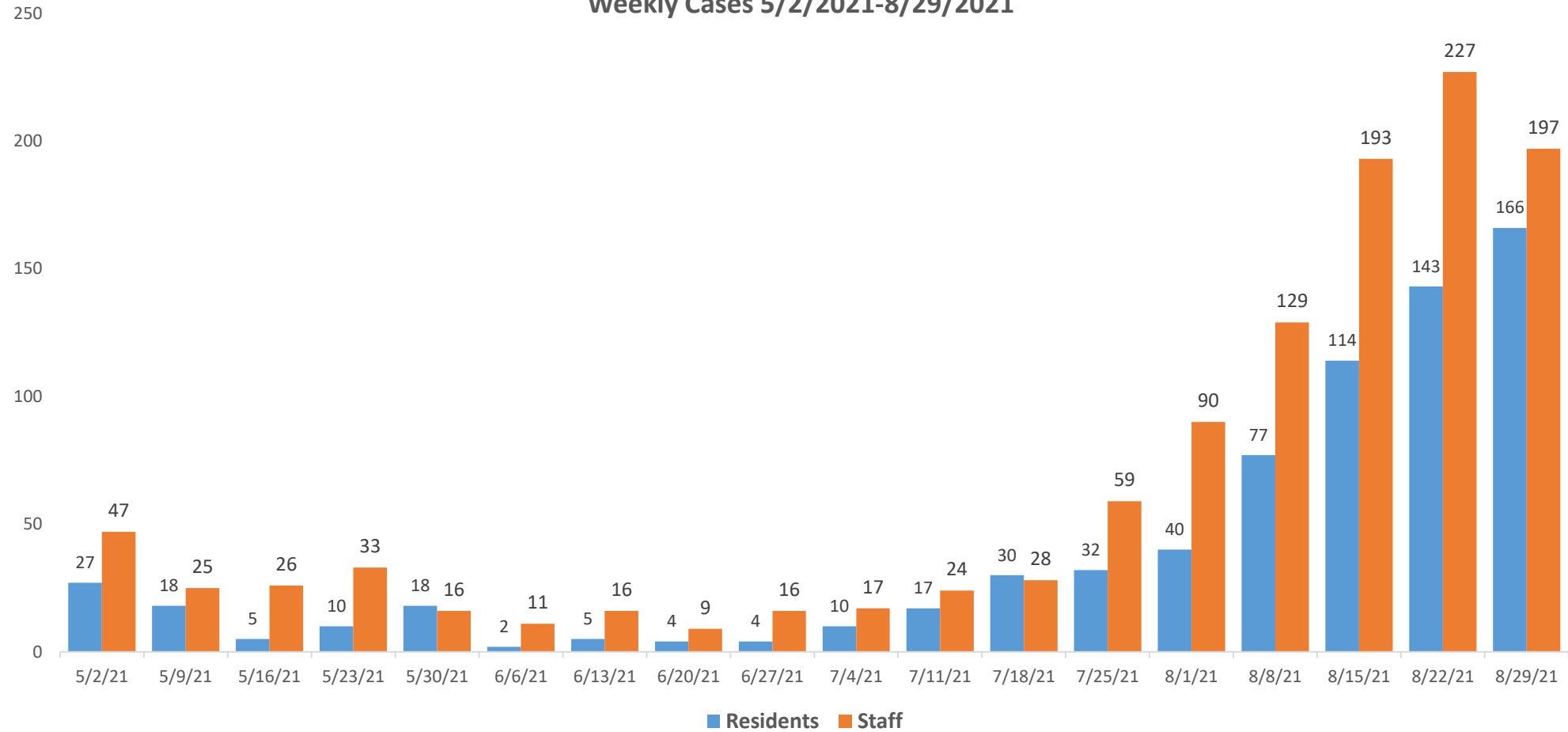
Andrea Flinchum, MPH, BSN, RN,
CIC, FAPIC



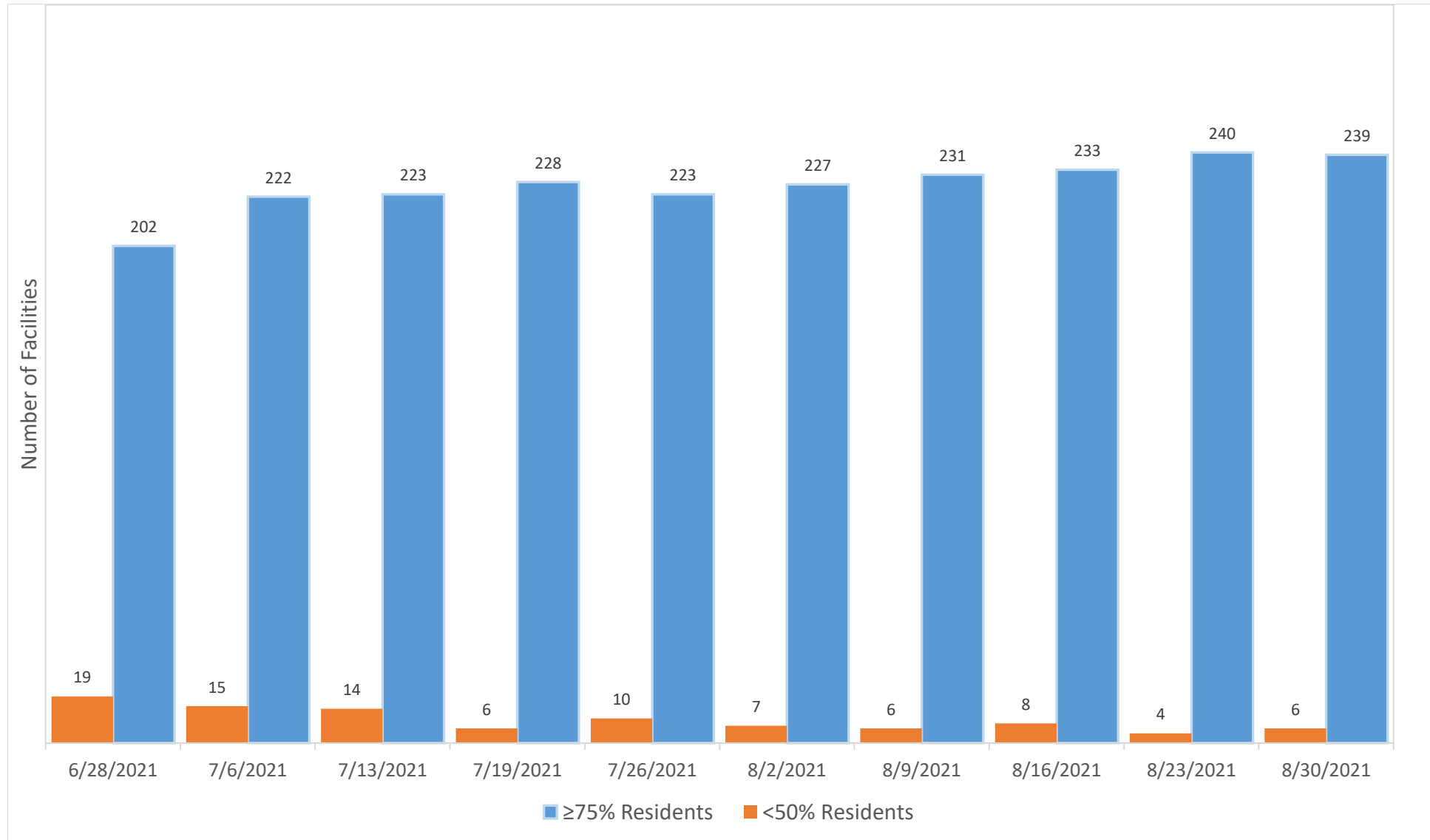
Kentucky Public Health
Prevent. Promote. Protect.

New COVID-19 Cases in LTC Facilities

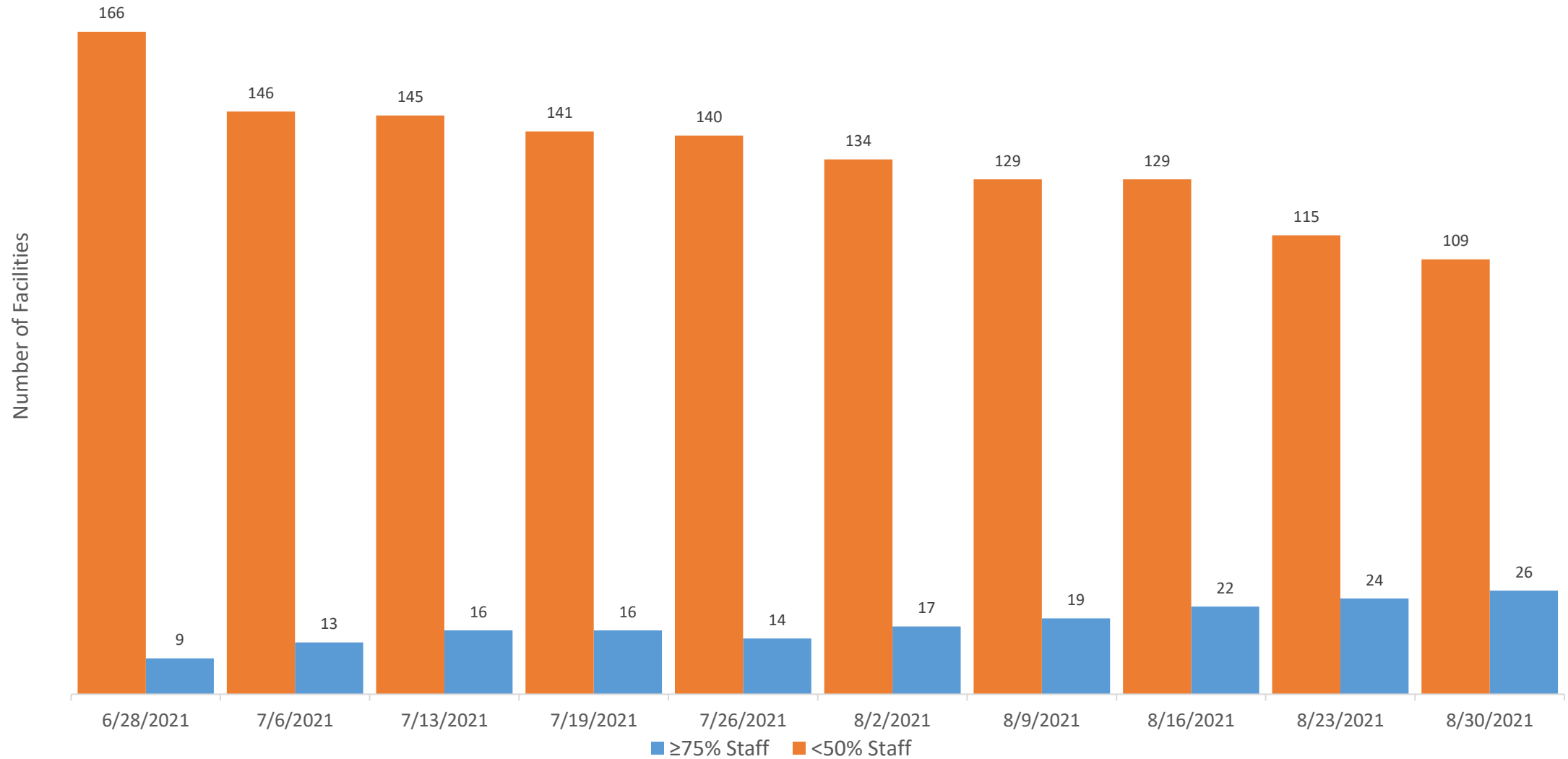
Long Term Care Facilities
Weekly Cases 5/2/2021-8/29/2021



Fully Vaccinated Residents in KY LTC Facilities



Fully Vaccinated Staff in LTC Facilities



Long Term Care Support

- Reinvigorated the Nurse Strike Team for Long Term Care facilities who are experiencing staffing crisis secondary to COVID-19
 - 2 Nurses and 4 Certified Nursing Assistants
- Facilities need to notify their Emergency Manager in their county/region so the request can be entered into WebEOC
- Request will be evaluated, follow-up call will be made to the facility, will need 72 hours to deploy team
- Questions – Andrea Flinchum at email andrea.Flinchum@ky.gov
Ruth Belflower at email ruth.belflower@ky.gov

Next KY COVID-19 Healthcare & Public Health Webinar

Date: October 19, 2021

Time: 11:30 EST



Kentucky Public Health
Prevent. Promote. Protect.

Question and Answer Time



Kentucky Public Health
Prevent. Promote. Protect.

Thank you!

***Bookmark your calendar for the next
Kentucky COVID-19 Clinical/Public Health Update!
Date: October 19, 2021***



Kentucky Public Health
Prevent. Promote. Protect.