CDC/IDSA Clinician Call

March 14, 2024

Welcome & Introductions

Dana Wollins, DrPH, MGC
Senior Vice President, Strategy
Infectious Diseases Society of America

- About the Clinician Call: Initiated in 2020 as a forum for information sharing among frontline clinicians caring for patients with COVID-19. Now expanded to address timely topics in infectious diseases—all from a clinical perspective.
- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.
- This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.

Updates on CDC's New Respiratory Virus Guidance, COVID Antivirals & the Emergence of Clade I Mpox

COVID-19 Real-Time Learning Network

Brought to you by CDC and IDSA

1. Clade-1 Monkeypox Virus – Informational Update and U.S. Preparedness

Agam Rao, MD, FIDSA
CAPT, U.S. Public Health Service
Medical Officer
Poxvirus and Rabies Branch
U.S. Centers for Disease Control & Prevention

2. CDC's New Respiratory Virus Guidance

Brendan Jackson, MD, MPH
CDR, U.S. Public Health Service
Lead, Respiratory Viruses Response
U.S. Centers for Disease Control & Prevention

3. COVID-19 Antivirals: Closing the Treatment Gap

COVID-19 Epidemiology Update
Pragna Patel, MD, MPH
Chief Medical Officer
Coronavirus & Other Respiratory Viruses Division
National Center for Immunization & Respiratory Diseases
U.S. Centers for Disease Control & Prevention

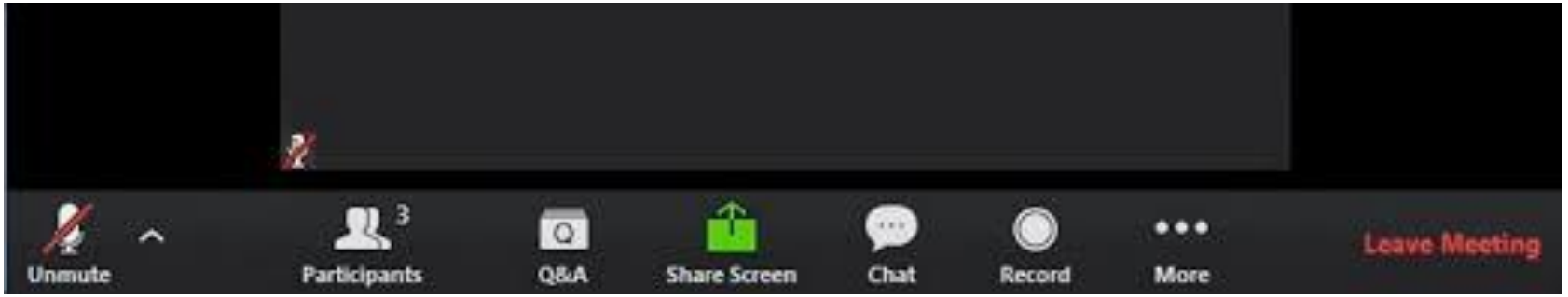
Real-World Effectiveness of COVID-19 Antivirals: The Latest Data
Therese Tripler, PhD
Scientific Program Manager
National Center for Advancing Translational Sciences
National Institutes of Health

Closing the Treatment Gap Clinical Considerations
Peter V. Chin-Hong, MD
Professor of Medicine and
Associate Dean for Regional Campus
Director, Transplant and Immunocompromised Host Infectious Disease Program
University of California, San Francisco

4. Q&A/Discussion

Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button



Clade-1 Monkeypox Virus – Informational Update and U.S. Preparedness

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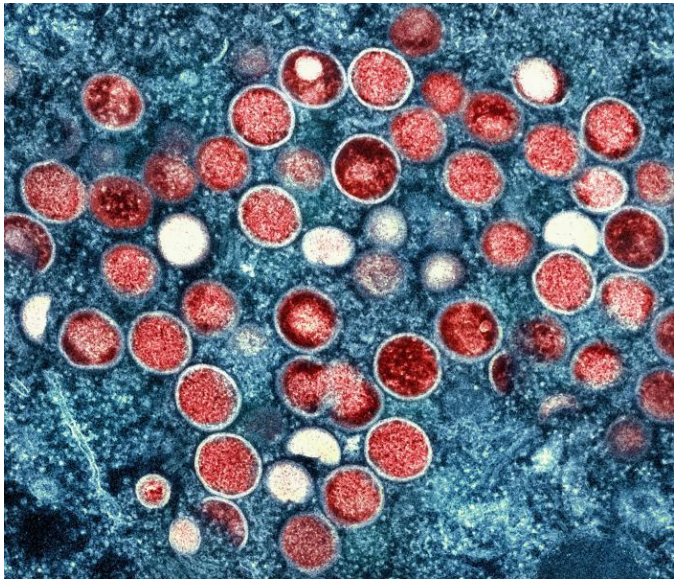
Clade I Monkeypox virus—Informational Update and U.S. Preparedness



Agam Rao, MD

CAPT, US Public Health Service

Poxvirus and Rabies Branch

Centers for Disease Control and Prevention

CDC/IDSA Clinician Call

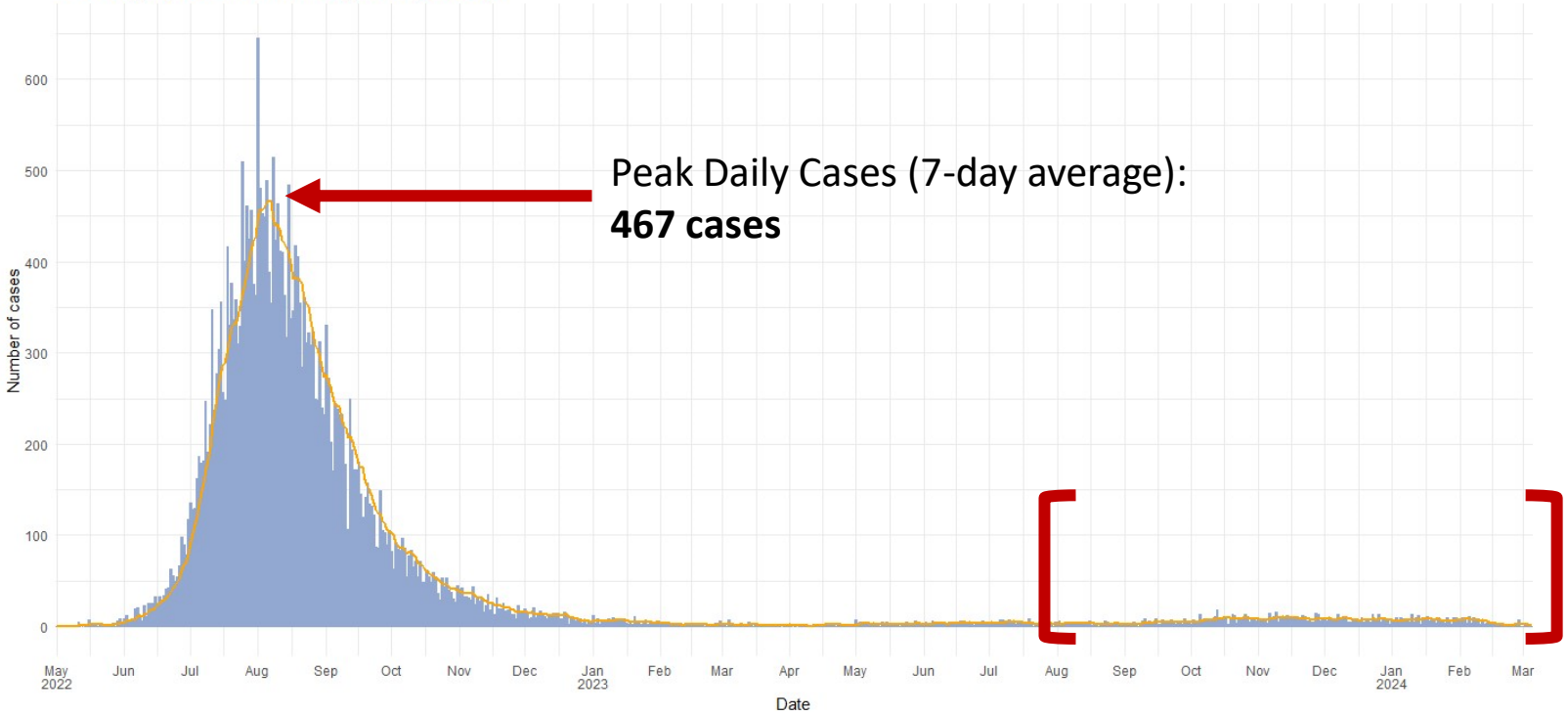
March 14, 2024

Global Monkeypox virus (MPXV) Clade II outbreak, 2022-present

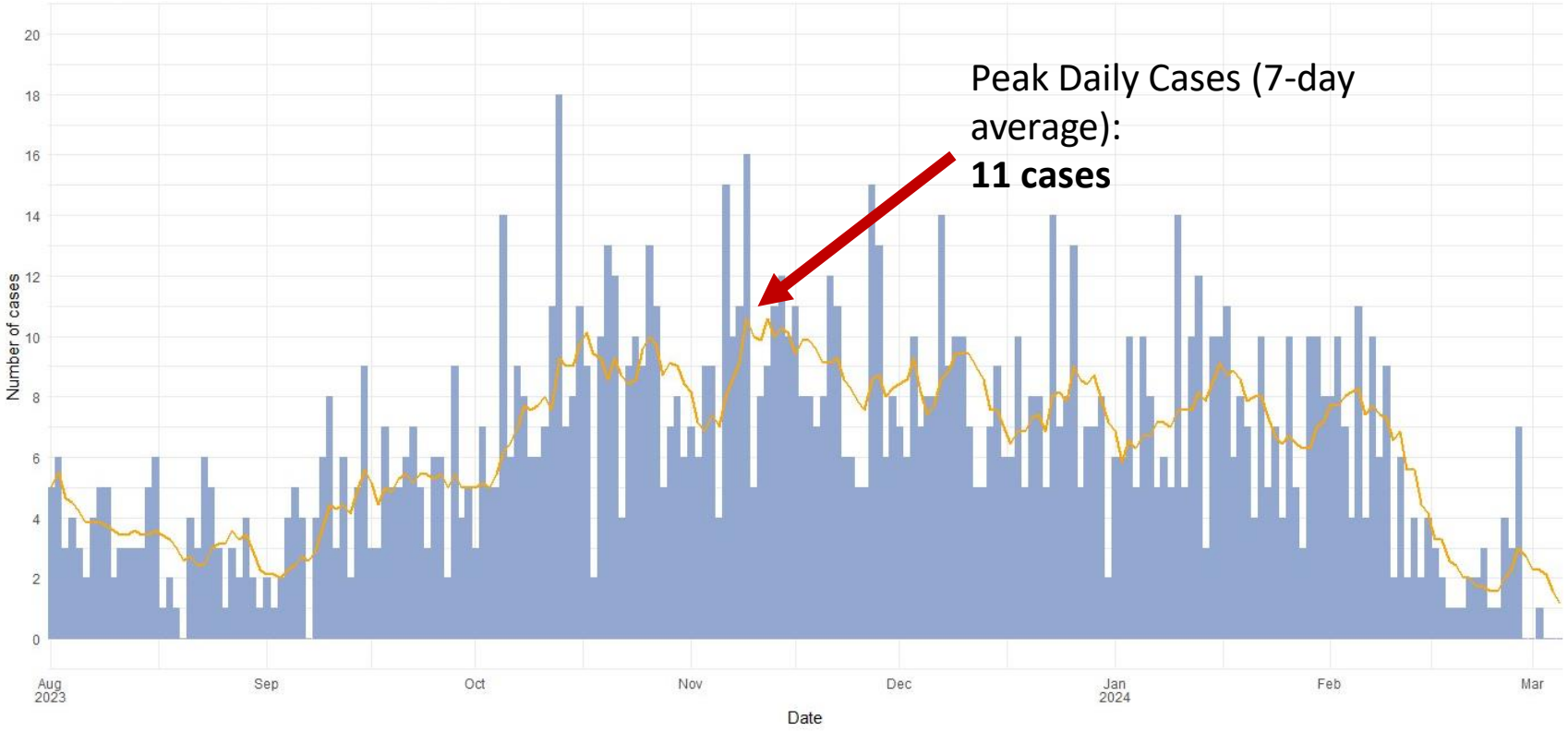
- Associated with Clade II which is endemic in certain African countries
- First U.S. cases associated with travel
- Primarily affecting gay, bisexual, and other men who have sex with men (MSM); transgender and nonbinary persons
- Associated with person-to-person spread via close skin-to-skin contact (including sex)
- Deaths have occurred, primarily among persons with severe immunocompromise from advanced HIV
- U.S. case counts and deaths comprising more than a third of global cases
  - >32,000 U.S. cases
  - 58 U.S. deaths

Clade II MPXV: Countries historically known to be endemic

Mpox Clade II Epi-Curve—United States, 2022-present



U.S. Clade II cases continue to occur



Recommendations of the Advisory Committee on Immunization Practices—October 25, 2023

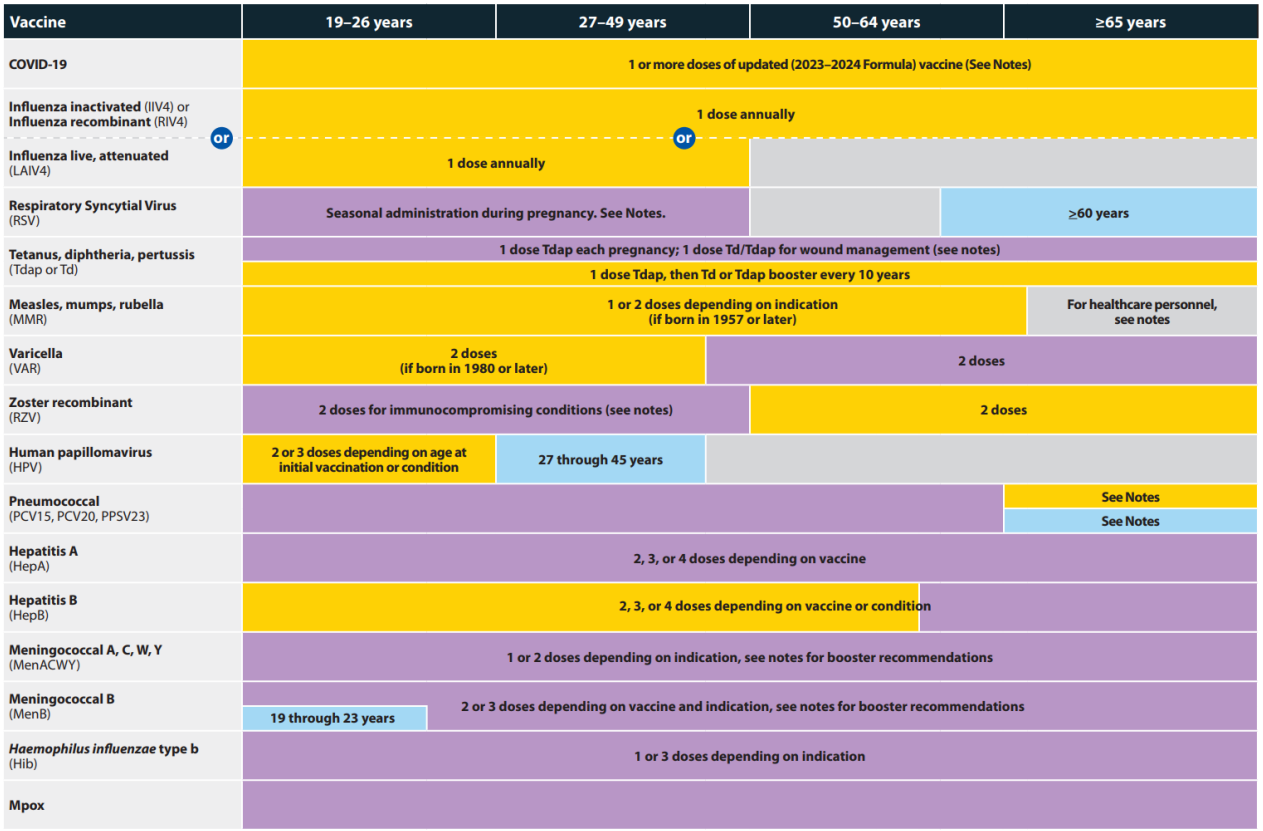
ACIP recommends vaccination with the 2-dose JYNNEOS vaccine series for persons aged 18 years and older at risk for mpox¶

¶Persons at risk

- 1. Gay, bisexual, and other men who have sex with men, 2. transgender people or 3. nonbinary people who, in the past 6 months, have had one of the following
  - New diagnosis of ≥ 1 sexually transmitted disease
  - More than one sex partner
  - Sex at a commercial venue
  - Sex in association with a large public event in a geographic area where mpox transmission is occurring
- Sexual partners of persons with the risks described above
- Persons who anticipate experiencing any of the above

Mpox vaccine on routine immunization schedule

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2024



Mpox vaccination

Special situations

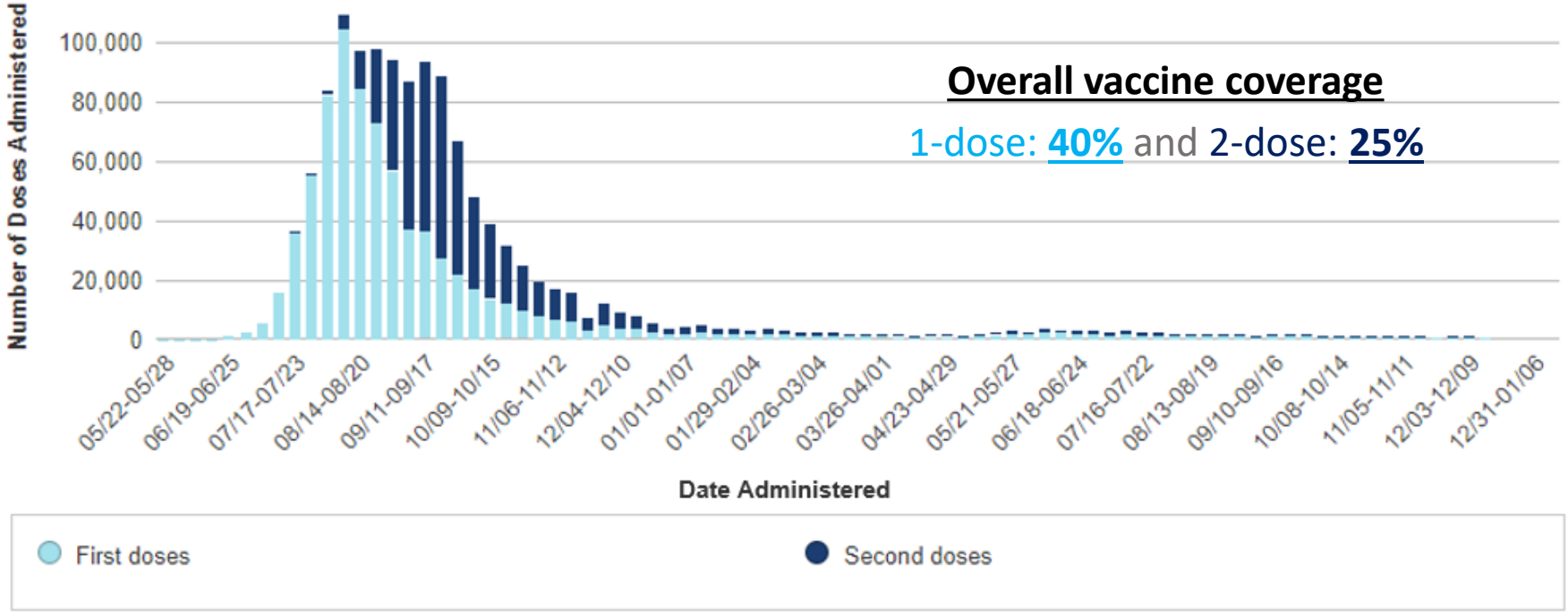
- **Any person at risk for Mpox infection:** 2-dose series, 28 days apart.

Risk factors for Mpox infection include:

- Persons who are gay, bisexual, and other MSM, transgender or nonbinary people who in the past 6 months have had:
  - A new diagnosis of at least 1 sexually transmitted disease
  - More than 1 sex partner
  - Sex at a commercial sex venue
  - Sex in association with a large public event in a geographic area where Mpox transmission is occurring
- Persons who are sexual partners of the persons described above
- Persons who anticipate experiencing any of the situations described above

www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

U.S. JYNNEOS Administration Data, 2022-2024*



Overall vaccine coverage

1-dose: **40%** and 2-dose: **25%**

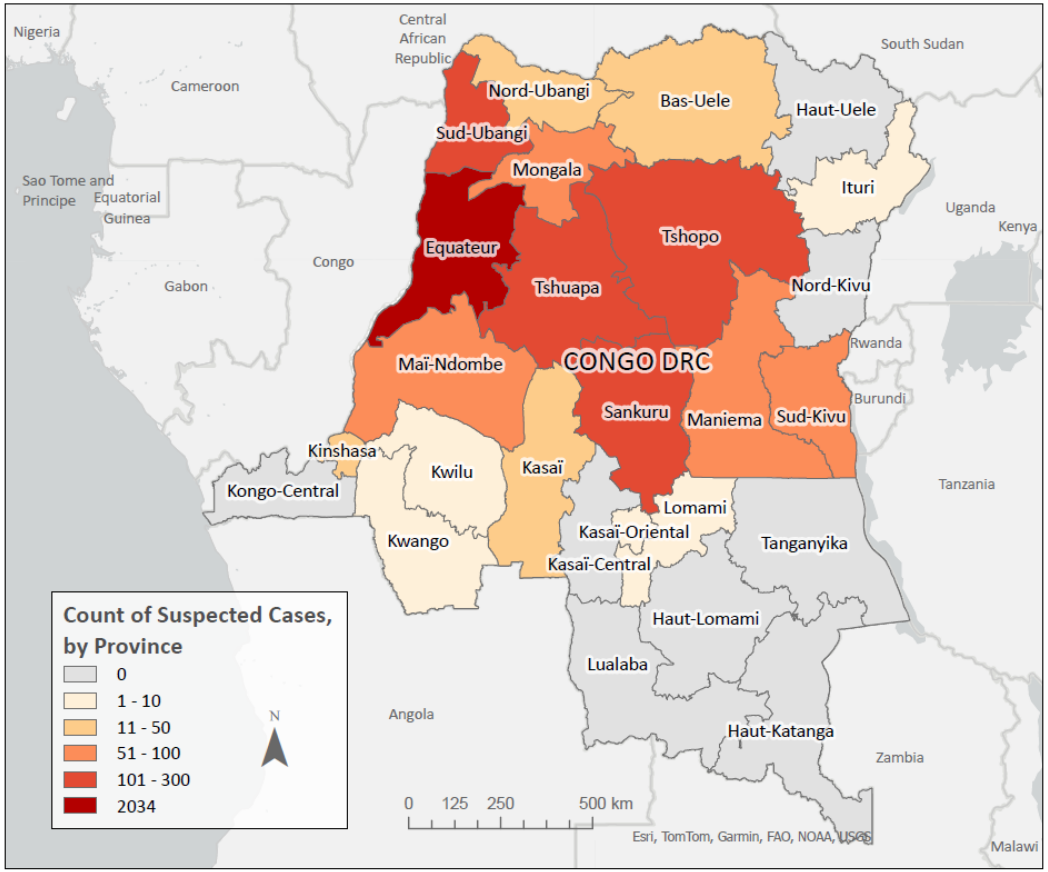
*Data reported to CDC between May 22, 2022 and January 9, 2024

Clade I MPXV

At this time, NO Clade I cases identified outside of countries known to be endemic for this MPXV clade

Clade I MPXV: Countries historically known to be endemic

Ongoing Clade I outbreak: Democratic Republic of Congo



- Identified in parts of the country without previous cases
- Some cases associated with sex; however, both genders involved
- Children most affected

Ongoing suspected* Clade I outbreak—Democratic Republic of Congo

Year	Suspected Cases	Suspected Deaths
2021	2,497	68
2022	5,697	234
2023	14,626	654
2024 Total (Week 9)*	3,576 (+365)	265 (+25)

*Most cases are based on clinical suspicion; only a fraction of cases are laboratory-confirmed

§ Preliminary data for weeks 1-9 and subject to change. Note cases numbers reported in previous epi weeks may increase or decrease in the current week's data. This can result in changes in the cumulative number of cases reported. Additional investigation is underway.

	Ways in which both clades are similar
Clinical presentation	Firm, deep-seated, sometimes umbilicated lesions; presents along a clinical continuum (mild to severe)
Transmission of virus	Contact with skin lesions, fomites, respiratory secretions (e.g., via kissing)
Diagnostic testing	FDA cleared non-variola orthopoxvirus (NVO) test used by many laboratories
Hospital waste management	Category B*
IPC for healthcare providers	Gown, gloves, eye protection, N-95; in addition to standard precautions, suspected mpox infections have additional IPC precautions
Patient management	Dependent on severity of illness or potential for severe illness
Use of JYNNEOS vaccine and therapeutics	Expected to be effective regardless of clade

*https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2024-03/PHMSA%20Safety%20Advisory%20Notice%20-%20Classification%20of%20MPXV%20Diagnostic%20Samples%20and%20Waste.pdf

§ https://www.cdc.gov/poxvirus/mpox/clinicians/infection-control-healthcare.html

	Ways in which Clade I cases differ from Clade II
Populations impacted	Might not affect predominantly MSM; uncertain if other populations could be impacted
Clinical presentation	More of the severe cases *could* occur: disseminated lesions, prodromal symptoms, hospitalization
Diagnostic testing	Clade II specific testing available in some labs but not others
IPC for healthcare providers	Patients may shed more virus; adherence to IPC practices* particularly important

*https://www.cdc.gov/poxvirus/mpox/clinicians/infection-control-healthcare.html

Interim clinical guidance for severe MPXV infections (regardless of Clade)

- Tecovirimat (intravenous or oral)
- Brincidofovir or cidofovir
- Vaccinia immune globulin intravenous
- Trifluridine ophthalmic solution

- CDC, through health departments, available for consultations for severe mpox (i.e., involving patients with severe immunocompromise)


CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™
Search
Morbidity and Mortality Weekly Report (*MMWR*)

Interim Clinical Treatment Considerations for Severe Manifestations of Mpox — United States, February 2023

Weekly / March 3, 2023 / 72(9);232–243

Please note: This report has been corrected.

Agam K. Rao, MD[1]; Caroline A. Schrodt, MD[1]; Faisal S. Minhaj, PharmD[1,2]; Michelle A. Waltenburg, DVM[3]; Shama Cash-Goldwasser, MD[2]; Yon Yu, PharmD[4]; Brett W. Petersen, MD[1]; Christina Hutson, PhD[1]; Inger K. Damon, MD, PhD[3] (VIEW AUTHOR AFFILIATIONS)

https://www.cdc.gov/mmwr/volumes/72/wr/mm7209a4.htm?s_cid=mm7209a4_w

CDC's preparedness messaging*

- Remain vigilant to Clade II MPXV: it has never gone away
  - Continue to include MPXV on differential for consistent rash, particularly in the setting of epidemiologic risk factors
  - Encourage vaccinations for eligible persons during clinic appointments
- Regardless of clade, treatment is dependent on severity of infection
- At this time, no Clade I cases outside of endemic countries
- If cases identified in U.S., characterization of illnesses and additional guidance (including regarding vaccinations) will be provided

Mpox Caused by Human-to-Human Transmission of Monkeypox Virus with Geographic Spread in the Democratic Republic of the Congo

Print

HAN HEALTH ALERT NETWORK

This is an official CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
December 7, 2023, 10:45 AM ET
CDCHAN-00501

Summary

The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Advisory to notify clinicians and health departments about the occurrence, geographic spread, and sexually associated human-to-human transmission of Clade I Monkeypox virus (MPXV) in the Democratic Republic of the Congo (DRC). MPXV has two distinct

*https://emergency.cdc.gov/han/2023/han00501.asp

Additional guidance

- For patients with mpox and a history of recent travel to DRC, contact public health authorities as soon as possible so that Clade specific testing can be expedited
- Regardless, clade specific testing is occurring for most positive specimens in the United States; CDC is collaborating with many private and public health laboratories

Thank you

poxvirus@cdc.gov

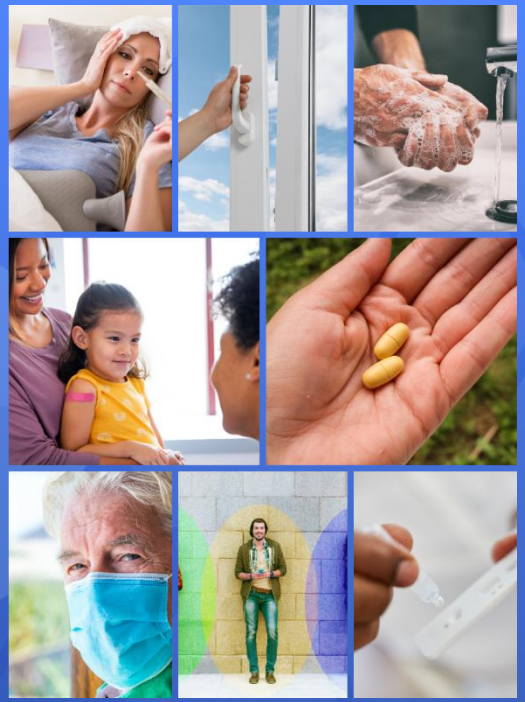
For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

CDC's New Respiratory Virus Guidance

Brendan Jackson, MD, MPH
CDR, U.S. Public Health Service
Lead, Respiratory Viruses Response
U.S. Centers for Disease Control & Prevention

Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases



Respiratory Virus Guidance

Brendan Jackson, MD, MPH
Respiratory Viruses Response

NCIRD
National Center for Immunization and Respiratory Diseases

Goals of the Respiratory Virus Guidance

To provide streamlined guidance built on effective strategies so that more people take action to prevent respiratory disease.

Provide **practical** recommendations that are clear and actionable

Streamline guidance across common respiratory virus illnesses

Highlight strategies that **effectively reduce risk**

Balance current, post-emergency risks with other health and societal needs

The COVID-19 Threat has Changed

DRIVERS

Effective vaccines and treatments

Each cut the risk of severe disease in half

Broad immunity

>98% of US population now has some protective immunity from vaccination, prior infection, or both, BUT this subscription needs to be renewed with updated vaccines

Other effective tools

Masks, hygiene, steps for cleaner air, tests

RESULTS

Fewer hospitalizations

Weekly hospital admissions down >75% from Jan 2022 peak; now in range of flu; 95% of people hospitalized with COVID-19 not up to date on vaccine

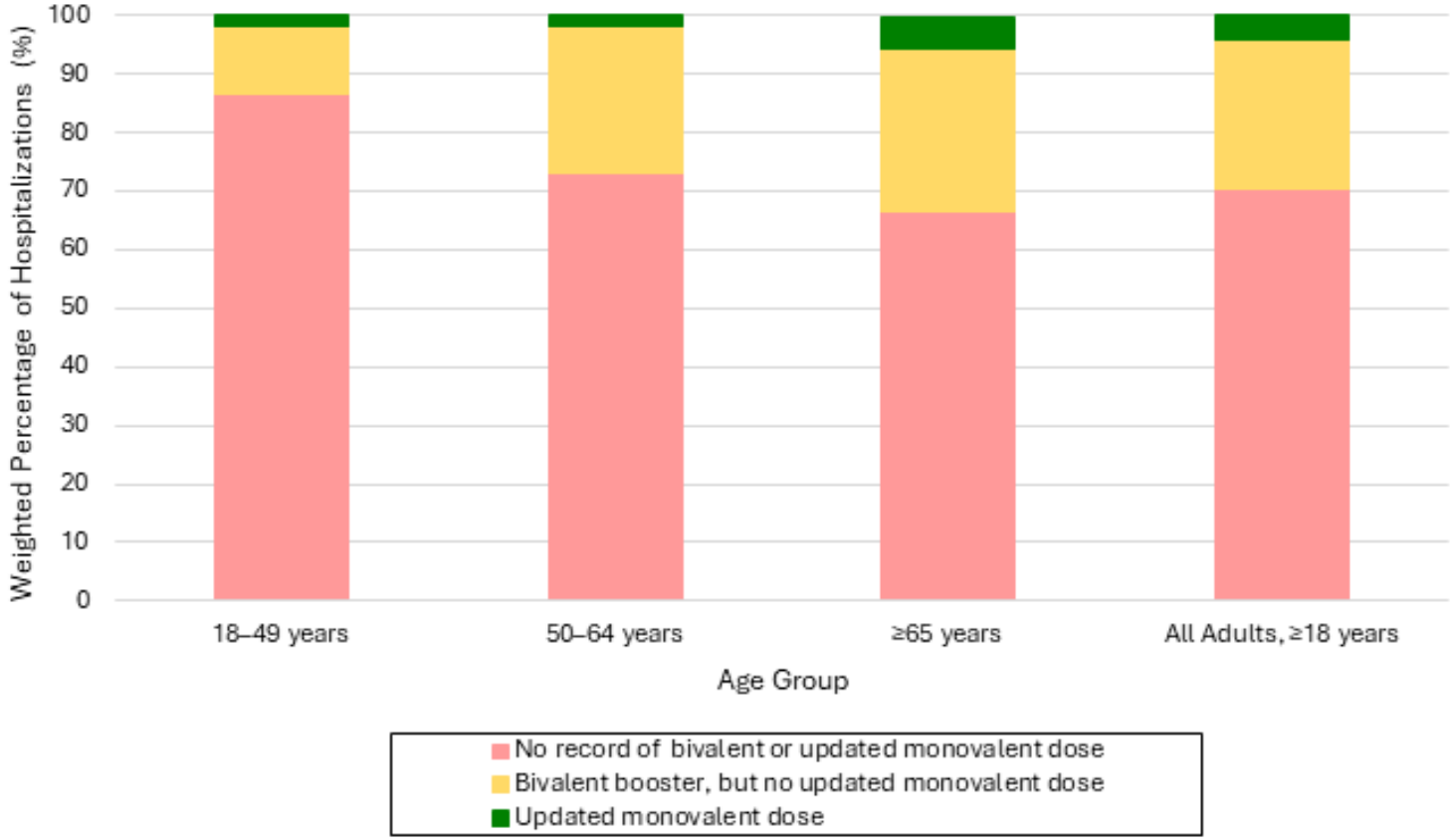
Fewer deaths

COVID-19 went from the 3rd leading cause of death in 2021 to 10th in 2023

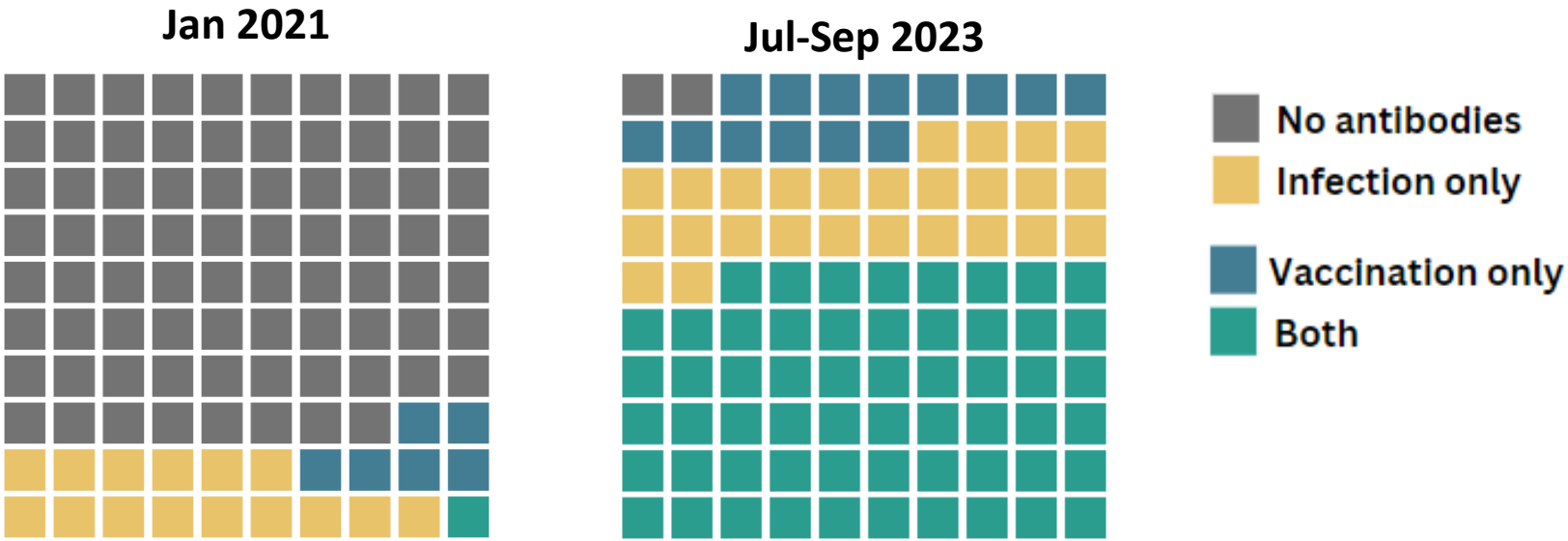
Fewer cases of other complications

Multisystem inflammatory syndrome in children (MIS-C) and Long COVID are now also less common

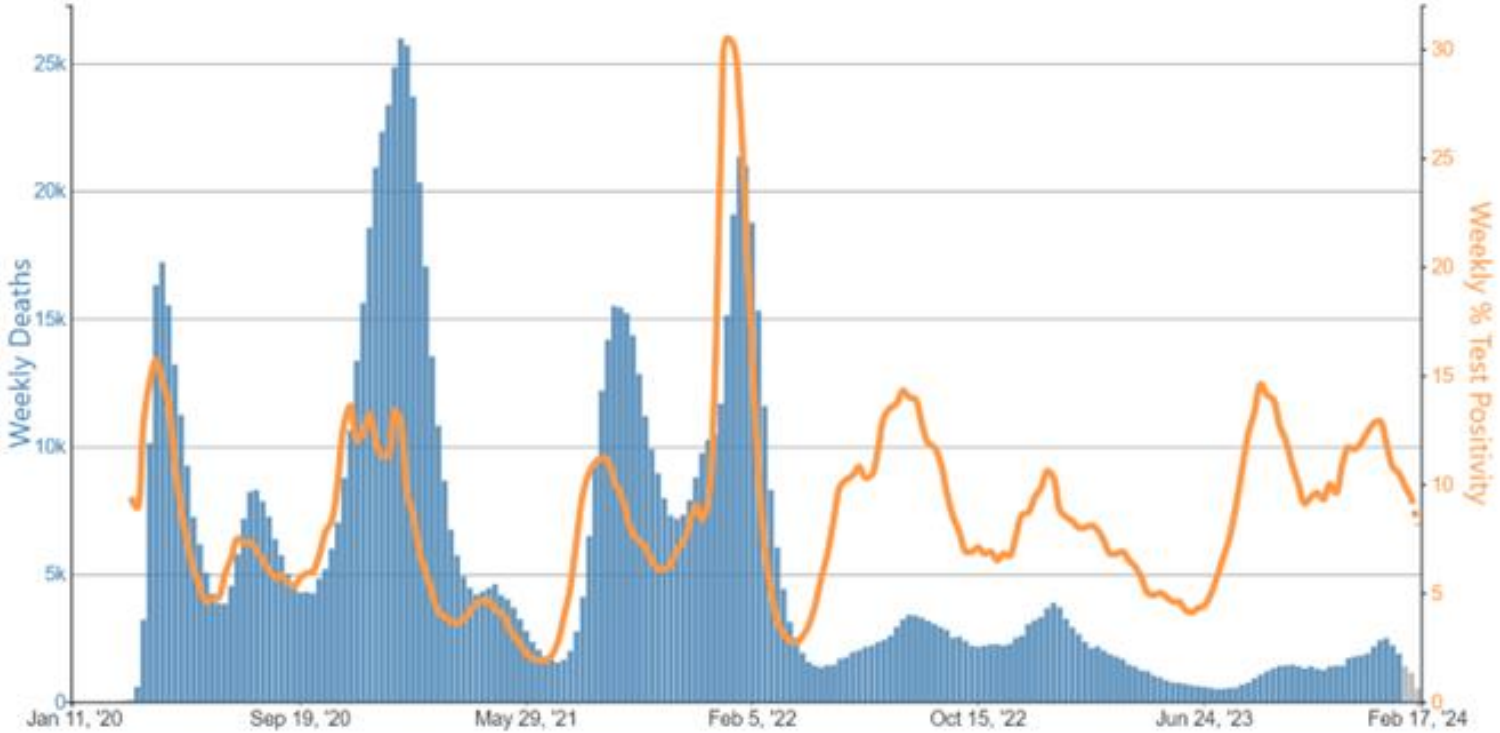
Vaccination Protects Against Severe Outcomes



>98% of the US population now has some protective immunity



COVID-19 test positivity has remained elevated, but deaths have declined substantially



Provisional COVID-19 Deaths and COVID-19 Nucleic Acid Amplification Test (NAAT) Percent Positivity, by Week, in The United States, Reported to CDC.
Sources: *Provisional Deaths from the CDC's National Center for Health Statistics (NCHS) National Vital Statistics System (NVSS) National Respiratory and Enteric Virus Surveillance System (NREVSS) Figure from CDC's COVID Data Tracker.*

CDC's Respiratory Virus Guidance provides **practical recommendations and information** to help people lower health risks posed by a range of common respiratory viral illnesses.

It includes **core** and **additional prevention strategies**.

Respiratory Virus Guidance Snapshot

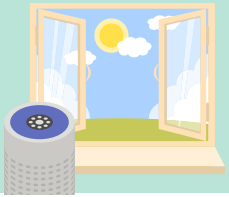
CORE STRATEGIES

Core prevention strategies

Immunizations

Hygiene

Steps for Cleaner Air



Treatment

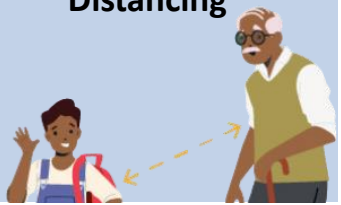
Stay Home and Prevent Spread*

ADDITIONAL STRATEGIES

Additional prevention strategies

Masks

Distancing



Tests

Layering prevention strategies can be especially helpful when:

- ✓ Respiratory viruses are causing a lot of illness in your community
- ✓ You or those around you have risk factors for severe illness
- ✓ You or those around you were recently exposed, are sick, or are recovering

***Stay home and away from others until, for 24 hours BOTH:**

Your symptoms are getting better

+

You are fever-free (without meds)

Then take added precaution for the next **5 days**

Have respiratory virus symptoms that aren't better explained by another cause?

1

Stay home and away from others

When, for 24 hours, both your symptoms are improving overall **and** you haven't had a fever (without fever-reducing medicine), you can move to the next step.

2

Resume normal activities <u>taking precaution</u> for the next 5 days

such as taking additional steps for cleaner air and/or hygiene, masks, physical distancing, and/or testing when you will be around other people indoors.

Test positive for a respiratory virus but you have no symptoms?

1

<u>Take precaution</u> for the next 5 days

such as taking additional steps for cleaner air and/or hygiene, masks, physical distancing, and/or testing when you will be around other people indoors.

Risk Factors for Severe Illness Pages

- In addition to the general Respiratory Virus Guidance, there are several special consideration pages related to people with certain risk factors for severe illness:
  - Older Adults
  - Young Children
  - People with Weakened Immune Systems
  - Pregnant Persons
  - People with Disabilities

...

Thank You

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COVID-19 Antivirals: Closing the Treatment Gap

COVID-19 Epidemiology Update

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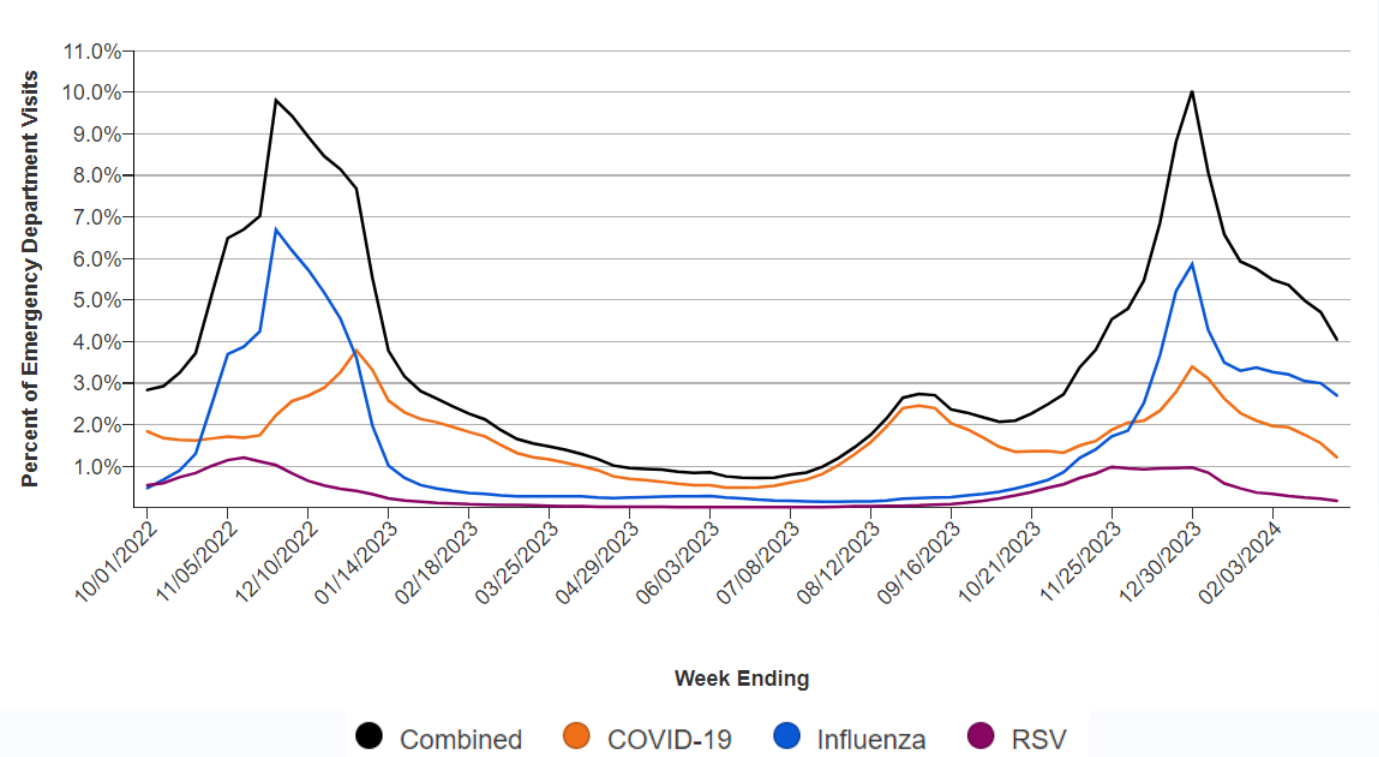
U.S. Centers for Disease Control & Prevention

Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases

COVID-19 Epidemiology

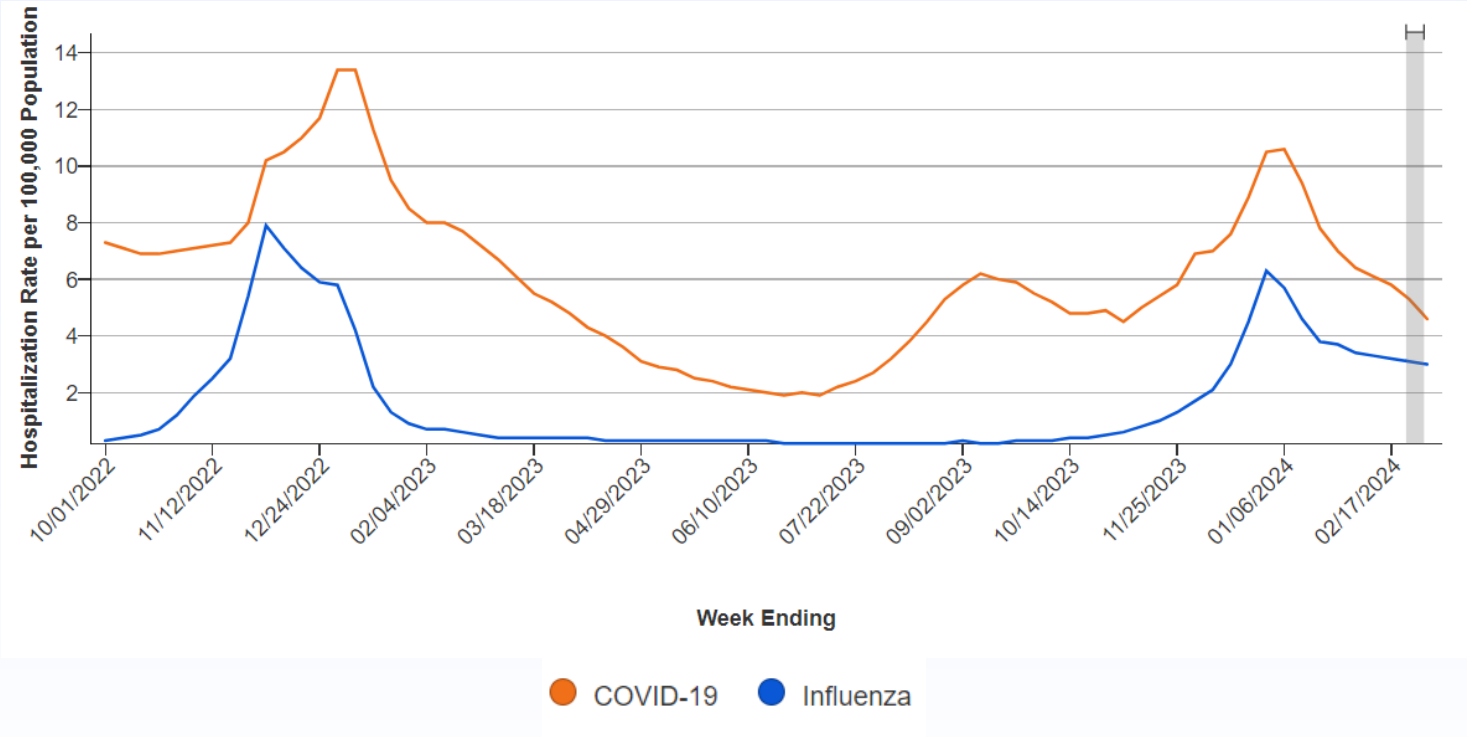
Pragna Patel, MD MPH
Chief Medical Officer
March 14, 2024

Emergency Department Visits for Viral Respiratory Illness
October 1, 2022 to March 2, 2024



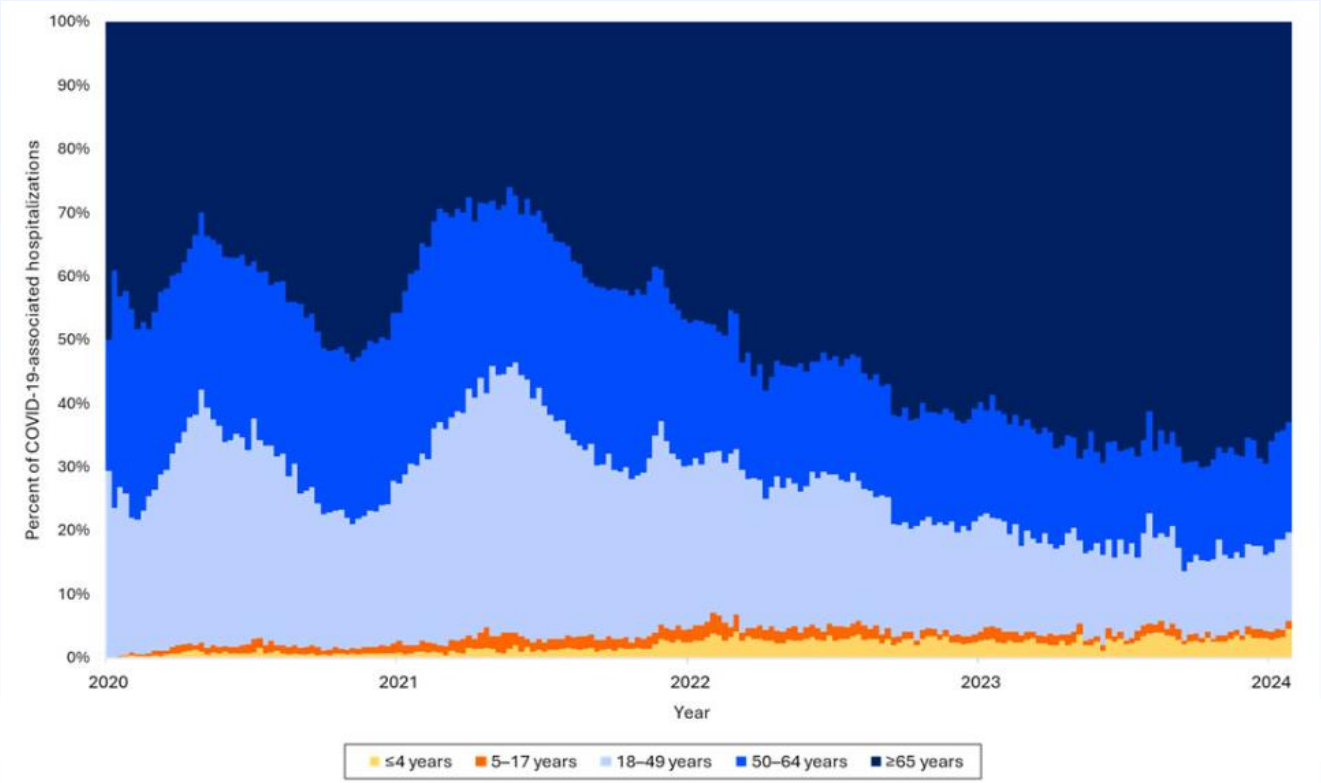
Total number of new hospital admissions of patients with laboratory-confirmed COVID-19 and influenza in the previous week (including both adult and pediatric patients), reported to CDC's National Healthcare Safety Network (NHSN); data as of 3/6/24, data through 3/2/24. Respiratory Virus Data Channel Weekly Snapshot (cdc.gov)

Hospital Admissions Due to COVID-19 and Influenza
October 1, 2022 to March 2, 2024



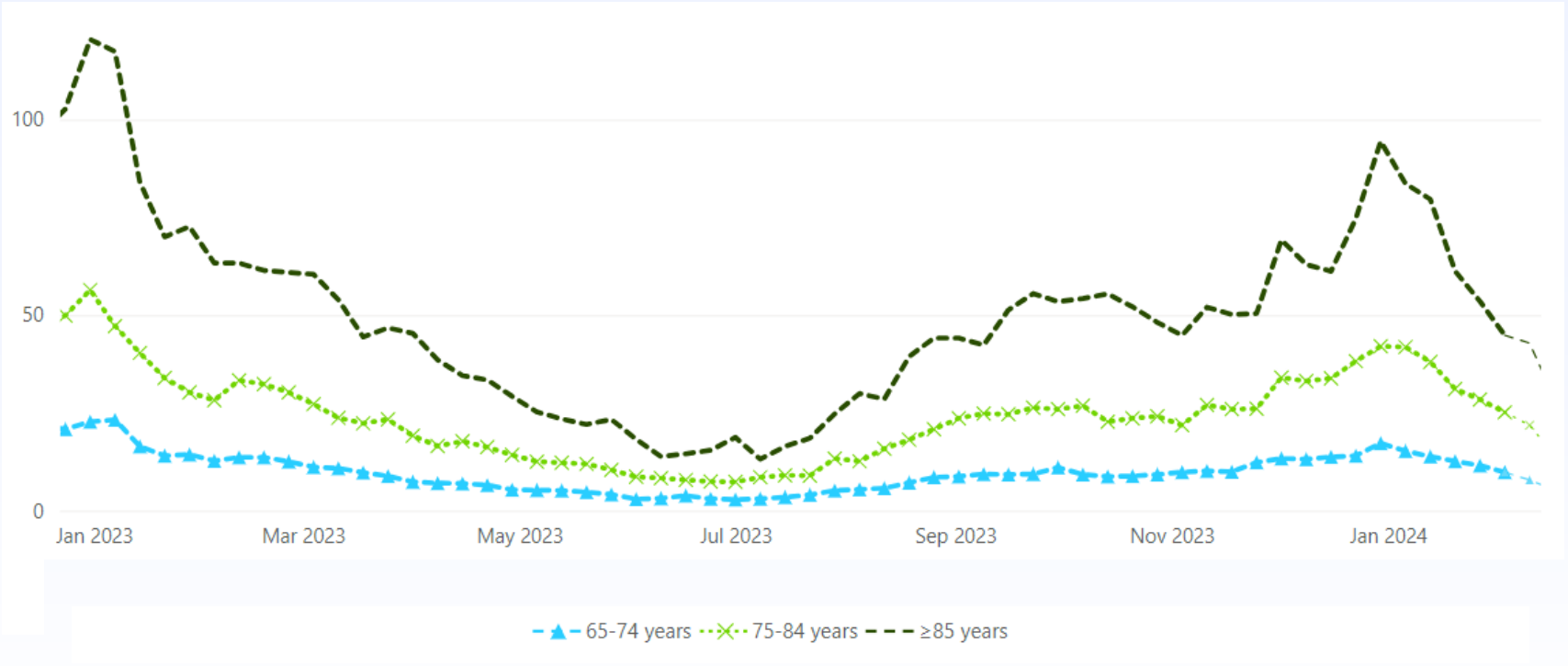
Total number of new hospital admissions of patients with laboratory-confirmed COVID-19 and influenza in the previous week (including both adult and pediatric patients), reported to CDC's National Healthcare Safety Network (NHSN); data as of 3/7/24, data through 3/2/24. Respiratory Virus Data Channel Weekly Snapshot (cdc.gov)

Percent of weekly COVID-19-associated hospitalization by age group, March 1, 2020 – January 27, 2024



CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network.

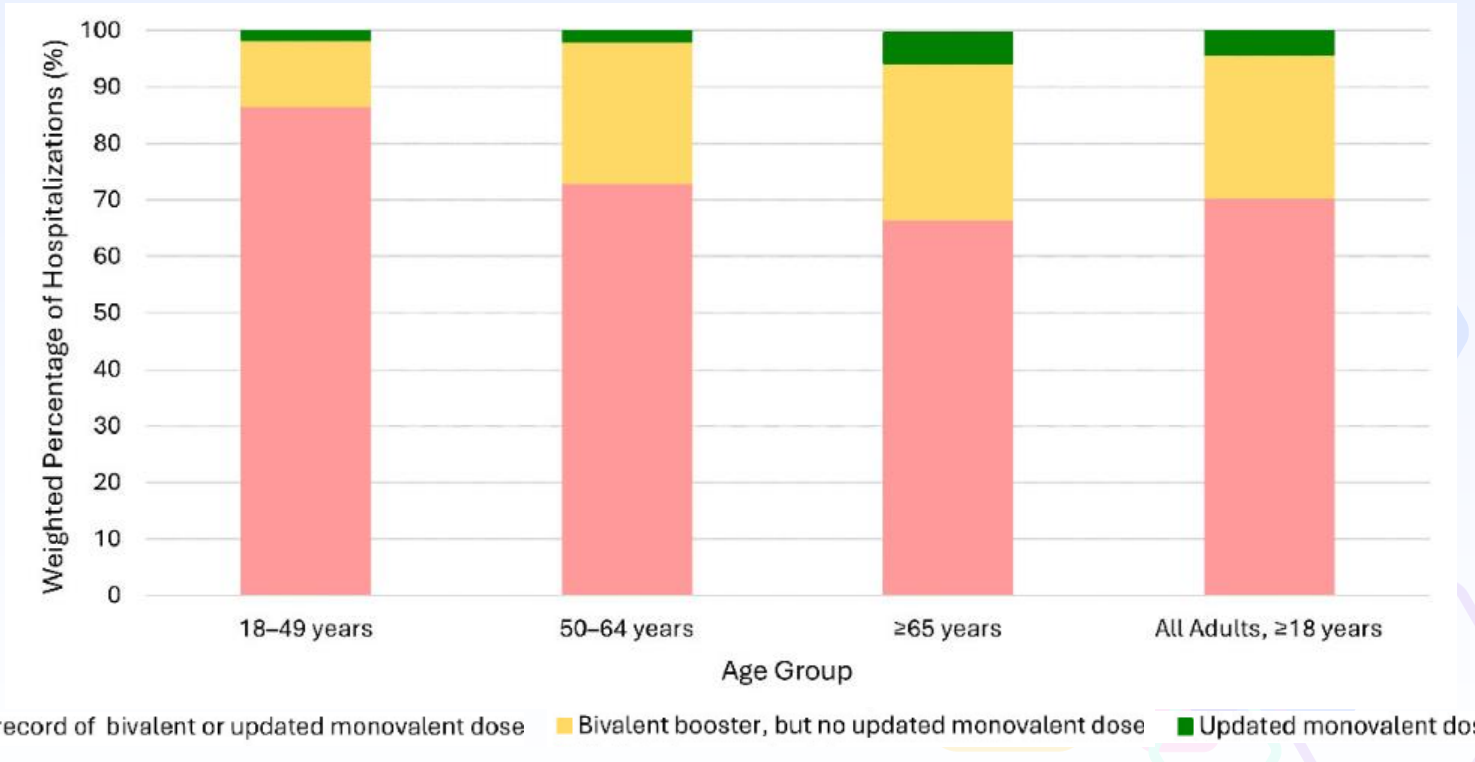
Weekly population-based rates of COVID-19-associated hospitalization among adults ages ≥65 years, January 1, 2023 – January 27, 2024



Thin dashed lines on the far right indicate potential reporting delays and interpretation of trends should exclude these weeks.

CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network. Accessed February 6, 2024

Vaccination Status by Age Group among Adults Ages ≥18 Years Hospitalized with COVID-19, October–November 2023 *(Preliminary)*

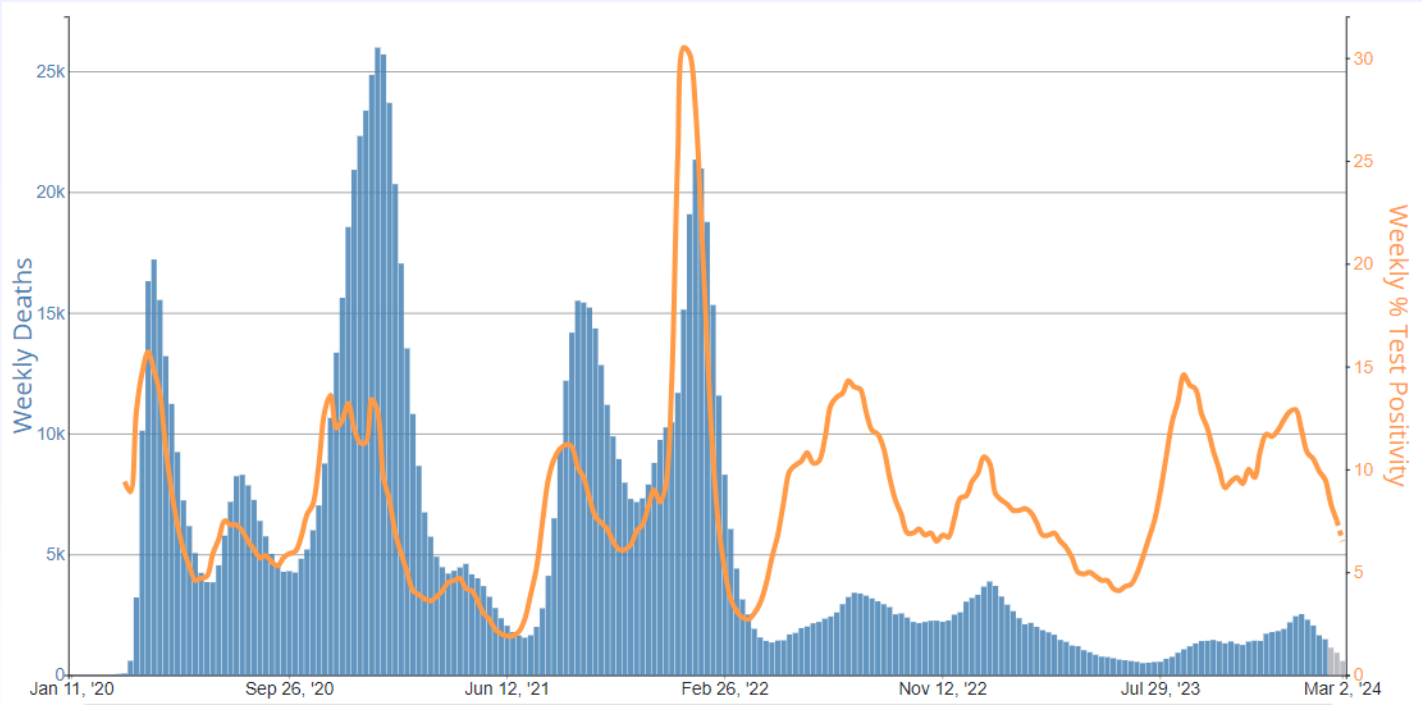


Data from COVID-NET. Data are preliminary as they only include two months of hospitalization data for which the updated monovalent vaccine dose was recommended. Continued examinations of vaccine registry data are ongoing. **No record of bivalent or updated monovalent dose**: No recorded doses of COVID-19 bivalent or updated 2023-2024 monovalent dose. **Bivalent booster, but no updated monovalent doses**: Received COVID-19 bivalent booster vaccination but no record of receiving updated 2023-2024 monovalent booster dose. **Updated monovalent dose:** Received updated 2023-2024 monovalent dose. Persons with unknown vaccination status are excluded.

Percent with Underlying Medical Conditions among Adults Ages ≥18 Years hospitalized with COVID-19, by Age Group, October 2022–October 2023

Condition	18–49 yrs	50–64 yrs	65–74 yrs	≥75 yrs
Chronic lung disease	**24**	**37**	**45**	35
Asthma	19	17	15	10
COPD/Bronchitis	4	16	24	17
Cardiovascular disease	**21**	**47**	**60**	**67**
CAD/CABG/MI	5	16	26	28
CHF/Cardiomyopathy	6	19	24	25
Stroke/TIA	3	12	15	21
Diabetes	**21**	**40**	**44**	**38**
Immunocompromising condition	12	19	21	13
Neurologic condition	18	26	30	**42**
Dementia	0	1	6	28
Renal Disease	8	22	23	**31**
Obesity	**42**	**43**	**38**	22

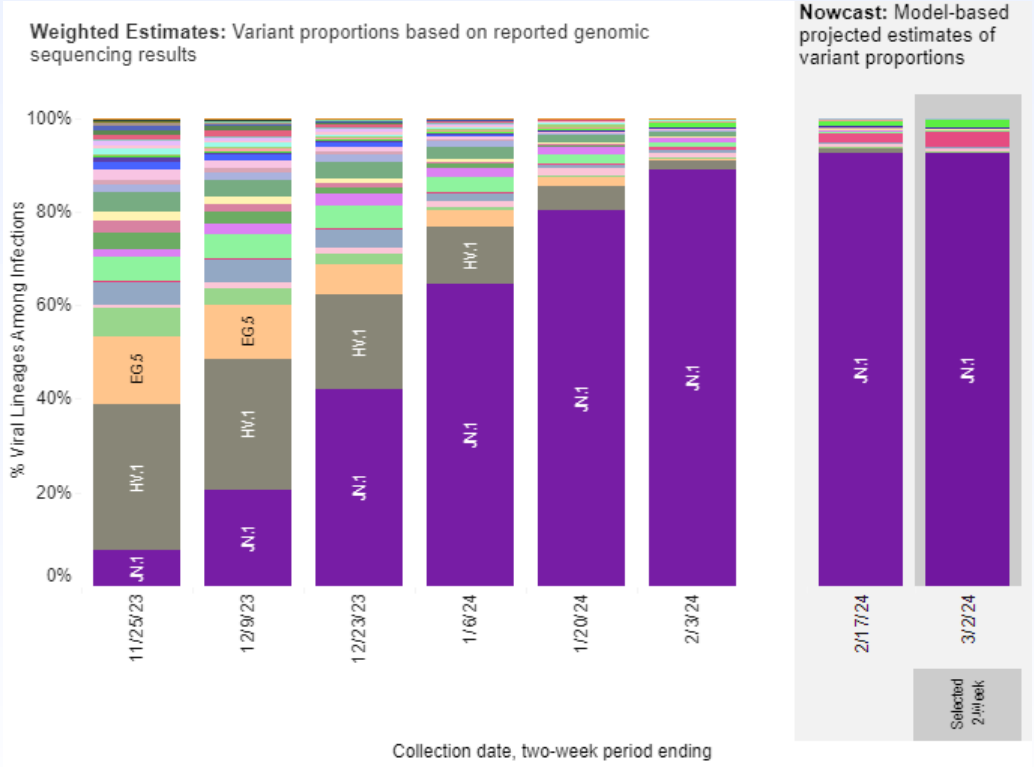
COVID-19 Deaths and COVID-19 Nucleic Acid Amplification Test (NAAT) Percent Positivity, by Week, March 1, 2020 – March 2, 2024



Provisional Deaths from the CDC's National Center for Health Statistics (NCHS) National Vital Statistics System (NVSS) National Respiratory and Enteric Virus Surveillance System (NREVSS) Figure from CDC's COVID Data Tracker.

Current SARS CoV-2 Variant Proportions in the United States November 12, 2023 to March 2, 2024

- JN.1 is the predominant variant in the United States
- JN.1 is similar to BA.2.86 but has an additional mutation in the spike protein which increased its transmissibility
- No evidence that JN.1 causes more severe illness than previous variants
- **Existing vaccines, tests, and treatments work well against JN.1**



Weighted and Nowcast estimates in United States for 2-week periods from November 12,2023 to March 2, 2024. Available at: CDC COVID Data Tracker: Variant Proportions and CDC Continues to Track the Growth of JN.1 | CDC

COVID-19 Antivirals: Closing the Treatment Gap

Real-World Effectiveness of COVID-19 Antivirals: The Latest Data

Therese Tripler, PhD
Scientific Program Manager
National Center for Advancing Translational Sciences
National Institutes of Health

NCATS

COLLABORATE. INNOVATE. ACCELERATE.

NCATS OpenData Portal:
A curated resource on the real-world effectiveness of COVID-19 antivirals

Therese Tripler, PhD

Scientific Project Manager

Curator: Real-World Evidence Studies & Clinical Data

therese.tripler@nih.gov

NCATS OpenData Portal Team

National Center for Advancing Translational Sciences (NCATS)

National Institutes of Health (NIH)

NIH National Center for Advancing Translational Sciences

NCATS OpenData Portal

National Center for Advancing Translational Sciences

POLICY FORUM

BIOMEDICINE

The NIH-led research response to COVID-19

Investment, collaboration, and coordination have been key

By Francis Collins[1], Stacey Adam[2], Christine Colvis[2], Elizabeth Desrosiers[4], Ruxandra Draghia-Akli[5], Anthony Fauci[6], Maria Freire[7], Gary Gibbons[7], Matthew Hall[8], Eric Hughes[9], Kathrin Jansen[9], Michael Kurilla[3], H. Clifford Lane[6], Douglas Lowy[10], Peter Marks[11], Joseph Menetski[12], William Pao[9], Eliseo Pérez-Stable[12], Lisa Purcell[13], Sarah Read[6], Joni Rutter[3], Michael Santos[2], Tara Schwetz[14], Jeffrey Shuren[11], Timothy Stenzel[11], Paul Stoffels[15], Lawrence Tabak[16], Karen Tountas[2], Bruce Tromberg[16], David Wholley[2], Janet Woodcock[11], John Young[17]

Though the COVID-19 pandemic, which has claimed the lives of at least 6.5 million individuals worldwide, is not yet over, it is not too soon to consider the strengths and weaknesses of the research response and some of the lessons that can be learned. Much important research has investigated key public health and clinical issues such as masking, indoor air ventilation, and prone ventilation. But, arguably, no research has been more innovative and impactful than that of the biomedical community around vaccines, therapeutics, and diagnostics. Drawing on our experience leading US-driven elements of this global biomedical research effort, we review here major cross-sector initiatives led by the National Institutes of Health (NIH) and its partners. We outline key milestones (see the figure) and crucial lessons learned, with the goal of informing and guiding the research community's response to future pandemics (see the box).

As emphasized by the Lancet Commission (*1*) and many others, COVID-19 has reaffirmed the importance of international coordination in addressing public health challenges. The US biomedical research community has learned much from—and shared much with—their international partners. Yet it is also essential to recognize the value of sustained learning and constant preparation because, in the past, many aspirational goals have failed to be fully realized (*2*).

INVESTING IN VACCINE DEVELOPMENT AND EVALUATION

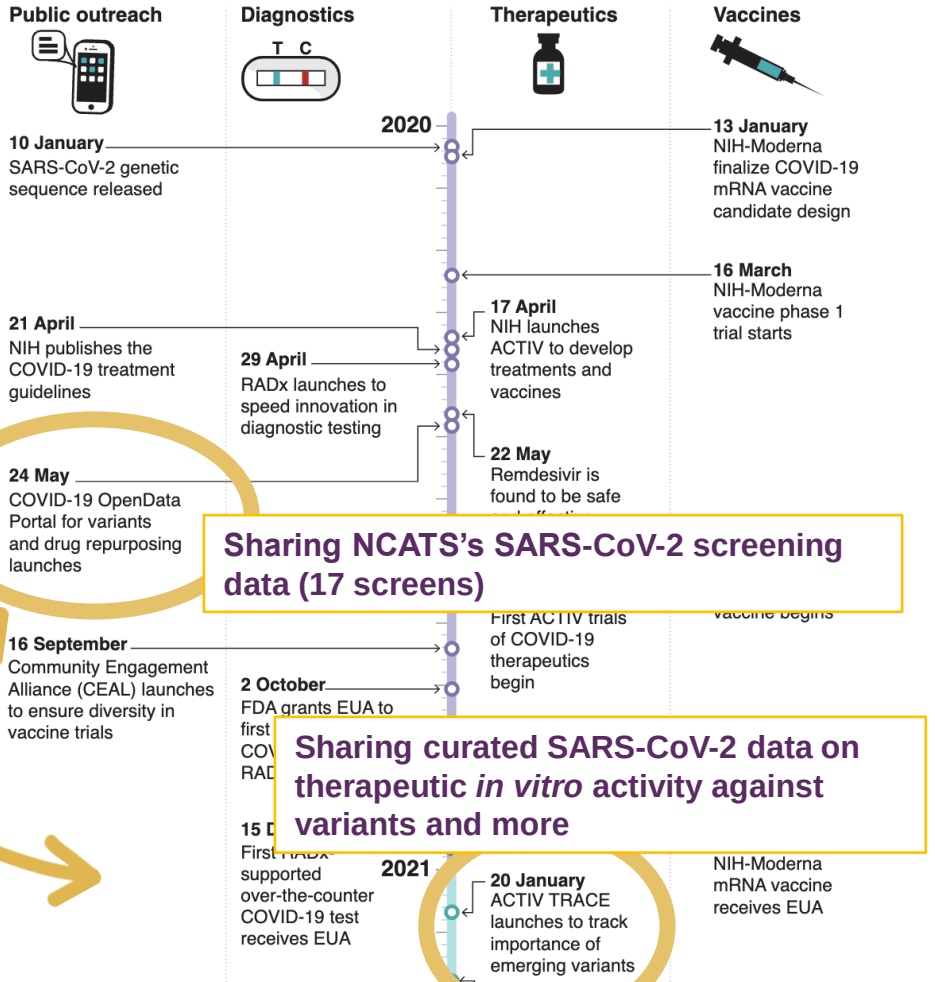
The research response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the novel coronavirus that causes COVID-19, was not invented from scratch. Decades of basic research in virology, molecular biology, genomics, immunology, structural biology, epidemiology, and multiple other scientific fields made it possible to mount therapeutic and vaccine efforts within days of the public release of the sequence of the viral genome (*3*). Before the COVID-19 pandemic, mRNA vaccines had not yet been proven safe and effective for any infectious disease. However, data that had been gathered over the past two decades, including codon optimization and refinement of delivery systems, provided confidence that this approach could work—and ultimately saved months in the face of a rapidly spreading pandemic. Only the nucleotide sequence of SARS-CoV-2 posted on the internet on 10 January 2020 was needed to start the design. In an effort that has been well described elsewhere (*3*, *4*), the first injections in research volunteers were initiated in a phase 1 NIH-Moderna clinical trial just 65 days after the posting of the viral genome sequence. A parallel effort by Pfizer-BioNTech proceeded at the same fast pace, and Janssen, AstraZeneca, and Novavax followed closely behind. Of critical importance was the initiation of a US government program, Operation Warp Speed (OWS), to provide financial support for large-scale vaccine and therapeutic trials and support for the manufacturing of millions of doses of vaccines at financial risk to the US government even before their safety and efficacy had been shown (*4*). Clinical trial endpoints were harmonized, and five of the six pivotal studies were overseen by a single NIH-convened Data and Safety Monitoring Board. As part of this, NIH HIV vaccine evaluation networks were partnered with units based in contract research organizations (CROs).

When unblinded in November 2020, the results of the randomized phase 3 clinical trials of the mRNA vaccines outperformed all but the most optimistic expectations—more than 90% efficacy in preventing symptomatic disease and an excellent safety record. In just 11 months from identification of the pathogen, two vaccines received emergency use authorization (EUA) from the US Food and Drug Administration (FDA). Most other vaccines have taken at least a decade to develop.

BUILDING DIVERSITY IN CLINICAL TRIALS

One hallmark of the pandemic is that the burden of COVID-19 has not been evenly distributed across populations. In the United States, the burden has fallen heavily on older individuals and Black, Hispanic, and American Indian people, particularly those in underserved communities—hospitalizations and deaths were significantly higher among these groups. For scientific credibility and public acceptance, it was critical to include volunteers in vaccine and therapeutic clinical trials who represented the diversity of the US population. At the start of the phase 3 vaccine trials, the individuals most likely to participate were white, and the diversity was expected to be limited. Leadership from NIH, the Surgeon General's office, participating companies, and trial recruitment centers convened weekly to identify ways to ensure diversity. The NIH Community Engagement Alliance (CEAL) Against COVID-19 Disparities (https://covid19community.nih.gov/) was formed and expedited efforts to work directly with disproportionately affected communities in multiple states (*5*). This initiative was

[1]National Human Genome Research Institute, Bethesda, MD, USA. [2]The Foundation for the National Institutes of Health, North Bethesda, MD, USA. [3]National Center for Advancing Translational Sciences, Bethesda, MD, USA. [4]Merck, Rahway, NJ, USA. [5]The Janssen Pharmaceutical Companies of Johnson & Johnson, Titusville, NJ, USA. [6]National Institute of Allergy and Infectious Diseases, Bethesda, MD, USA. [7]National Heart, Lung, and Blood Institute, Bethesda, MD, USA. [8]Pfizer Pharmaceuticals, Tel Aviv, Israel. [9]Pfizer, New York, NY, USA. [10]National Cancer Institute, Bethesda, MD, USA. [11]Food and Drug Administration, Silver Spring, MD, USA. [12]National Institute on Minority Health and Health Disparities, Bethesda, MD, USA. [13]National Institute of Dental and Craniofacial Research, Bethesda, MD, USA. [14]National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, USA. [15]Janssen Research & Development, Titusville, NJ, USA. [16]National Institute of Biomedical Imaging and Bioengineering, Bethesda, MD, USA. [17]Office of the Director, National Institutes of Health, Bethesda, MD, USA.



Francis Collins et al.,
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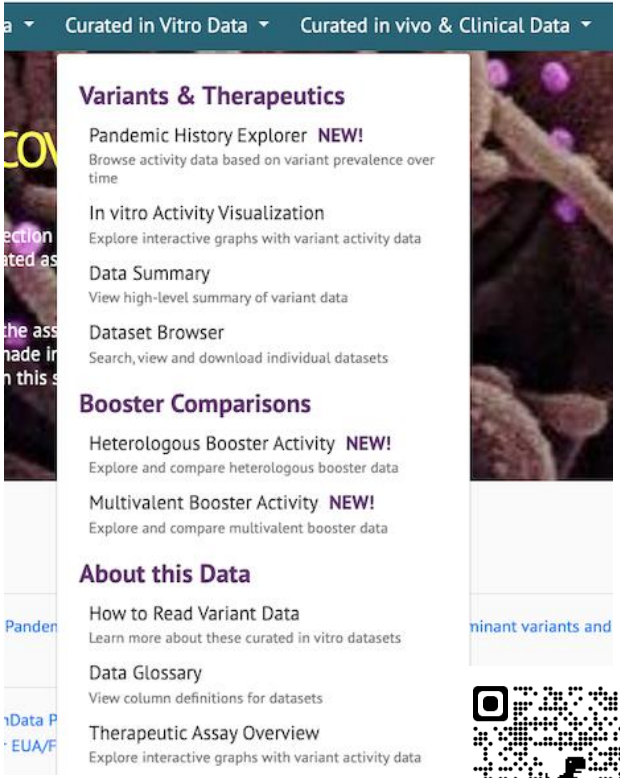
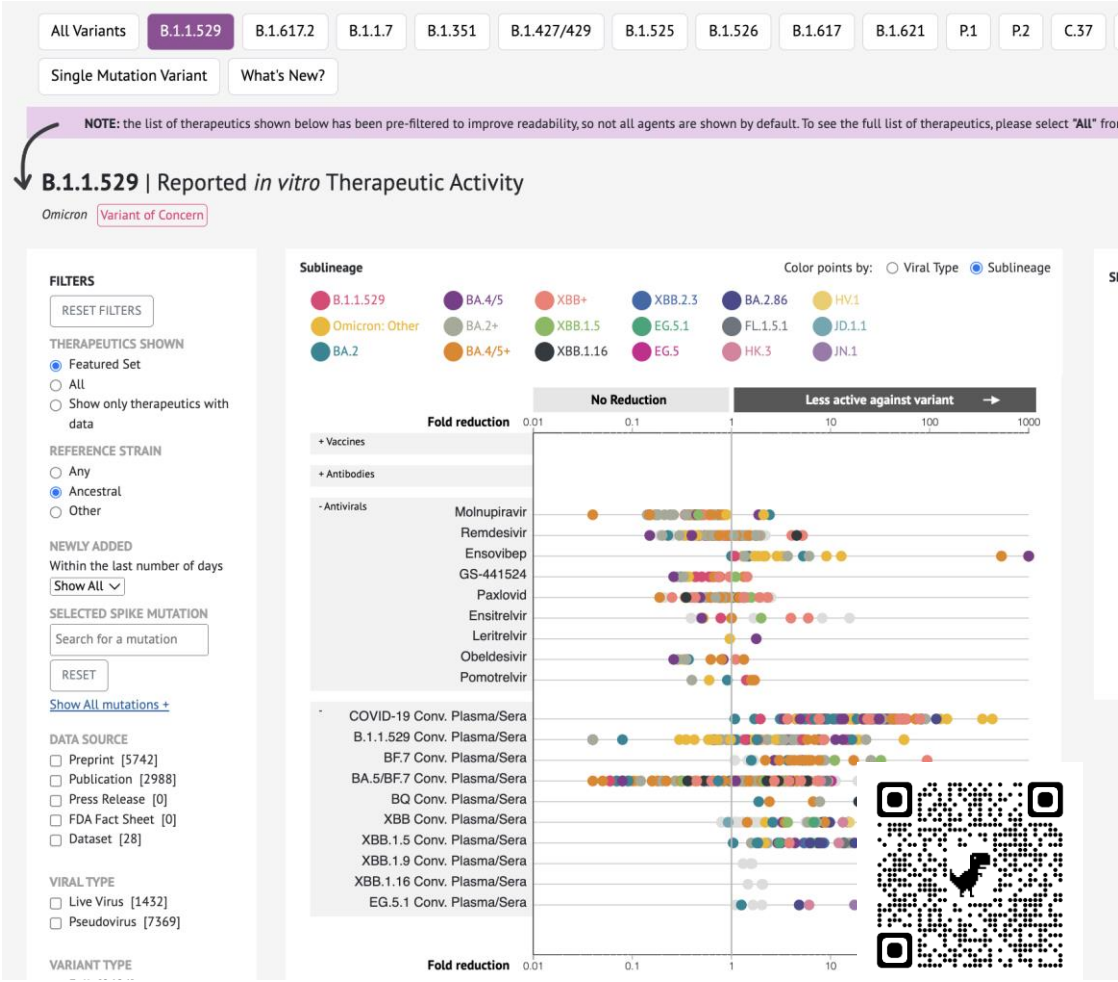
NCATS OpenData Portal



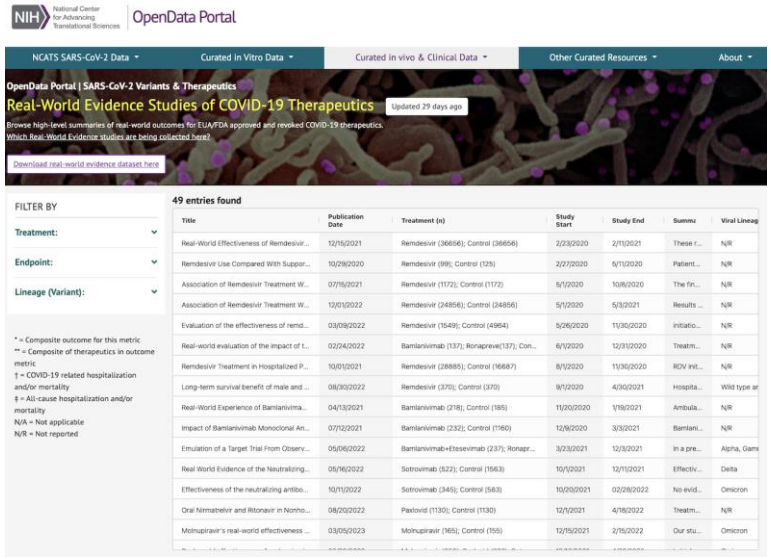


Empowering the scientific community to explore…

how COVID-19 antivirals are affecting real-world outcomes

Real-World Evidence Studies Page

Goal: collect published real-world outcomes for approved COVID-19 therapeutics and enable users to browse high-level summaries of the data



Which Real-World Evidence studies are being collected?

Preprints/publications met the following inclusion criteria:

1. Included a COVID-19 EUA or FDA approved or revoked therapeutic
2. Included a metric of analysis, such as hazard or odds ratio
3. Included a comparator or control in analysis
4. Reported a cohort size ≥ 10

Link: https://opendata.ncats.nih.gov/covid19/variant/real-world-evidence

NIH National Center for Advancing Translational Sciences

Real-World Evidence Studies Page

FILTER BY

Treatment:
- Bamlanivimab
- Bamlanivimab/Etesevimab
- Bebtelovimab
- Evusheld
- Molnupiravir
- Paxlovid
- Remdesivir
- Sotrovimab

Endpoint:
- Hospitalization
- Mortality
- Other

Lineage (Variant):
- Alpha, Gamma, Delta, Beta, Eta
- Delta
- Delta, Omicron
- N/R
- Omicron
- Wild type and alpha

49 entries found

Title	Publication Date	Treatment (n)	Study Start	Study End	Summa	Viral Lineag
Real-World Effectiveness of Remdesivir...	12/15/2021	Remdesivir (36656); Control (36656)	2/23/2020	2/11/2021	These r...	N/R
Remdesivir Use Compared With Suppor...	10/29/2020	Remdesivir (99); Control (125)	2/27/2020	5/11/2020	Patient...	N/R
Association of Remdesivir Treatment W...	07/15/2021	Remdesivir (1172); Control (1172)	5/1/2020	10/8/2020	The fin...	N/R
Association of Remdesivir Treatment W...	12/01/2022	Remdesivir (24856); Control (24856)	5/1/2020	5/3/2021	Results ...	N/R
Evaluation of the effectiveness of remd...	03/09/2022	Remdesivir (1549); Control (4964)	5/26/2020	11/30/2020	initiatio...	N/R
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Long-term survival benefit of male and ...	08/30/2022	Remdesivir (370); Control (370)	9/1/2020	4/30/2021	Hospita...	Wild type ar
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Molnupiravir's real-world effectiveness ...	03/05/2023	Molnupiravir (165); Control (155)	12/15/2021	2/15/2022	Our stu...	Omicron

Real-World Evidence Studies Page

FILTER BY

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Lineage (Variant):

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Real-World Evidence Studies Page

FILTER BY

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- [ ] Bamlanivimab
- [ ] Bamlanivimab/Etesevimab
- [ ] Bebtelovimab
- [ ] Evusheld
- [ ] Molnupiravir
- [x] Paxlovid
- [ ] Remdesivir
- [ ] Sotrovimab

Endpoint:

- [ ] Hospitalization
- [x] Mortality
- [ ] Other

Lineage (Variant):

12 entries found

Treatment (n)	Study Start	Study End	Summary	Viral Lineage	Hospitalization Endpoint	Mortality Endpoint	Othe Endp
Paxlovid (1130); Control (1130)	12/1/2021	4/18/2022	Treatment ...	N/R	Yes	Yes	Yes
Paxlovid (98060); Control (91485...	12/22/2021	2/28/2023	In Paxlovid...	N/R	Yes	Yes	No
Paxlovid (12541); Control (32010)	1/1/2022	7/17/20	In Paxlovid-eligible patients, treatment was associated with decreased risk of hospitalization and death.			Yes	No
Paxlovid (Trial 1: 1587; Trial 3: 53...	1/1/2022	2/28/2022	Nirmatrelvi...	Omicron	Yes	Yes	No
Paxlovid (4737); Control (175614)	1/1/2022	2/28/2022	This study ...	Omicron	No	Yes	Yes
Paxlovid (3902); Control (105352)	1/9/2022	3/31/2022	Among pati...	Omicron	Yes	Yes	No
Paxlovid(5704); Sotrovimab (332...	2/10/2022	11/27/2022	In routine c...	Omicron	Yes	Yes	No
Paxlovid (4836); Sotrovimab (28...	2/11/2022	10/1/2022	No substan...	Omicron	Yes	Yes	No
Paxlovid (3614); Control (4835)	3/26/2022	6/23/2022	This study ...	Omicron	Yes	Yes	Yes
Paxlovid (7168); Control (9361)	3/26/2022	8/25/2022	Nirmatrelvi...	Omicron	Yes	Yes	Yes
Paxlovid (7274); Control (126152)	4/8/2022	10/7/2022	In a setting...	Omicron	Yes	Yes	Yes
Paxlovid (195); Control (258)	4/7/2022	6/21/2022	All-cause d...	Omicron	No	Yes	Yes

Mortality Metric	Mortality Outcome (value (95% CI); p-value)	Other Defined
Odds ratio	0.5 (0.39–.67); 0.005, *, ‡	All-cause e...
Relative riisk	0.269 (0.179-0.370); N/R	N/A
Adjusted risk ratio	0.56 (0.42–0.75); N/R, * A...	N/A
Short-Term Outco...	Short-Term Outcomes, Nir...	1. ICU admi...
Hazard ratio	0.54 (39–.75); N/R, * 0.43 ...	1. Severe C...

0.269 (0.179-0.370); N/R

0.54 (39–.75); N/R, *
0.43 (0.85–.64); N/R, *
Adequate COVD-19 vaccnation:
No: 0.52 (0.32-0.82); N/R, *
Yes: 0.62 (0.39-0.98); N/R, *
Age < 60 years: 1.06 (0.36-3.15); N/R, *
Age ≥ 60 years: 0.52 (0.36-0.73); N/R, *
Males: 0.60 (0.40-0.91); N/R, *
Females: 0.46 (0.26-0.80); N/R, *
Arab: 0.75 (0.32-1.77); N/R, *
Ultra-Orthodox Jewish: 0.39 (0.05-2.89); N/R, *
General Jewish: 0.53 (0.37-0.76); N/R, *
Socoeconomic status:
Low: 0.74 (0.42-1.29); N/R, *
Middle: 0.47 (0.29-0.75); N/R, *
High: 0.45 (0.21-0.97); N/R, *
Diabetes:
No: 0.6 (0.40-0.93); N/R, *
Yes: 0.44 (0.25-0.75); N/R, *
Cardiovascular disease:
No: 0.64 (0.41-1.00); N/R, *
Yes: 0.43 (0.26-0.70); N/R, *
Chronic lung disease:
No: 0.45 (0.30-0.67); N/R, *
Yes: 0.96 (0.53-1.73); N/R, *
Chronic kidney disease:

Real-World Evidence Studies Page

FILTER BY

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Endpoint:

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** = Composite of therapeutics in outcome metric
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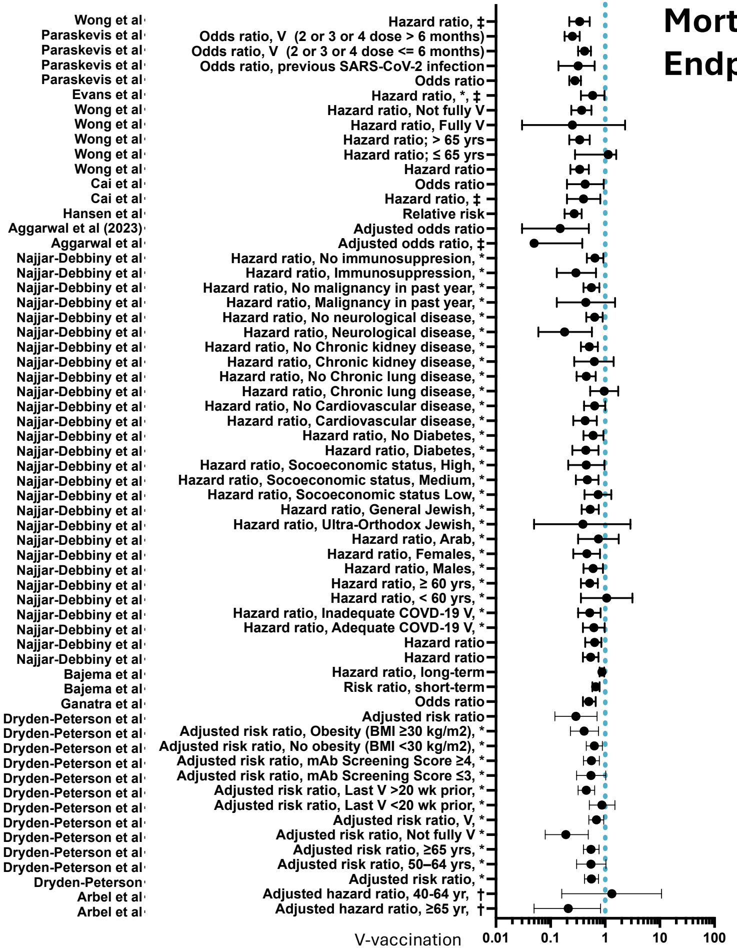
Example of available data | Paxlovid

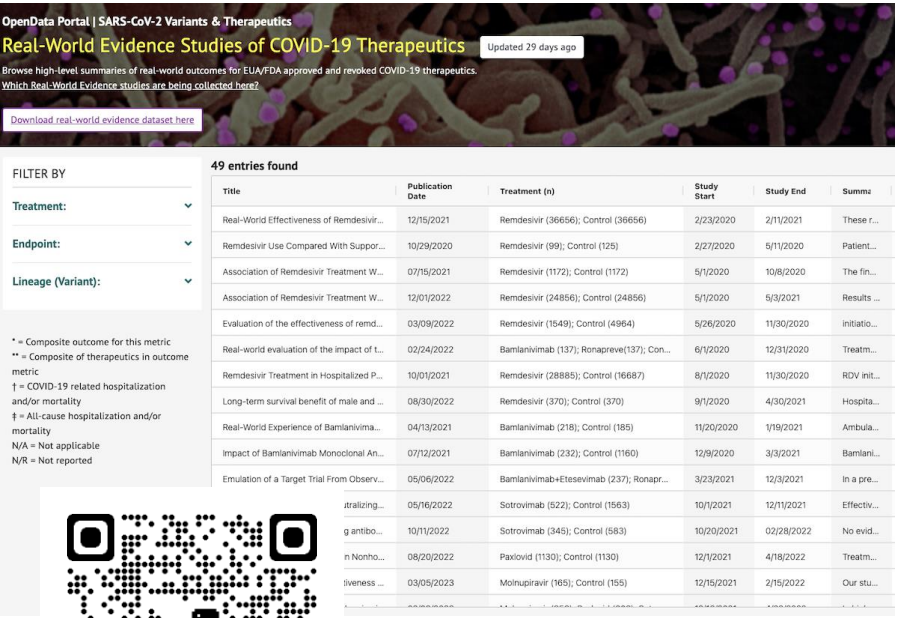
Study	Hospitalization	Mortality
Wong et al	N/A	↓
Paraskevis et al	↓	↓
Evans et al	↓	↓
Wong et al	N/A	↓
Cai et al	↓	↓
Hansen et al	↓	↓
Lewnard et al	↓	↓
Aggarwal et al	↓	↓
Najjar-Debbiny et al	N/A	↓
Bajema et al	↓	↓
Ganatra et al	↓	↓
Dryden-Peterson et al	↓	↓
Arbel et al	↓	↓

Mortality Endpoint



The data may be from preliminary reports that **have not been peer reviewed and thus should not be regarded as conclusive, guide clinical practice or health decisions, or be reported in news media as established information.

Real-World Evidence Studies



Resource currently includes RWE data from:

- **49** Publications
- **9** COVID-19 EUA/FDA approved/revoked treatments:
  - Paxlovid
  - Molnupiravir
  - Remdesivir
  - Sotrovimab
  - Evusheld
  - Ronapreve
  - Bamlanivimab
  - Bamlanivimab+Etesevimab
  - Bebtelovimab
- **Multiple Endpoints**:
  - Hospitalization
  - Mortality
  - Other (severe disease, supplemental oxygen, etc)
- **Multiple Outcomes:**
  - Hazard, odds, relative risk ratios and more

Future directions: a comprehensive systematic review and meta-analysis on this data is underway!

OpenData Portal Team

National Center for Advancing Translational Sciences

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Program Lead

ODP Development Team: Tongan Zhao, Kevin Duerr, Aaron Friedman, Brian Nezhad, Kunning Liu, Meka Mofor, DevOps

Contact us / Learn more!

Please reach out with any questions, feedback, or collaborative queries!

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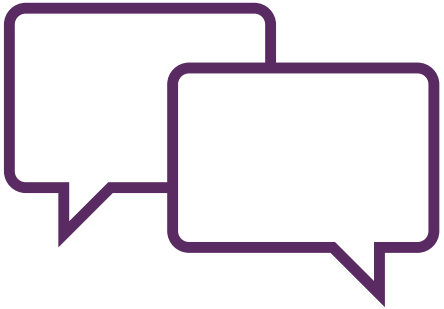
OpenData Portal team: opendataportal@nih.gov

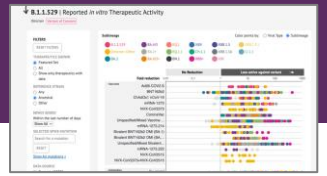


National Center for Advancing Translational Sciences | OpenData Portal

Other COVID resources on OpenData Portal:

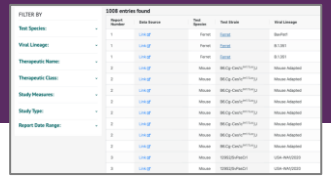
Variants & Therapeutics

Explore and interact with >21k points of in vitro variant activity data compiled from preprints & publications



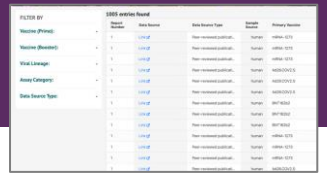
In vivo Variants

Browse high-level summaries of published/shared datasets with in vivo models of SARS-CoV-2 variant infection



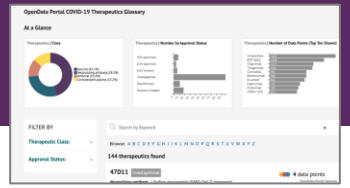
Heterologous & Multivalent Booster Datasets

Explore and compare heterologous and multivalent booster data



Therapeutic Glossary

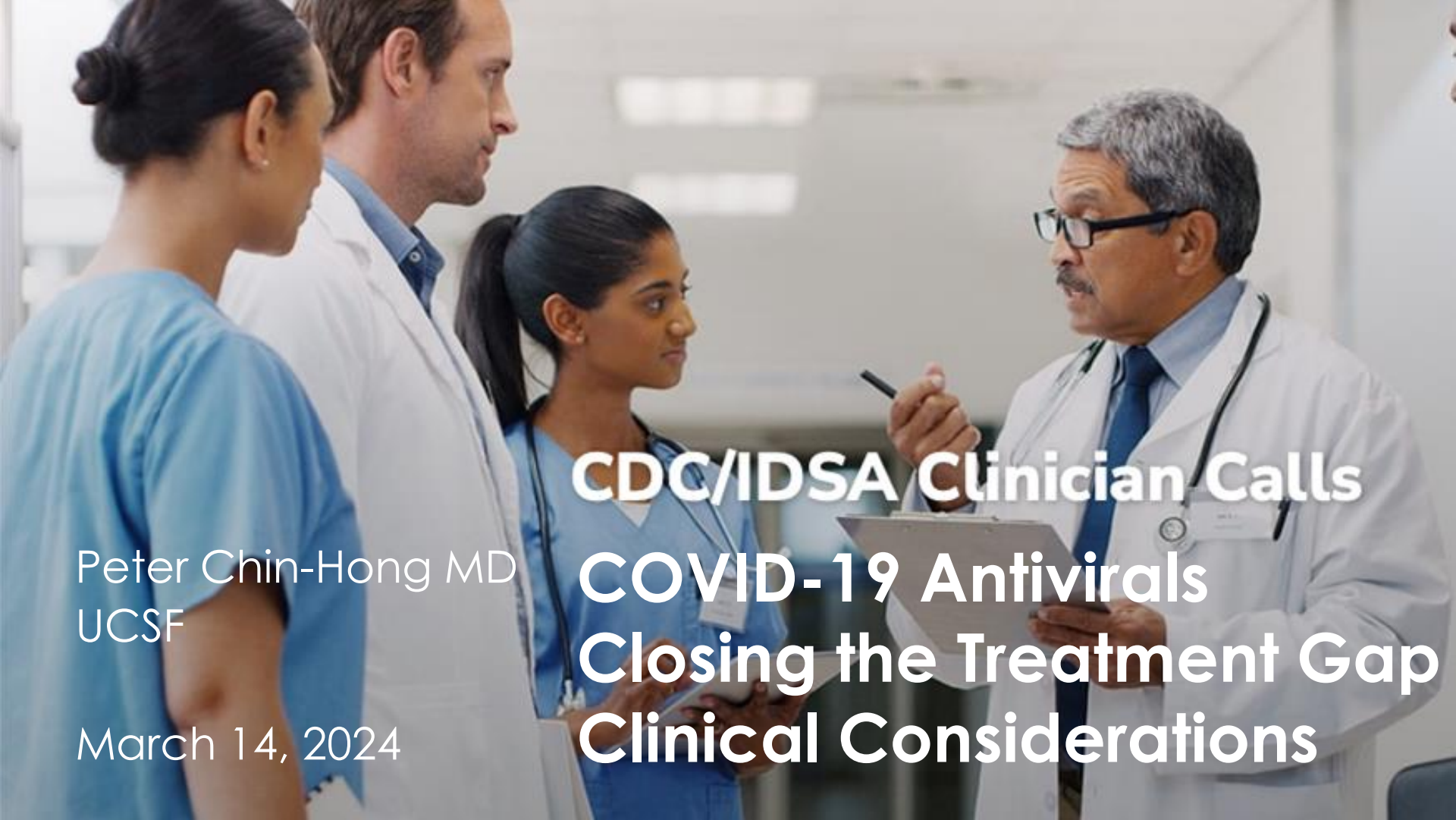
See data available on OpenData for each COVID-19 Therapeutic



COVID-19 Antivirals: Closing the Treatment Gap

Closing the Treatment Gap Clinical Considerations

Peter V. Chin-Hong, MD
Professor of Medicine and
Associate Dean for Regional Campus
Director, Transplant and Immunocompromised
Host Infectious Disease Program
University of California, San Francisco



CDC/IDSA Clinician Calls

COVID-19 Antivirals Closing the Treatment Gap Clinical Considerations

Peter Chin-Hong MD
UCSF

March 14, 2024

Disclosures

None

Barriers

- Health system
- Patient
  - Apathy
  - Diagnostic test availability (time is money)
  - Adverse effects
  - Cost
  - Misinformation
- Clinician
  - Who to treat?
  - Fear of rebound
  - Drug-drug interactions

Opinion | **The under-prescribing of Paxlovid may be our biggest covid policy failure**

By Leana S. Wen
Contributing columnist | + Follow

January 16, 2024 at 7:30 a.m. EST

Washington Post 1/16/24

Barriers

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10% Americans very concerned that they will be hospitalized

How Americans View the Coronavirus, COVID-19 Vaccines Amid Declining Levels of Concern

Continued decline in share of U.S. adults with up-to-date vaccination

BY ALEC TYSON AND GIANCARLO PASQUINI

Pew Research Center 3/7/24

Barriers

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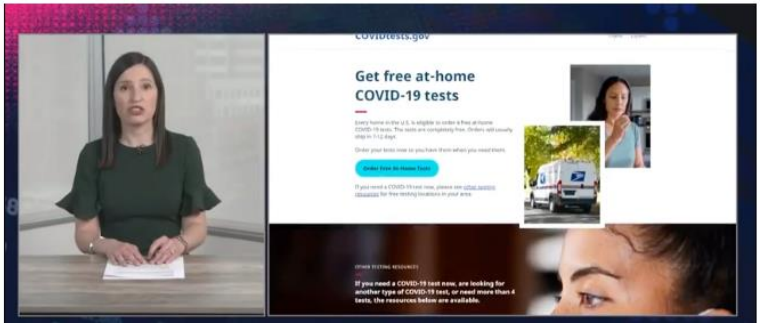
Free COVID tests: Why you can no longer order through government program via USPS delivery

Gabe Hauari
USA TODAY

Published 8:21 a.m. ET March 8, 2024 | **Updated 5:41 a.m. ET March 11, 2024**



USA Today 3/8/24

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This Candy Is the Only Thing That Helped My Terrible "Paxlovid Mouth"

The antiviral treatment for COVID left a monstrous taste in my mouth. Cinnamon candies were my savior.

BY EMILY FARRIS

June 24, 2022

Bon appetit 6/24/22

Barriers

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Pfizer to price COVID treatment Paxlovid at $1,390 per course

By **Michael Erman**

October 18, 2023 5:15 PM PDT · Updated 5 months ago

Reuters 10/18/24

Barriers

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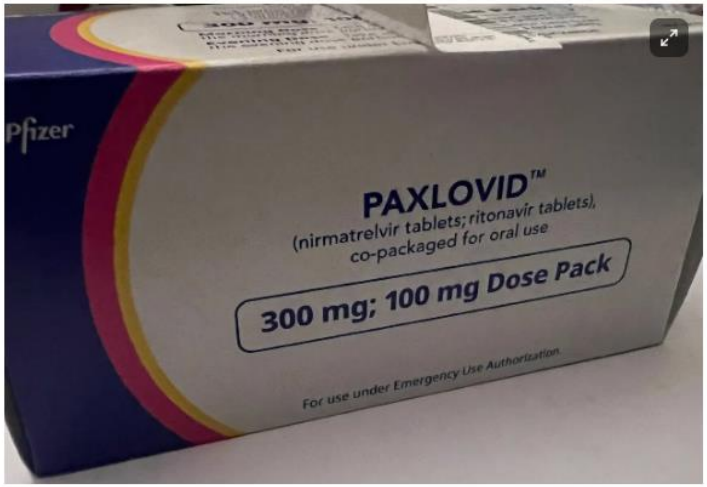
Are You an Anti-Paxxer?

As doctors drop Paxlovid because of drug interactions and research shows it causes Covid rebounds and virus shedding, Pfizer and MSM crank the PR machine to hide the facts and shame "anti-paxxers."

LINDA BONVIE
FEB 9, 2024

118 25 Share



Rescue with Michael Capuzzo 2/9/24

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Why Aren't More Doctors Prescribing Paxlovid to High-Risk Patients?

— It's not all about drug-drug interactions, experts say

by Katherine Kahn, Staff Writer, MedPage Today ; Cheryl Clark, Contributing Writer, MedPage Today
January 29, 2024

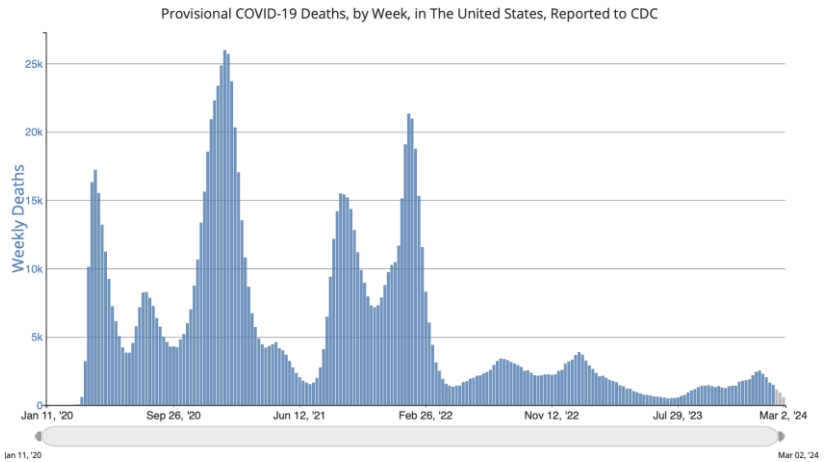
Last Updated February 1, 2024

Medpage 2/1/24

COVID antiviral myths

- Population immunity is high so my patient doesn't need Paxlovid
- My patients have a high chance of rebound if they take Paxlovid
- My patient has mild symptoms so Paxlovid or other early therapies won't help
- Drug-drug interactions make it impossible for my patient for my patient to get early therapy
- Paxlovid is easy to get after I prescribe it

Good news: Deaths down.
Not so good news: Still 576 deaths/week in US
(95% no recent COVID vaccine)



https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00

COVID antiviral myths

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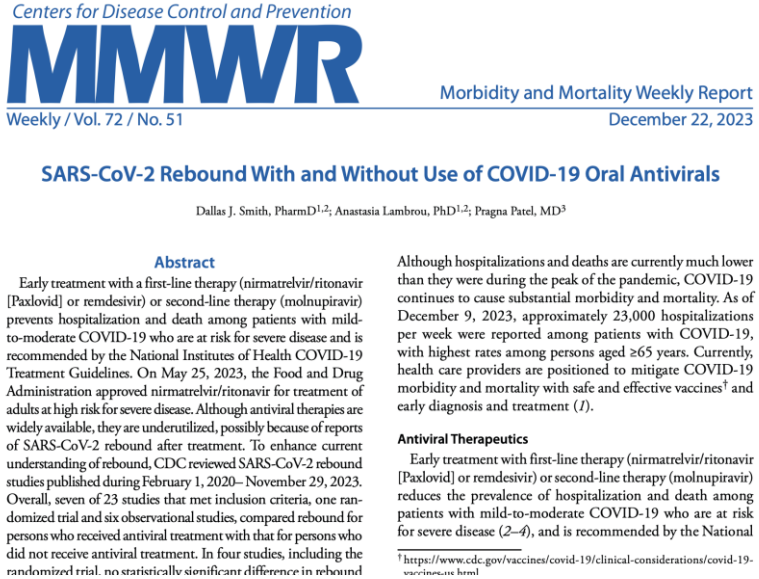
Small studies with mixed findings, short follow up, diff pop
(Paxlovid 20-32%, no treatment 2-20%)
Difference between virologic and symptomatic rebound
When it occurs, rebound is brief and mild



Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Weekly / Vol. 72 / No. 51 December 22, 2023

SARS-CoV-2 Rebound With and Without Use of COVID-19 Oral Antivirals

Dallas J. Smith, PharmD[1,2]; Anastasia Lambrou, PhD[1,2]; Pragna Patel, MD[3]

Abstract

Early treatment with a first-line therapy (nirmatrelvir/ritonavir [Paxlovid] or remdesivir) or second-line therapy (molnupiravir) prevents hospitalization and death among patients with mild-to-moderate COVID-19 who are at risk for severe disease and is recommended by the National Institutes of Health COVID-19 Treatment Guidelines. On May 25, 2023, the Food and Drug Administration approved nirmatrelvir/ritonavir for treatment of adults at high risk for severe disease. Although antiviral therapies are widely available, they are underutilized, possibly because of reports of SARS-CoV-2 rebound after treatment. To enhance current understanding of rebound, CDC reviewed SARS-CoV-2 rebound studies published during February 1, 2020– November 29, 2023. Overall, seven of 23 studies that met inclusion criteria, one randomized trial and six observational studies, compared rebound for persons who received antiviral treatment with that for persons who did not receive antiviral treatment. In four studies, including the randomized trial, no statistically significant difference in rebound

Although hospitalizations and deaths are currently much lower than they were during the peak of the pandemic, COVID-19 continues to cause substantial morbidity and mortality. As of December 9, 2023, approximately 23,000 hospitalizations per week were reported among patients with COVID-19, with highest rates among persons aged ≥65 years. Currently, health care providers are positioned to mitigate COVID-19 morbidity and mortality with safe and effective vaccines[†] and early diagnosis and treatment (*1*).

Antiviral Therapeutics

Early treatment with first-line therapy (nirmatrelvir/ritonavir [Paxlovid] or remdesivir) or second-line therapy (molnupiravir) reduces the prevalence of hospitalization and death among patients with mild-to-moderate COVID-19 who are at risk for severe disease (*2–4*), and is recommended by the National

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

Smith-Jeffcoat S et al, CID, 11/14/23
Edelstein G et al, Annals Intern Med, 11/14/23

Smith D et al, MMWR 72(51)
Harrington P et al, MMWR 72(51)

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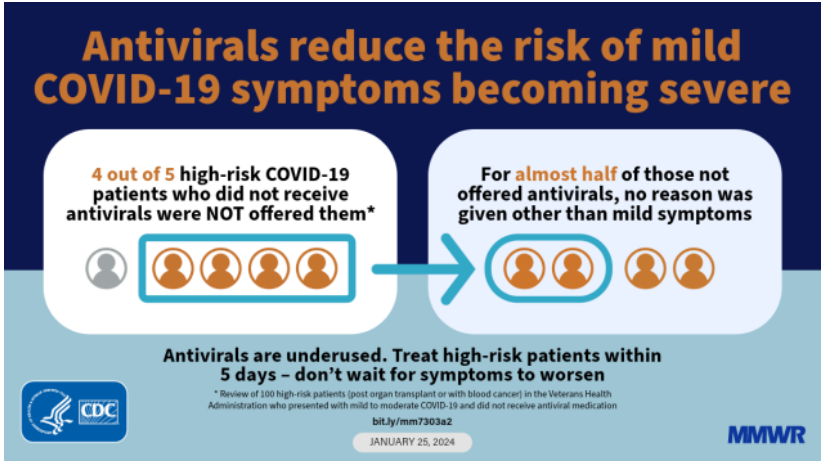

Monarch PA et al, MMWR, 2024, 73(3)

COVID antiviral myths

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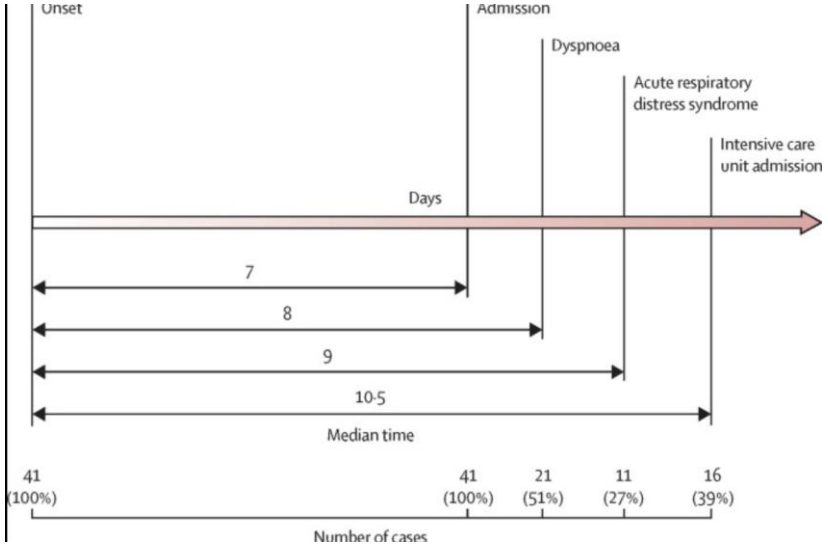
Hospitalizations 7-8 days after onset symptoms



Huang C et al, 2020, Lancet 395 (10223)

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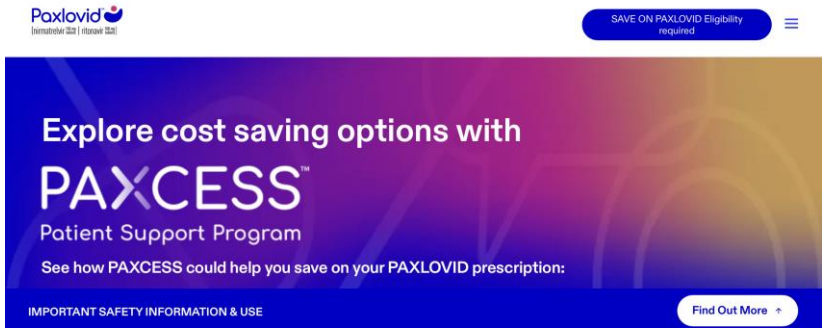



Thank you!

Q&A/ Discussion

Selected Resources

Program Links:

- This webinar is being recorded and can be found with the slides online at https://www.idsociety.org/cliniciancalls
- COVID-19 Real-Time Learning Network: https://www.idsociety.org/covid-19-real-time-learning-network/
- Vaccine FAQ: https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/vaccines-information--faq/

Dr. Rao

- www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf
- https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2024-03/PHMSA%20Safety%20Advisory%20Notice%20-%20Classification%20of%20MPXV%20Diagnostic%20Samples%20and%20Waste.pdf
- https://www.cdc.gov/poxvirus/mpox/clinicians/infection-control-healthcare.html
- https://www.cdc.gov/mmwr/volumes/72/wr/mm7209a4.htm?s_cid=mm7209a4_w
- https://emergency.cdc.gov/han/2023/han00501.asp

Dr. Jackson

- https://covid.cdc.gov/covid-data-tracker/#trends_weeklyhospitaladmissions_testpositivity_00

Dr. Patel

- https://www.cdc.gov/respiratory-viruses/data-research/dashboard/snapshot.html
- https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network
- https://covid.cdc.gov/covid-data-tracker/#trends_weeklyhospitaladmissions_testpositivity_00
- https://covid.cdc.gov/covid-data-tracker/#variant-proportions
- https://www.cdc.gov/ncird/whats-new/JN.1-update-2023-12-22.html

Selected Resources

Dr. Tripler

- https://www.science.org/doi/10.1126/science.adf5167
- https://opendata.ncats.nih.gov/covid19/variant/real-world-evidence

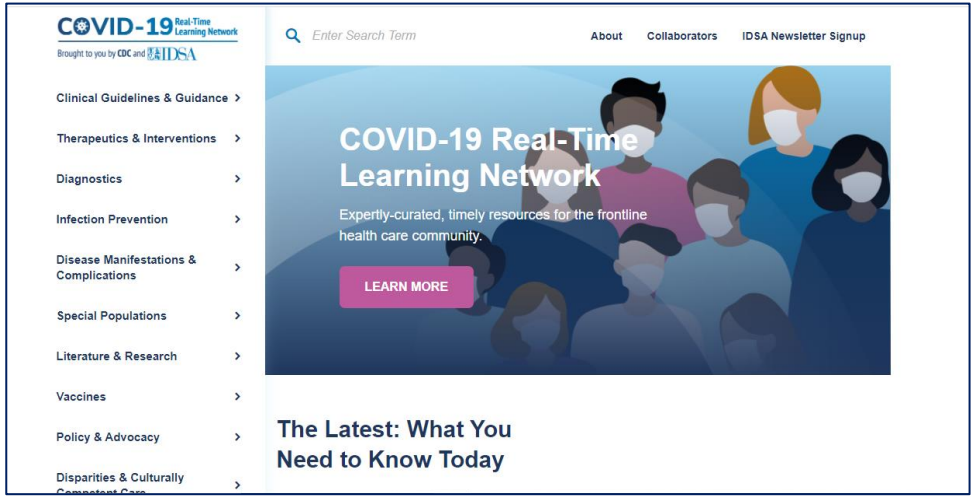
Dr. Chin-Hong

- https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00

COVID-19 Real-Time Learning Network

Brought to you by CDC and IDSA

An online community bringing together information and opportunities for discussion on latest research, guidelines, tools and resources from a variety of medical subspecialties around the world.



Specialty Society Collaborators

American Academy of Family Physicians
American Academy of Pediatrics
American College of Emergency Physicians
American College of Obstetricians and Gynecologists
American College of Physicians
American Geriatrics Society
American Thoracic Society
Pediatric Infectious Diseases Society
Society for Critical Care Medicine
Society for Healthcare Epidemiology of America
Society of Hospital Medicine
Society of Infectious Diseases Pharmacists

www.COVID19LearningNetwork.org
@RealTimeCOVID19
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THANK YOU

We want to hear from you!

Please complete the post-call survey.

A recording of this call, slides and the answered Q&A will be posted at
www.idsociety.org/cliniciancalls

-- library of all past calls available --

Contact Us:

Dana Wollins (dwollins@idsociety.org)
Deirdre Lewis (dlewis@idsociety.org)